



**9th international
symposium on the
diabetic foot**

'The Olympic games of the diabetic foot'

Abstracts

10-13 May 2023 | The Hague | The Netherlands



Kindly note that accepted abstracts were included as they were submitted.
They have not been edited.

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O.01-1

What cannot be measured cannot be improved – Setting the Standard for Interdisciplinary High Risk Foot Care in Australia

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Background/Aim National standards provide the benchmark for diabetes services aiming to achieve best practice care. Further, accreditation provides a means by which participating services can be recognised as meeting these standards. In addition, this process facilitates further quality improvement within the service.

The aim of the project is to develop and implement Australian High Risk Foot Service Standards and an Accreditation process and guide quality improvement activities. The ultimate goal is to improve outcomes for people with diabetes-related foot complications.

Methods The National Associations of Diabetes Centres (NADC) Collaborative Interdisciplinary High Risk Foot Service (iHRFS) Standards were developed after stakeholder national consultation and consideration of international standards. The Standards include categories of: interdisciplinary staffing, key equipment, and processes including application of evidence-based standards. To support the implementation of the Standards, a supporting Accreditation Program was developed. Applications undergo a robust independent, peer-reviewed assessment that allows centres to self-assess their service against the Standards. Services can be awarded Core Standard or Centre of Excellence. Accreditation awards are for a 4-year period.

Results As of December 1st 2022, 36 services have expressed interest in undertaking accreditation. Eleven services have achieved Centre of Excellence and 13 have achieved Core Standards, whereas 11% of services withdrew from the accreditation process citing issues related to time constraints and workforce demands. A further 8% of services were assessed as not adequately meeting the standards and were not awarded accreditation.

Services that have completed the accreditation program have provided feedback that the process was beneficial as it highlights gaps and opportunities leading to quality improvement activities. Assessor feedback has also assisted services to seek further funding support and consider changes to their models of care.

Discussion The NADC Standards and Accreditation process are new to Australasia and are comparable to the few other international programs that exist. The iHRFS Accreditation Program in Australia assesses services against a robust set of standards and ensures an interdisciplinary approach to care, continuous quality improvement, and data capture to achieve improved service delivery for people with diabetes requiring foot care.

O.01-2

The Australian Diabetes Foot Registry: Standardising national data collection and key learnings from our inaugural report

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Aim: The primary objective was to develop a standardised Australian Diabetes Foot Registry (ADFR). Secondary objectives were to: evaluate service and clinical outcomes, perform benchmarking, provide reports to participating services, and establish a platform for collaborative research.

Methods: The prospective longitudinal ADFR was first established in 2020. The dataset and outcome measures were derived by expert consultation, referencing the International Working Group of the Diabetic Foot Guidelines and National Association of Diabetes Centres Collaborative Interdisciplinary Diabetes High Risk Foot Services Standards. People with diabetes mellitus who had foot ulceration or Charcot foot from participating specialist foot services were included. Clinicians completed secure online data collection forms, centralised in real-time or via periodic transfer. An opt-out or waiver of consent approach was utilised.

Results: This inaugural report comprised 19 services, 1356 participants, 1447 care episodes and 2250 foot ulcerations. Initial assessment occurred a median of 3 (IQR 1-8) days from referral and 28 (IQR 8-76) days from ulceration onset. At presentation 49% of ulcerations were severe (SINBAD score ≥ 3) and 35% were ischaemic. Expedited initial assessment was associated with severe ulceration (median 3 vs 4 days, $p < 0.001$); however, not with ischaemic ulceration. Only 27% of care episodes involved the 'core interdisciplinary team' (endocrinologist/physician, podiatrist, diabetes educator). A vascular surgeon was consulted in 76% of care episodes with ischaemic ulceration. Non-removable knee-high devices were used in only 4% of care episodes involving plantar ulceration. At 12 weeks from initial assessment 29% of ulcerations had healed and 14% had required amputation, with 27% of participants ulceration-free. Healing was more likely in less severe ulceration (SINBAD score < 3 vs ≥ 3 ; 31% vs 25%, $p = 0.006$). Mortality was recorded in 3% of participants, extrapolated to a rate of 7.5% per person annually. Substantial inter-service variation was evident across key outcome measures.

Conclusion: The ADFR has enhanced collaboration across services and enabled outcome monitoring and benchmarking. Variations from established care Standards and Guidelines have been identified, presenting opportunities for quality improvement across all services.

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O.01-3

The financial burden of lower extremity amputation: analysis of total medical costs in the pre- and postoperative year in Belgium

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Background/Aim. Diabetes puts a high financial burden on health care systems worldwide. Diabetic foot is one of the main indications for lower extremity amputation (LEA). LEA is associated with high costs, both in the pre-and postoperative phase. Present study compared the total medical expenditures of individuals (with and without diabetes) undergoing LEA in Belgium, in the year preceding and following amputation, and juxtaposed these costs to costs of amputation-free controls.

Methods. All Belgian citizens undergoing LEA in 2014 were identified in a national health insurance database. Collected data were level of amputation (minor versus major) and presence of diabetes. All medical expenses in the 12 months preceding and the 12 months following LEA were calculated. Matched individuals with and without diabetes but remaining amputation-free were used as controls.

Results. 3 342 Belgian citizens underwent LEA: 2 130 individuals with diabetes (minor: 1 544; major: 586), compared to 1 194 individuals without diabetes (minor: 751; major: 443); the control group consisted of 32 599 individuals without LEA. Table 1 presents all costs in the year preceding and following LEA. A minor LEA increases the total medical cost roughly tenfold, with a further doubling for major LEA, both in the pre- and postoperative year.

Conclusions. Medical costs in individuals undergoing LEA are high, both before and after the amputation. Higher amputations are associated with higher costs. Diabetes also has a significant impact on costs, but the difference in costs compared to individuals without diabetes is less pronounced with higher amputation levels.

	Pre intervention cost			Post intervention cost		
	Diabetes	No diabetes	Diabetes vs. no diabetes	Diabetes	No diabetes	Diabetes vs. no diabetes
No LEA	2 894€ (1 246 – 8 510€)	1 366€ (560 – 4 156€)	< 0.001	2 303€ (855 – 8 530)	1 119€ (434 – 4344€)	< 0.001
Minor LEA	24 092€ (11 892 – 45 959€)	16 221€ (3 422 – 35 375€)	< 0.001	21 428€ (9 976 – 44 033€)	12 208€ (4 060 – 29 077€)	< 0.001
Major LEA	49 914€ (32 358 – 89 652€)	37 664€ (20 918 – 63 731€)	< 0.001	45 700€ (23 982 – 77 017€)	37 860€ (17 720 – 65 848€)	< 0.001

Table 1: Total median costs (Quartile 1 and 3 between brackets) of individuals with and without diabetes undergoing minor and major LEA during the 12 months preceding and following LEA, as compared to amputation-free controls. Costs are expressed in 2014 Euro's. P-values were calculated using Mann-Whitney U test, reweighted for age and gender.

0.01-4

Presentation Time to An Established Interdisciplinary High Risk Foot Service Reflects the Possible: An Audit of 20-Years of Real-World Data

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Longer time to presentation (TTP) for diabetes-related foot ulcer (DFU) to specialised inter-disciplinary High Risk Foot Services (iHRFS) may adversely affect healing outcomes. Patient factors, delayed (or absence of) primary care referral, triage and waiting times, contribute to presentation delay while addressing barriers to access and use of guidelines should reduce delay. Time to presentation (TTP) is an important performance indicator used within our service, in-line with recommendations within the UK, Australia and the IWGDF.

Aim: To determine if days from ulcer occurrence to ulcer presentation at the HRFS has reduced, and to relate TTP to DFU severity and healing outcomes.

Methods: Audit of our Diabetes Centre iHRFS database, with data analysed serially across five 4-year time intervals from the year 2000, up to the COVID pandemic onset.

Results: Across all time periods, 4,749 ulcers in 1,914 patients were assessed, with a mean±SD age of 61.8±13.8 years at ulcer presentation. Based on progressive weekly presentation time interval categories, increasing TTP was associated with lower overall healing ($P<0.0001$) and longer median healing time ($P<0.0001$). The median[IQR] TTP in the 2016-2019 cohort (876 ulcers in 388 patients), was 18[7-38] days and 30[16-79] days the subgroup of new patients to the service. Most DFU were superficial (59.6%) and were usually not infected or ischaemic (53.5%). Overall, 71% healed. Ulcers to bone had a median(IQR) of 31(20-89) days to presentation and worse outcomes with 41.2% healing. There was no recent trend of improvement in TTP for DFU of any Grade or Stage.

Conclusion: Improvement in time to presentation for patients to our established iHRFS has plateaued. Foot protection plans including education at discharge, for known patients, may explain their earlier presentation. New patients take longer to present. A target of less than 30 days for non-infected, non-ischaemic ulcers, before depth extends, is likely to improve overall healing outcomes and represents an achievable goal, aligned to local and international guidelines. The delay in presentation for ulcers with higher Stage or Grade and data suggest ischaemic ulcers are being under-appreciated in their presence and significance by referrers, representing an area for targeting improvement strategies.

O.01-5

Appraisal of Charcot neuroarthropathy guidelines across Europe using the AGREE-II tool

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Background/Aim Clinical practice guidelines (CPGs) are intended to optimise patient care. They are informed by a systematic review of evidence, and an assessment of risk/benefit, cost-effectiveness and acceptability. The aim of this study was to critically assess the methodological quality and rigour of acute Charcot neuroarthropathy (CN) CPGs.

Methods CPGs were collated through a systematic review (Pubmed, ScienceDirect, Scopus and CINAHL databases) and through known diabetic foot associations and contacts. CPGs published within Europe after the year 2000 were included. Their methodological quality was evaluated using the Appraisal of Guidelines for Research & Evaluation (AGREE) II tool¹ by two independent reviewers. This instrument consists of 23 items organised into 6 domains and an overall assessment section. Scores for the 23 items across the 6 domains were combined to generate a percentage rating. A score from 1 to 7 was then assigned to provide an overall assessment of the guideline. Guidelines were recommended for use if they scored ≥ 6 .

Results 15 guidelines were assessed, with 20% (n=3) reaching the threshold for recommendation (Figure1).

Conclusions Overall, the methodological rigour of CPGs was poor. This review highlights the need (1) to improve the process of guideline development for acute CN, (2) to increase patient and public involvement, (3) for clear rationale as to how the evidence links to recommendations and (4) to support clinicians to implement and audit guidelines.

We would like to acknowledge the support of the DFSG.

1. Brouwers, M. Can Med Assoc J. Dec 2010, 182:E839-842; doi: 10.1503/cmaj.090449

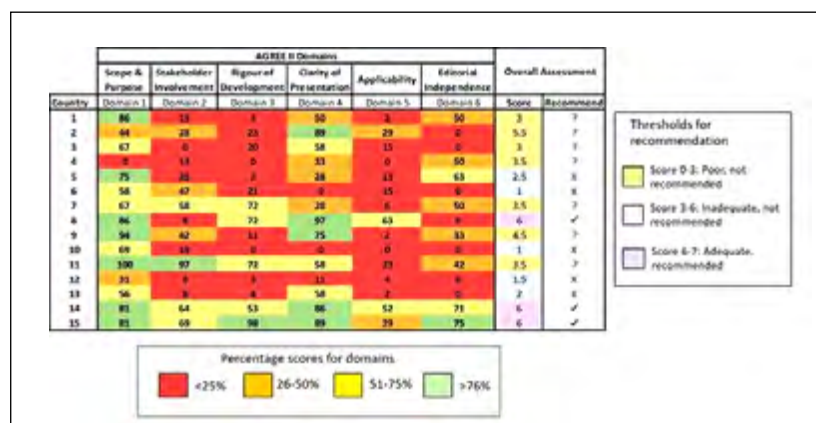


Figure 1: Percentage scores for each AGREE-II domain assessed for each national European guideline with corresponding overall scores and recommendations

O.02-1

What is the clinical utility of SEM measurement for the detection of diabetic foot ulceration among adults with DM

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Purpose Previous research has shown that the measurement of sub-epidermal moisture (SEM) identifies increased risk of PU by allowing early identification of cellular oedema. For the first time, this study aimed to assess the effectiveness of SEM in the early identification of DFU.

Methods In this prospective observational study SEM measurements using the SEM ScannerTM were taken from 216 individuals attending outpatient diabetes clinics in a large urban teaching hospital in Ireland as part of a comprehensive diabetic foot assessment. Measurements were taken at foot sites associated with ulceration-plantar hallux, first metatarsophalangeal joint, fifth metatarsophalangeal joint and the heel. Those participants identified at increased risk at baseline had an additional 2 assessments within the next 7 days.

Results Of the 216 participants, 22% (n=47) were identified as high risk using standard assessment, 70% (n=152) had suboptimal diabetes control, 23% (n=49) had loss of protective sensation and 2% (n=5) had non-palpable pulses. Elevated SEM was identified in 32% (n=69). There was agreement between SEM and standard risk assessment tools in 62% (n=42) of these cases. Of the 13% (n=9) of the high risk participants who developed a visual DFU during the 7 day period, 88% (n= 8) had an elevated SEM prior to ulceration. Abnormal SEM was correlated with DFU and this correlation was statistically significant. SEM readings had a high sensitivity and specificity.

Risk status	No DFU Low	DFU Moderate	High	Low	Moderate	High	Sensitivity	Specificity
SEM								
Normal (<0.5)	92 (90%)	55 (82%)	8 (21%)	0	0	1 (11%)	88.9%	
(52.8% to 99.7%)	74.9%							
(68.4% to 81.0%)								
Abnormal (≥0.5)	10 (10%)	12 (18%)	30 (79%)	0	0	8 (89%)		
Abnormal SEM readings were also seen in higher risk groups using the Scottish risk assessment tool. SEM								
Abnormal (≥0.5), n(%)								
Normal (<0.5), n(%)	Low							
10 (10%)								
92 (90%)	Moderate							
12 (18%)								
55 (82%)	High							
38 (81%)								
9 (19%)	Total							
60 (28%)								
156 (72%)								

Conclusion Whilst tentative, initial analysis from this study shows that similar to early stage PU identification, that SEM measurement can also result in the earlier detection of DFU through identifying cellular oedema and local inflammation.

O.02-2

Effects of a group-based foot-ankle exercise program for people with diabetic neuropathy on physical functionality and musculoskeletal clinical outcomes

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Background/Aim Recently, the IWGDF guidelines for treating and preventing diabetic foot complications included foot-ankle exercises program as an alternative approach, since it has been shown promising results for improving diabetic neuropathy (DPN) signs and symptoms and foot-ankle ROM. However, there is still room for debate about the best therapeutic approach for delivering foot-ankle exercises and there is some skepticism if increasing the level of activity due to exercises program would also increase the risk for ulceration. Thus, we designed a randomized controlled trial to determine whether a group-based approach of a foot-ankle exercise program can improve daily physical activity (number of steps), fast and self-selected gait speed, without increasing the risk for ulcerations.

Methods 78 participants with DPN were randomly allocated into a control group (CG: n=39, 60.1±8.9yrs), which received usual care, and an intervention group (IG: n=39, 61.5±11.7yrs), which received usual care plus the group-based foot-ankle exercise program. Number of steps and gait speed were evaluated by 3D accelerometers and two photocells, respectively. Ulcers incidence was monitored for one year. Other secondary clinical outcomes were also evaluated (ankle ROM, plantar tactile sensitivity, quality of life, DPN symptoms). Comparisons between groups and time points (baseline, 6, 12, 24 weeks and 1-year followup) were performed by Generalized Linear Mixed Models followed by Bonferroni post hoc ($p < 0.05$).

Results The adherence to the program was 92.3%. The number of steps and self-selected gait speed did not change significantly in either group after the program, however fast-gait speed ($p=0.020$), ankle ROM ($p=0.048$), and vibration perception ($p=0.030$) were improved compared with usual care at 12-week. At 24-week, IG showed better quality of life than CG ($p=0.048$). At 1-year, fast-gait speed and vibration perception remained higher in the IG versus CG. Over a 1-year followup, only 2 participants (one from each group) developed a plantar ulcer.

Conclusion A group-based approach of a foot-ankle exercise program showed positive changes in fast-gait speed, ankle ROM and vibration perception, suggesting an improvement on physical function, without increasing the risk for ulceration. The program may be a complementary treatment strategy for improving musculoskeletal and functional deficits related to DPN.

O.02-3

Health literacy and Cognition independently predict incident foot ulcers after 4 years – the SHELLED cohort study

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Background/Aim: Poor health literacy is associated with retinopathy and cerebrovascular disease in people with diabetes but little is known about its effects on index foot ulceration. The aim of this study was to determine whether health literacy is associated with index diabetic foot ulcer development.

Methods: The Southern Tasmanian Health Literacy and Foot Ulcer Development in Diabetes Mellitus (SHELLED) Study is a 4-year prospective study of people with diabetes. People aged over 40 attending a tertiary hospital outpatient clinic with no history of diabetic foot disease were assessed at baseline for diabetic foot disease risk factors such as peripheral neuropathy, peripheral artery disease and foot deformity. Health Literacy was measured using the short form Test of Functional Health Literacy in Adults (s-TOFHLA) and the nine domains of the Health Literacy Questionnaire (HLQ). Other key covariates measured at baseline include demographic characteristics, medical and smoking history, cognition (Montreal Cognitive Assessment), foot care and diabetes self-efficacy and diabetes-related distress. The primary outcome was development of a first foot ulcer within the 4-year follow up period, confirmed by participants' treating practitioners.

Results: Of 222 participants, 191 (86.0%) completed the study, of whom 13 (5.9%) developed an incident ulcer. In multivariable models, every unit increase in S-TOFHLA score reduced the odds of foot ulcer development by 6% (OR 0.94, 95% CI 0.88 to 0.99). Better scores on two HLQ domains reduced the odds of foot ulcer (actively managing my health (OR 0.23, 95% CI 0.08 to 0.65) and understanding health information well enough to know what to do (OR 0.39, 95% CI 0.19 to 0.78). This was independent of risk for foot disease at baseline.

Conclusions: These data provide novel evidence that health literacy is an important clinical risk factor for index foot ulceration. People with poor health literacy should be identified and their needs accommodated in health policy and communication to improve diabetic foot disease prevention.

0.02-4

Cost-effectiveness and cost-utility of at-home foot temperature monitoring for diabetes-related foot ulcer prevention: a health-economic multicentre randomized controlled trial (DIATEMP)

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Background/Aim: Diabetes-related foot ulcers frequently recur. To better inform stakeholders on ulcer recurrence prevention, we economically evaluated the effectiveness of at-home foot skin temperature monitoring.

Methods: In this multicentre RCT, we randomly assigned people with diabetes, neuropathy, foot ulcer history or Charcot's neuro-arthropathy to usual care plus daily foot skin temperature measurements at 6-8 sites (enhanced therapy) or usual care. Foot care costs were obtained via questionnaires and medical records. Health-related quality of life was assessed with the EQ-5D-3L. Clinical outcome was foot ulcer recurrence in 18 months. Incremental cost-effectiveness and cost-utility ratios were calculated and visualized through cost-effectiveness planes and corresponding cost-effectiveness acceptability curves for willingness-to-pay/accept levels up to €100,000 after non-parametric bootstrapping.

Results: Foot care costs per participant during 18 months were non-significantly lower for enhanced therapy (n=151; mean:€6,067 (SD:€13,778)) compared to usual care (n=153; mean:€7,376 (SD:€15,790); P=0.45). Enhanced therapy saved €11,580 per ulcer prevented and had 79% probability of being cost-effective at a willingness-to-pay of €0 per ulcer-free participant (Fig.1). Quality-adjusted life years were non-significantly lower in enhanced therapy (mean:1.085 (SD:0.33)) compared to usual care (mean:1.119 (SD:0.31); P=0.35). Enhanced therapy saved €37,389 per QALY lost and had 45% probability of being cost-effective at a willingness-to-accept of €50,000 per QALY lost (Fig.1). **Conclusions:** In this first-ever health-economic RCT in diabetic foot ulcer prevention, at-home foot temperature monitoring was cost-effective over usual care in ulcers prevented, but at best equally cost-effective when focusing on QALYs.

Funding: Netherlands Organization for Health Research and Development.

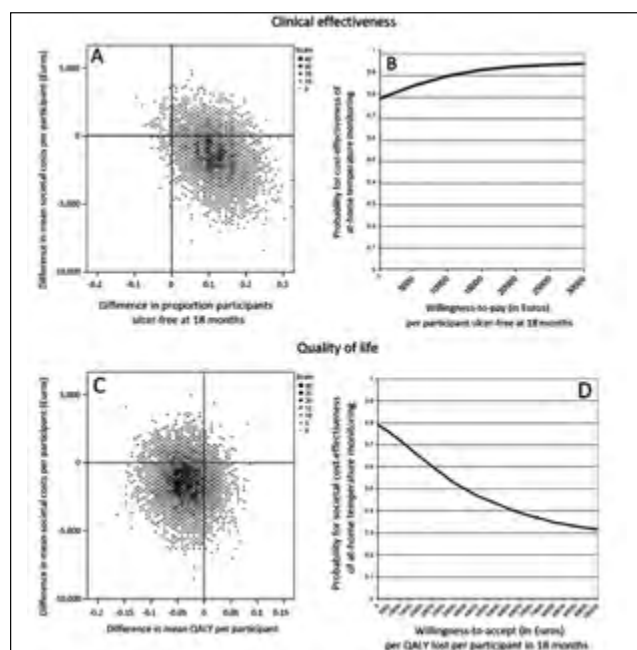


Figure 1: Cost-effectiveness of at-home foot temperature monitoring for diabetic foot ulcer prevention

O.02-5

Validation of IWGDF risk stratification for a first ever ulcer in a diabetic population with loss of protective sensation

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Aim: Ulcer risk for patients with loss of protective sensation (LOPS) but no previous foot ulcer is classified in the IWGDF 2019 risk stratification as being moderate (in those with peripheral arterial disease (PAD) or deformity) or low (in those without either). The aim of this study was to validate the predictive value of the stratification for the first ever ulcer (FEU).

Method: Newly presenting consecutive patients with diabetes complicated by LOPS but without any previous foot ulcer were identified in a regular foot check between January 2017 and September 2018. LOPS was diagnosed by vibration perception <4/8 (tuning fork) and foot deformity in a subgroup according to nurses' assessment. PAD was regarded as present if not all pulses were palpable on both feet. Patients were followed up by routine foot checks, phone interview or by letter until occurrence of a FEU, death or end of the observation period. Time to FEU was estimated in the framework of an accelerated failure time (AFT) model.

Results: All pulses were present in 96 patients, 1-3 in 24 and no pulses in 11. Foot deformity was present in 13 of 94 subgroup patients (6 with PAD). Ulcer risk was stratified as low in 64 and moderate in 30 patients. 130 of 132 patients were followed up for a median of 48.3 month. A FEU occurred in 24 while 106 patients remained ulcer free. Patients with PAD had a 2.7 times higher risk of FEU than those without (95%-KI = [1.3, 5.4]; $p=0.001$), survival curves differed significantly ($p=0.003$). Deformity was not a risk factor for FEU in the subgroup. Estimated median time to FEU in AFT model was 67 months for moderate versus 152 months for low risk patients.

Conclusion: PAD in addition to LOPS is of high predictive value for a future FEU. In contrast, existence of deformity does not predict FEU, maybe due to the lack of clear definition. The relative risk for FEU is twice as high and estimated time to FEU is less than half as long in patients with LOPS plus PAD compared to patients with LOPS only.

0.03-1

Minimally invasive correction of the hindfoot and ankle deformities in Charcot neuroarthropathy: proof-of-concept

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Background: Charcot neuroarthropathy (CN) of the hindfoot or ankle often results in significant deformity, instability, chronic ulceration, and infection that, without adequate treatment, could lead to trans-tibial amputation. Several surgical procedures for the reconstruction of hindfoot and ankle CN deformities have been described. Their main disadvantage includes the extensive dissection of soft tissue, which could lead to infection, necrosis and osteosynthesis failure.

Methods: We introduce a novel technique of minimally invasive surgery (MIS) for correction of deformities, followed by retrograde intramedullary nailing of hindfoot for stabilisation of correction. MIS aims to correct deformities through tiny percutaneous incisions using high speed burrs under control of fluoroscopic imaging.

We report the postoperative outcomes of 4 patients (2 men, 2 women, 4 feet) with unstable hindfoot Charcot deformities and pressure ulcers who underwent MIS.

Results: The mean age of the patients was 54.5 years (42 to 76); their median American Society of Anaesthetists score was 3 (2 to 4). All presented with unstable severe deformities and chronic ulceration. Three patients underwent a single-stage procedure, and one patient underwent a two-stage surgical treatment. No postoperative infections occurred. Complete healing of ulceration was achieved at 5 weeks. Hindfoot angle improved from 36° (26 to 46) to 6° (2 to 9), ($p < 0.05$). At a mean follow-up of 19 months (17 to 23), limb preservation was achieved in all patients. All patients regained independent mobilisation with fully weight bearing in custom foot orthoses. There was no failure of correction or fixation. The mean American Orthopaedic Foot & Ankle Society (AOFAS) score improved from 45.3 (30 to 57) to 84.5 (81 to 92), ($p < 0.05$).

The mean Euroqol EQ-5D-5L score improved from 0.55 (0.42 to 0.66) to 0.87 (0.74 to 0.96), ($p < 0.05$).

Conclusion: This proof-of-concept shows that MIS of hindfoot deformities can be a safe and efficient procedure for patients with severe CN deformities, chronic ulcerations and hindfoot instability, providing short-term healing of pressure ulcers and long-term improvement of function and quality of life.

O.03-2

Surgical timing for Charcot foot reconstruction: Pattern of paradigm shift from a systematic review of recent literature

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Introduction: The optimal timing to surgically intervene in Charcot foot arthropathy remains controversial. Classical teaching is to avoid intervention in the active stage of Charcot foot, because of the worry of soft tissue and bony complications. However, several authors had advocated the paradigm shift to intervene early in active Charcot foot, to allow deformity correction and stabilization before further deformity develops. This article aims to investigate the current pattern of paradigm shift and the outcomes after intervention in the active and inactive stages of Charcot foot.

Methods: This study was done in accordance with the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-analysis). A literature search was done on Pubmed, Embase, Cochrane Library, and Clinicaltrials.gov. An effort was made to search for all relevant articles in unpublished sources such as conferences as well as the reference list of included studies. All relevant articles published within the last 5 years were included, with the exclusion of case reports.

Results: 269 articles were screened, and 17 studies were included. There were 11 studies with surgery in the inactive stage of Charcot foot, 6 studies with surgery in both the active and inactive stages of Charcot foot, and no study was done in the active stage alone. The amputation rate for surgery in the inactive stage was 10.5% while that of active and inactive stages was 12.3%. The re-operation rate for surgery in the inactive stage was 31.2% while that of active and inactive stages was 50.0%. The non-union rate after surgery in the inactive stage was 13.0% while that of active and inactive stages was 32.5%.

Conclusion: Most surgeons still prefer to intervene surgically in the inactive stage of Charcot foot. Amputation rate, re-operation rate, and non-union rates were higher in studies that included surgery in both active and inactive stages of Charcot foot. Therefore, surgeons should be cautious in deciding optimal surgical timing for Charcot foot reconstruction and avoid the active stage of the disease if possible.

0.03-3

Calcaneus fracture open reduction and internal fixation in patients with Diabetes mellitus: Will this patient heal?

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Background/Aim: Treatment of calcaneal fractures in patients with Diabetes mellitus (DM) is challenging. Historically, adverse outcomes are more frequent in patients with complications of DM. The purpose of this study was to compare post-operative outcomes after open reduction and internal fixation (ORIF) for calcaneus fracture in patients with complicated DM, uncomplicated DM, and patients without DM.

Methods: The PearlDiver Database identified 51,305 patients who underwent ORIF of calcaneus fractures from 2015 to 2021 who were followed for a minimum of one year [38,843 without DM (76%), 8250 uncomplicated DM (16%), 4,212 with complicated DM (8%)]. Post-operative complications of nonunion and amputation were assessed at one year, as well as 30-day and 90-day rates of reoperation, acute kidney injury, cardiac arrest, dehiscence, CVA, DVT, MI, pulmonary embolism, sepsis, pneumonia, surgical site infection, and wound disruption.

Results: Amputation ($p < 0.0001$), delayed union ($p < 0.0001$), reoperation ($p < 0.0001$), AKI ($p < 0.0001$), MI ($p < 0.0001$), wound disruption ($p < 0.0001$), and sepsis ($p < 0.0001$) were significantly higher in patients with complicated DM compared to uncomplicated DM. In both DM groups (uncomplicated DM, complicated DM) higher rates of amputation (OR 5.27 and 10.09, respectively) were observed compared to patients without DM. See Table 1.

Conclusions: Complicated DM is associated with significantly higher risk of adverse events after calcaneus fracture ORIF. Patients with complicated DM have nearly tenfold higher likelihood of amputation following calcaneus ORIF than patients without DM. Calcaneus fractures in patients with complicated DM may serve as a useful comparison for hindfoot Charcot neuroarthropathy.

Table 1: Comparison of patient outcomes after calcaneus fracture open reduction internal fixation at 1 Year

Adverse Event	No Diabetes (N, %)	Diabetes without Complications (N, %)	Diabetes with Complications (N, %)	OR, p-value
Non-Union	474 (1.22%)	134 (1.62%)	110 (2.61%)	a 1.34 $p = 0.004$ b 2.17 $p = <0.0001$ c 1.62 $p = 0.0002$
Delayed Union	565 (1.45%)	134 (1.62%)	117 (2.79%)	a 1.12 $p = 0.2475$ b 1.94 $p = <0.0001$ c 1.73 $p = <0.0001$
Reoperation	194 (0.50%)	191 (2.32%)	164 (3.89%)	a 4.72 $p = <0.0001$ b 8.07 $p = <0.0001$ c 1.71 $p = <0.0001$
Acute Kidney Injury	533 (1.37%)	1312 (15.90%)	1002 (23.79%)	a 13.59 $p = <0.0001$ b 22.44 $p = <0.0001$ c 1.65 $p = <0.0001$
DVT	193 (0.50%)	115 (1.39%)	87 (2.07%)	a 2.03 $p = <0.0001$ b 4.22 $p = <0.0001$ c 1.49 $p = 0.005$
Myocardial Infarction	435 (1.12%)	797 (9.54%)	503 (11.94%)	a 9.31 $p = <0.0001$ b 11.97 $p = <0.0001$ c 1.29 $p = <0.0001$
Pulmonary Embolism	139 (0.36%)	128 (1.55%)	56 (1.33%)	a 4.39 $p = <0.0001$ b 3.75 $p = <0.0001$ c 0.85 $p = 0.332$
Sepsis	147 (0.38%)	219 (2.65%)	217 (5.15%)	a 7.18 $p = <0.0001$ b 14.30 $p = <0.0001$ c 1.99 $p = <0.0001$
Surgical Site Infection	204 (0.53%)	133 (1.61%)	102 (2.42%)	a 3.10 $p = <0.0001$ b 4.70 $p = <0.0001$ c 1.51 $p = 0.002$
Wound Disruption	840 (2.16%)	358 (4.34%)	279 (6.62%)	a 2.05 $p = <0.0001$ b 3.21 $p = <0.0001$ c 1.56 $p = <0.0001$
Below Knee Amputation	82 (0.21%)	91 (1.10%)	88 (2.09%)	a 5.27 $p = <0.0001$ b 10.09 $p = <0.0001$ c 1.91 $p = <0.0001$

^aNo DM vs DM without complications
^bNo DM vs DM with complications
^cDM without complications vs DM with complications

O.03-4

Nothing “minor” about minor diabetic foot amputation; despite ability to perform as day-cases it’s associated substantial mortality and morbidity

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Background/Aim: Much focus seems to be placed on prevention of major amputation and not so much for prevention of minor diabetic foot amputation. Within a good setting most minor amputation does seem straight forward and can be performed as a day case procedure. The aim was to conduct a retrospective analysis of minor amputations done as day case procedures with analysis of clinical outcomes.

Methods: We conducted a retrospective analysis of all minor amputations done as day case procedures between 2015 and 2017 with analysis of patient demographics, clinical outcomes including mortality at 30day, one year and 5 year.

Results: Over the 3 year period there were a total of 320 episodes of minor amputations in 232 patients, 19%(60/320) were done as day case procedures on 50 patients, of which 73% were male, 82% with type 2 diabetes, mean HbA1c of $8.5 \pm 2.2\%$, CRP of 88.4mg/L and WCC of $10.3 \pm 3.8 (10^9/L)$. Of the procedures 60%(36/60) were done within and during the Multidisciplinary Diabetic Foot Clinic, most of which were done as an emergency surgery within the clinic, and 37%(22/60) were done as a planned procedure in the hospital Day Surgery unit. 60% were documented as Other specified amputation of toe, 15% were for Amputation of great toe, 15% were for Amputation of phalanx of toe, 5% were for Amputation through metatarsal bones, and 5% were for Unspecified amputation of toe. 95%(57/60) of procedures were done by a vascular surgeon and the remaining 5% were done by an Orthopaedic surgeon. The 5 year mortality was 47%, with a one year and 30day mortality of 28% and 17% respectively. The mortality risk was irrespective of minor amputation level, number of procedures nor baseline biochemistry.

Conclusions: Complex minor amputations can be done as day cases within the MDfT clinic to prevent hospital admissions. But irrespective of the type of minor amputation, it can still be associated with significant mortality. As such more weight or emphasis also needs to be placed on the need to prevent patients from getting to or needing to undergo minor diabetic foot amputation.

O.04-1

The daily change in distal perfusion as measured by toe pressure post revascularisation

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Background/Aim Toe pressure (TP) can be utilised to provide a measure of small arterial function in peripheral artery disease in patients with and without diabetes. (1) A cornerstone of treatment of diabetic foot disease is effective revascularisation, however the physiological changes in foot perfusion in the days following revascularisation are less understood. The aim of this study was to determine if pedal perfusion, as measured by toe pressure, alters over consecutive days following revascularisation.

Methods Patients undergoing revascularisation were recruited over 25-week duration from June to December 2022 at a single tertiary centre. Baseline demographics, pre-revascularisation TP and type of revascularisation was recorded. After revascularisation, TP was measured every day until patients were discharged from hospital. Patients were rested in supine position in a temperature controlled room for 15 minutes prior to TP measurement.

Results There were 46 participants, with 55 revascularised limbs. Overall, 20 (43.5%) participants had diabetes, and 31 (56.4%) limbs underwent endovascular revascularisation. Median TP improved from day 1 post revascularisation to date of discharge (day one 32mmHg (6–101) vs. last day 41mmHg (5–103), $p<.001$). In patients with diabetes, the improvement in median TP post revascularisation was less pronounced compared to patients without diabetes (diabetes: day one 32mmHg (11–101) vs. last day 39.5mmHg (6–101), $p=.021$; no diabetes: day one 37mmHg (6–80) vs. last day 46mmHg (5–103), $p=.002$.) Open revascularisation had greater TP at discharge (day one 38.5mmHg (6–80) vs. last day 48.5mmHg (22–103), $p<.001$) compared to endovascular (day one 31.5mmHg (7–101) vs. last day 33mmHg (5–101), $p<.001$).

Conclusions TP gradually increases during the days following a revascularisation procedure. However, patients with diabetes may experience a slower increase than patients without diabetes. Furthermore, limbs that undergo open revascularisation may have faster and greater reperfusion than those that undergo endovascular revascularisation.

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0.04-2

Evolution of patient characteristics and outcomes concerning diabetic foot ulcer care in Belgium between 2008 and 2020

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Background/Aims: Since 2005, recognized Belgian multidisciplinary diabetic foot clinics (MDFCs) participate to biennial audit-feedback cycles, allowing to study the epidemiology of diabetic foot ulcers (DFU) and monitor/improve quality of care. We investigated how patient and foot characteristics, treatment and outcome evolved between 2008 and 2020.

Methods: Data were cross-sectionally collected between 2008 and 2020. Recognized MDFCs included the first 52 patients with a new DFU of Wagner 2 or higher during the audit period. Person and ulcer characteristics were recorded at baseline together with treatment and outcome during a 6-month follow-up period. A neutral weighting was applied to all variables. Evolution over time was studied in a repeated cross-sectional way using Generalized Estimating Equations (SAS9.4).

Results: The number of people with a new DFU included were 985 in 2008 (20 MDFCs) and increased to 1.579 in 2020 (35 MDFCs). Patients became older (2008: 68.2±0.4 years; 2020: 70.1±0.3 years; $p<0.0001$), had a longer median (P25-P75) diabetes duration (2008: 14.2 (7.5-23.4) years; 2020: 16.3 (9.5-24.5) years; $p=0.0002$) and more often type 2 diabetes (2008: 87.8%; 2020: 91.2%; $p=0.0013$). Comorbidity rates were high. Presentation to the MDFC on the patient's own initiative strongly elevated over time (collected since 2011: 20.6%; 2020: 35.1%; $p<0.0001$). Moreover, median (P25-P75) patient-reported presentation delay reduced significantly from 4 (2-8) weeks in 2008 to 3 (1-8) weeks in 2020 ($p=0.0134$). Proportion of severe DFU (SINBAD≥3) diminished across the audits (2008: 91.6%; 2020: 82.3%; $p=0.0115$). Proportion of patients receiving offloading (collected since 2011: 74.6%; 2020: 63.2%; $p=0.4750$), undergoing a revascularization when having critical limb ischemia (2008: 66.4%; 2020: 67.0%; $p=0.7860$), minor amputation (2008: 16.8%; 2020: 21.1%; $p=0.1636$) or major amputation (2008: 3.6%; 2020: 2.9%; $p=0.5882$) remained unchanged over time. Nonetheless, healing after 6 months follow-up decreased slightly from 47.2% in 2008 to 43.8% in 2020 ($p=0.0296$). Inter-center variability remained high throughout time.

Conclusions: Despite the positive evolution of faster presentation to the MDFC with less severe DFU, the outcome did not change over time and even a slight decrease in healed DFU after 6 months could be observed. A negative trend towards less offloading might be an underlying cause.

0.04-3

The effects of custom-made footwear on stability during walking in people with diabetes and peripheral neuropathy

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Background/Aim: Custom-made footwear for people with diabetes and neuropathy aims to reduce peak plantar pressures and helps reduce the risk of foot ulceration. This footwear redistributes plantar pressure effectively but can also introduce instability during walking, which could lead to a higher fall risk. Our aim was to explore the effects of custom-made footwear on stability during walking.

Methods: In a cross-sectional design 39 participants (75 feet) with diabetic neuropathy at high risk of ulceration and in possession of custom-made footwear completed both barefoot and in-shoe pressure measurements during walking. From these data, the maximum velocity of the Center-of-Pressure (CoP) was calculated for the loading response, midstance, terminal stance and preswing of stance, and compared for shod vs barefoot walking. An increase in maximum velocity defined an increase in instability. In secondary analysis we compared feet with and without an amputation at any level of the foot. We used paired and independent t-tests for statistical analyses.

Results: The maximum velocity of the CoP was significantly higher for shod vs barefoot walking during loading response ($t(74)=3.03$, $p=0.003$) and preswing ($t(74)=2.38$, $p=0.020$) (Fig.1). A decrease in maximum velocity of CoP was found during shod walking for amputated vs non-amputated feet during loading response but this was not significant.

Conclusion: Custom-made footwear can increase instability during loading response and preswing of walking in people with diabetic neuropathy. Further research is needed into which footwear design aspects contribute to this change and its effect on biomechanical, clinical and patient-related outcomes.

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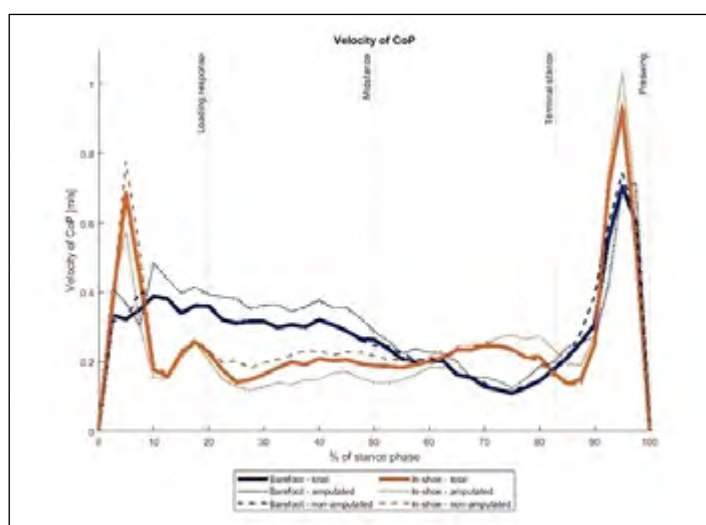


Figure 1: Median velocity of the Center of Pressure in m/s during the stance phase. Data is shown for barefoot and shod walking, and separately for amputated and non-amputated feet.

O.04-4

Clinical characteristics and risk factors for mortality in patients with diabetic foot ulcers

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Background: To explore the risk factors for mortality in patients with diabetic foot ulcer (DFU) and to analyze their clinical characteristics.

Methods: This study included DFU patients who were admitted for the first time to a diabetic center between January 2012 and December 2020. Follow-up until March 2022 or death, divided into death and survival groups based on whether the final follow-up is alive.

Results: The cohort included 993 patients with DFU, and 772 patients were followed, of which 251 (32.5%) died. The cumulative mortality rates at 1-, 3-, and 5-year inpatient DFU were 7.4%, 18.6%, and 30.1%, respectively, with a median survival time of 90 months (95% CI: 83-98 months). Compared with the survival group, the deceased group were older, and who have more comorbid conditions such as hypertension, coronary heart disease, chronic kidney disease (CKD), and ischemic foot ulcers. Patients with more severe foot ulcers and peripheral arterial disease (PAD) ($ABI \leq 0.4$: 5.6% vs. 1.6%, $P < 0.05$). In the deceased group, baseline serum albumin (ALB), hemoglobin and estimated glomerular filtration rate were lower, higher nephrotic index levels, and higher levels of inflammatory markers. Age, hypertension, CKD (stage 45), foot gangrene, decreased ALB, and elevated CRP were all significantly associated with death in DFU patients, according to multivariate logistic regression. DFU patients with CKD4-5 had a 3.5-fold increased risk of death when compared to patients without CKD (HR 4.454, 95% CI: 2.003-9.906, $P < 0.001$). DFU patients with hypertension had a 2.6-fold increased risk of death when compared to patients without hypertension (HR 3.616, 95% CI: 1.840-7.107, $P < 0.001$). DFU patients with foot gangrene had a 2.0-fold increased risk of death compared to patients without gangrene (HR 2.0, 95% CI: 1.222-3.392, $P = 0.006$).

Conclusions: In hospitalized patients with DFU, age is an independent risk factor for death, and patients with hypertension and CKD have a significantly increased risk of death. Low ALB and high CRP levels may be risk factors for death in patients with DFU. Cardiovascular disease is the leading cause of death in patients with DFU, and falls cannot be ignored.

O.05-1

Plantar pressure reduction in the heel region through self adapting insoles with a heel cup

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Background Rocker shoes and insoles can be used to offload high plantar peak pressure (PP) in patients with diabetes and loss of protective sensation (LOPS) to prevent ulcers. If the shape parameters are chosen correctly, rocker profile shoes have proven to be effective in reducing PP in the forefoot region. However, often an increase in pressure in the heel region is seen. Although more ulcers are seen in the forefoot region, heel ulcers are harder and more expensive to treat. A possible way to reduce PP in the heel region is to push the fat pad underneath the bony prominences of the calcaneus by a tight fitting heel cup with high edges.

Methods 10 patients with diabetes and LOPS with PP >200 kPa in the heel region walked on a treadmill with standard shoes and individually optimized rocker profile shoes, both with and without an self-adapting insoles with heel cup while the in-shoe PP was measured. The rocker profile was 3D printed and the shape was individually optimized based on an algorithm. The forefoot part of insoles consisted of elements that buckle down if pressure reaches a threshold of 190kPa and with that, offloading pathological PP. The heel part consisted of a tight fitting heel cup.

Results Non parametric tests show significant decreases in PP both with standard and rocker profile shoes of 17% with use of the self-adapting insole with heel cup (standard shoe: from 243±32 to 204±24kPa; rocker shoe from 259±37 to 217±25kPa). Likewise, the number of sensors with PP>200kPa decreased significantly from 6.2±3.9 to 1.8±2.6 in standard shoes and from 8.0±3.4 to 2.7±3.6 in rocker shoes.

Conclusions Self-adapting insoles with heel cup are effective in reducing the PP in the heel region and in decreasing the area with pressure over 200 kPa both in standard shoes and in rocker profile shoes. With the use of this type of insole the pressure increasing effect of rocker profile shoes in the heel region can be nullified.

0.05-2

Falls in people with diabetes and peripheral neuropathy and their association with physical activity and gait quality

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Background/Aim: Peripheral neuropathy in people with diabetes mellitus is a strong predictor of falls. To prevent falls, people with diabetes and peripheral neuropathy at high risk should be identified. While peripheral neuropathy can lead to functional decline and impaired gait quality, it is unknown whether daily-life physical activity and gait quality are associated with falls within this population. Our aim was to determine fall incidence and its association with physical activity and gait quality characteristics in people with diabetes and peripheral neuropathy.

Methods: In an observational prospective cohort design, we longitudinally followed 43 participants with diabetes and neuropathy (9 females, age: 64.1 (SD:8.9) years, BMI: 30.0 (SD:5.7) kg/m², all IWGDF risk 3) for 6 months. Falls were reported in a fall diary. Participants wore a tri-axial accelerometer for seven consecutive days to obtain data on physical activity and gait quality measures. We tested associations between falls and physical activity and gait quality using forward multivariate logistic regression analysis, with characteristics selected via Student's t-test ($p < 0.2$).

Results: In total, 17 participants (40%) reported a total 23 falls during 6 months follow-up. Fallers had a lower number of lying episodes per day than non-fallers (fallers: 8.8 (SD:5.1), non-fallers: 12.8 (SD:5.6)), which was significantly associated with falls in multivariate analysis ($p = 0.02$). Compared to non-fallers, fallers were more often female (fallers: 35%, non-fallers: 21%), had lower walking speed (fallers: 0.8 (SD:0.2) m/s, non-fallers: 0.9 (SD:0.2) m/s) and more consistent gait pattern (fallers: 0.6 (SD:0.2) power spectral density, non-fallers: 0.5 (SD:0.1) power spectral density). However, none of these characteristics were significantly associated with falls in multivariate analysis.

Conclusions: In total, 40% of people with diabetes and neuropathy had a fall incident during 6 months follow-up, which was comparable to the literature for healthy older adults (35%) [1]. A lower number of lying episodes per day was the only characteristic significantly associated with falls in people with diabetes and peripheral neuropathy. Fall prevention programs may consider the amount of lying episodes in order to reduce the risk of falling.

Acknowledgements: Funded by Amsterdam Movement Sciences and ZGT Wetenschapsfonds.

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0.05-3

The conjuring of diabetes and obesity on human walking strategy

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Aim: Diabetes Mellitus (DM) and Obesity (OB) represent pathologies conditioning human motion strategy. Our study aimed to identify differences in biomechanical aspects of gait determined by DM and OB.

Methods: we recruited all patients admitted for bariatric surgery in our Hospital with body mass index (BMI) between 38 and 47 kg/m², stratified them according to presence (Group 1) or absence (Group 2) of DM and compared them with non obese diabetic patients (Group 3) and healthy volunteers (Group 4). Subjects performed, before bariatric surgery, 3-D Gait Analysis walking barefoot at self-selected speed. Spatio-temporal and kinematic data were compared.

Results: We consecutively enrolled 100 patients: 25 in Group 1 (M/F 14/11; mean age 49.7±9.1 yrs BMI 42.6 ± 2.7 kg/m²), 25 in Group 2 (M/F 8/17; mean age 45.1±8.7 yrs, BMI 42.2 ± 2.3 kg/m²), 25 in Group 3 (M/F 18/7; mean age 54.9±5.1 yrs BMI 23.4 ± 1.6 kg/m²) and 25 in Group 4 (M/F 12/13; mean age 49.7±9.1 yrs, BMI 22.8 ± 2.0 kg/m²). Group 1 compared to Group 4 showed increased in stance duration (0.85±0.20 vs 0.70±0.09 s, p=0.04), double support time (10.63±4.5% of gait cycle (GC) vs 7.21±3.0, p=0.02) and step width (0.19±0.04 vs 0.13±0.03 m, p<0.01) and reduction in step length (0.45±0.09 vs 0.55±0.17 m, p<0.001), stride length (0.93±0.17 vs 1.18±0.13 m, p<0.0001), cadence (88.62±15.42 vs 98.7±10.50 step/min, p=0.015) and walking velocity (0.68±0.19 vs 0.98±0.17 m, p<0.01). Group 1 compared to Group 3 showed increased stride time (1.40±0.3 vs 1.17±0.24 s, p=0.04). Step width in Group 1 was increased also compared to Group 3 (0.19±0.04 vs 0.13±0.04 m, p<0.01). Kinematics data in Group 1 compared to Group 4 showed a significant reduction in ankle plantarflexion during push-off (6.24±9.91° vs 12.16±5.22°, p<0.02), knee (46.54±16.05° vs 62.45±9.76°, p<0.001) and hip peak flexion during swing (35.48±9.64° vs 42.63±8.95°, p=0.001) and knee dynamic excursion during normal walking (0.96±6.86° vs 4.28±6.95°, p<0.001).

Conclusions: Our data point out that diabetic-obese subjects present gait features typical of both conditions. The specific worsening of dynamic joint impairment provides evidence of a synergistic effect on human ambulatory function.

0.05-4

Differences in adherence to using removable cast walker treatment during daytime and nighttime in people with diabetes-related foot ulcers

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Background/Aim:

Patients' adherence to using knee-high offloading treatment is critical to effective healing of diabetes-related foot ulcers (DFU). Previous studies have found patients generally have low adherence to using removable knee-high offloading treatments; yet no study has investigated if their adherence differs during daytime and nighttime. This study aimed to investigate the levels and factors associated with adherence to using knee-high removable cast walker (RCW) treatment during daytime and nighttime weightbearing activities in people with DFUs.

Methods

This was a secondary analysis of data collected from a multi-centre cross-sectional study investigating adherence to using knee-high RCWs among 57 participants with DFUs. All participants had multiple socio-demographic, physiological, and psychosocial factors collected, before having their adherence to using RCWs during weight-bearing activity monitored over a one-week period using the dual activity monitor method. Adherence data were categorized into daytime (06:00-18:00) and nighttime (18:00-06:00) periods and calculated separately. Multiple linear regression was used to identify factors associated with daytime and nighttime adherence.

Results

Mean adherence to using RCW during weight-bearing activities in people with DFU was higher during daytime compared with nighttime (39.9% (SD 18.9) VS 20.4% (SD 16.7), $p < 0.001$). Factors independently associated with lower adherence during daytime were being male, longer diabetes duration, not having peripheral artery disease (PAD), and higher perceived RCW heaviness. Factors associated with lower adherence during nighttime were higher mean daytime steps, not having retinopathy and having dyslipidemia.

Conclusions

Adherence to using RCWs during weight-bearing activities reduced significantly at nighttime compared to daytime among people with DFUs and this was associated with different factors. Interventions to improve adherence, in research and clinical practice, should incorporate methods to target daytime or nighttime adherence specifically.

Acknowledgements

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Keywords

Diabetes-related foot ulcers, offloading, removable cast walker, adherence

O.05-5

Effects of a group-based foot-ankle exercise program for people with diabetic neuropathy on foot kinematics and plantar pressures during gait

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Background/Aim There are several risk factors for the development of plantar ulcers in people with diabetic neuropathy (DPN), among which we can mention limited foot-ankle ROM and higher plantar pressures during gait [1]. Therefore, interventions that focus on the functional improvement of these outcomes would contribute for the reduction of the risk for plantar ulceration. Recently, the IWGDF guidelines for treating and preventing diabetic foot complications included foot-ankle exercises program as an alternative approach for improving the modifiable risk factors for ulcers. The aim of this randomized controlled trial was to evaluate if a group-based approach of a foot-ankle exercises program could improve foot-ankle kinematics, lower limb kinetics and plantar pressure distribution after 12 weeks.

Methods Sixty-six participants with clinical diagnosis of DPN were randomly allocated into a control group (CG: n=31, 60.5±9.6yrs) or an intervention group (IG: n=35, 61.3±9.6yrs). The IG performed 12 weeks of a group-based foot-ankle exercises (warm-up exercises, strengthening of intrinsic and extrinsic foot muscles and functional exercises). The CG received usual care recommendations. Kinematics, kinetics and plantar pressure loadings were evaluated by 8 cameras at 100Hz, force plate and emed pressure platform, respectively. Comparisons between groups and assessments (Baseline and 12-week) were performed by Generalized Linear Mixed Models followed by Bonferroni post hoc ($p<0.05$).

Results The adherence to the program was 92.3%. After 12 weeks, there was a greater hip extensor moment at push-off and greater hallux contact area in the IG than CG. An intra-group analysis revealed a larger arch motion during stance and higher peak pressure and pressure-time integral at the central forefoot in the IG after 12 weeks compared to baseline. There were no other significant group difference or changes over time in foot-ankle kinematics or in any other outcome related to overall lower limb biomechanics.

Conclusion A group-based approach of a foot-ankle exercise program showed positive changes in the plantar pressure loading and hip kinetics after 12 weeks, suggesting an improvement in the propulsion phase, with greater participation of the forefoot in foot rollover.

O.06-1

No Difference in amputation risk or Frequency of Surgical Interventions Between Patients with Diabetic Charcot Arthropathy and Those Without

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Background The cause of Charcot neuro-osteoarthropathy (CN) is diabetes in approximately 75%. No study has compared the clinical course of patients initially treated initially nonoperatively for diabetic and nondiabetic CN.

Methods Of all patients treated for CN between January 1, 2006, and December 31, 2018, we included 159 patients with diabetic CN and 78 patients with nondiabetic CN. Patients with diabetic CN were younger (59 ± 11 years versus 68 ± 11 years; $p < 0.01$), more likely to smoke cigarettes (37% [59 of 159] versus 20% [12 of 60]; $p = 0.02$), and had longer follow-up (6 ± 4 years versus 5 ± 3 years; $p = 0.02$). Group-specific risks of the frequencies of major amputation, surgery, and CN reactivation were calculated, accounting for competing events. Group comparisons and confounder analyses were conducted on these data with a Cox regression analysis.

Results The risk of major amputation was not different between the diabetic CN group and nondiabetic CN group at 10 years (8.8% [95% confidence interval 4.2% to 15%] versus 6.9% [95% CI 0.9% to 22%]; $p = 0.4$) after controlling for potentially confounding variables such as smoking and peripheral artery disease. The risk of any surgery was no different between the groups at 10 years (53% [95% CI 42% to 63%] versus 58% [95% CI 23% to 82%]; $p = 0.3$), with smoking (hazard ratio 2.4 [95% CI 1.6 to 3.6]) and peripheral artery disease (HR 2.2 [95% CI 1.4 to 3.4]) being associated with diabetic CN. Likewise, there was no between-group difference in CN reactivation at 10 years (16% [95% CI 9% to 23%] versus 11% [95% CI 4.5% to 22%]; $p = 0.7$). Contralateral CN occurred in 17% of patients the diabetic group and in 10% in the nondiabetic group. Ulcers occurred in 74% of patients in the diabetic group and in 65% of those in the nondiabetic group.

Conclusion Irrespective of whether the etiology of CN is diabetic or nondiabetic, our results suggest that orthopaedic surgeons should use similar nonsurgical treatments, with total-contact casting until CN activity has resolved, and then proceed with orthopaedic footwear.

O.06-2

Medium-term results of Charcot foot reconstruction in the Netherlands

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Background/Aim: The treatment options for patients with chronic, deformed, and infected Charcot foot are relatively uncommon in the Netherlands, which is why amputation is almost always chosen for this patient category. Several studies describe a treatment using a correction, often with good results. This treatment aims to create a stable, plantigrade infection-free foot that can be properly shod so that amputation can be prevented and the patient regains mobility.

Method: From July 2018 to August 2020, we performed foot reconstructions on patients with a chronic, deformed Charcot foot. Treatment consists of open reduction and arthrodesis of the dislocated joints using internal or external fixation. The follow-up treatment consists of 8 weeks of unloaded mobilization, after which full weight bearing may be carried out for 8 weeks in a Total Contact Cast. The outcomes of the treatments have been analysed retrospectively.

With this procedure the primary outcome is limb salvage, thereby preserving the limb as much as possible and preventing major amputation. The secondary outcome is a stable, plantigrade, infection-free foot.

Results: In this case series 19 patients and 20 feet who were scheduled for major limb amputation were followed for 40 (28-54) months. All patients underwent a foot reconstruction. In 12 out of 20 feet, limb salvage was achieved with a stable, plantigrade, and infection-free foot. In 2 patients limb salvage was achieved but there was an unstable situation that made shoeing difficult. A below-knee amputation was performed in 4 patients due to infection or recurrent ulceration. And 2 patients died during follow-up due to causes outside the operated foot.

Conclusion: In this case series, we had a limb salvage rate of 70%, and we achieved a stable infection-free and well-shod foot in 60% of the patients compared to the 100% predicted major amputation rate/risk. This technique can therefore be a good alternative treatment for patients that are normally scheduled for amputation.

O.06-3

One in three people undergoing casting therapy for an active Charcot foot show persistent bone marrow oedema at clinical resolution

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Background/Aim: Magnetic resonance imaging (MRI) is increasingly used in the assessment of the hot swollen foot in diabetes as it depicts bone marrow oedema (BMO), a hallmark of the active Charcot foot. However, its usefulness to monitor resolution has not been validated. The aim of this study was to assess the effect of casting therapy on BMO in 35 consecutive patients with active Charcot feet who participated in a double-blind clinical trial of subcutaneous recombinant human parathyroid hormone (rh-PTH) versus placebo.

Methods: A blinded assessor rated MRI scans at baseline and follow up (clinical resolution or at 12 months) as improved (BMO regression), unchanged (persistent BMO) or deteriorated (expanding/migrating BMO). Clinical resolution was defined as a skin foot temperature difference of $<2^{\circ}\text{C}$ at two consecutive monthly visits, stable foot deformity and reduction of oedema.

Results: Overall, 29 patients reached clinical resolution (13 treated with rh-PTH and 16 with placebo). On follow up, BMO showed regression in 23 patients, (11 treated with rh-PTH and 12 with placebo). However, in 9 patients, BMO remained unchanged (3 treated with rh-PTH and 6 with placebo), while in 3 (2 treated with rh-PTH and 1 with placebo), BMO expanded/migrated to other regions. None of these differences were statistically significant and were unrelated to therapy with rh-PTH or placebo.

Conclusions: At clinical resolution or at 12 months, whole foot non-contrast MRI shows persistent or expanding/migrating BMO in 34% of patients despite below knee immobilisation. The significance of this delay between clinical resolution and regression of BMO on MRI requires further studies.

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O.06-4

Shape and texture features in normal appearing radiographs as predictors of subsequent Charcot foot

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Background Early cases of Charcot foot are frequently misdiagnosed due to an absence of overt radiographic features. This pilot study investigates whether there are specific radiographic predictors associated with Charcot foot, occurring prior to development of an overt radiographic (\geq Eichenholtz Stage-1) presentation.

Methods A dataset of 'normal' appearing radiographs from subjects with a history of Charcot foot were retrospectively collected (26 cases). This dataset included subjects with:

- Stage-0 Charcot foot (13),
- Subjects 1-4 years before the development of Charcot foot (9),
- Normal radiographs from the uninvolved limb in active Charcot (6).

35 normal control images were also collected from neuropathic subjects with no history of Charcot foot.

All images were free from overt radiographic Charcot changes. Radiographs were processed using research software- BoneFinder® (www.bone-finder.com) -to extract quantitative information concerning bone shape and image texture. These shape and texture features were entered individually into a series of logistic regression models. A false discovery rate (FDR) correction penalised all model P-values. Adjusted odds ratios were obtained for candidate variables which retained significance post FDR correction.

Results Of 95 discreet radiographic features studied, 9 showed a significant relationship with the 'History of Charcot foot' label. One feature, shape-feature SC3, retained significance post-FDR correction. SC3 had an uncorrected P-value of 0.0002, a corrected P-value of 0.02 and an odds ratio of 5.77 in univariate models, which demonstrated minimal change when adjusted for age, BMI, gender and other covariates. Visual inspection of SC3 appeared to indicate forefoot inversion and navicular orientation are associated with having history of Charcot foot.

Conclusions This pilot appears to be the first study which identifies quantitative radiographic features in radiographs of 'normal' appearance, which are associated with a subsequent history of Charcot foot presentation. Use of the BoneFinder® software enables a novel approach to the quantification of foot morphology. These results demonstrate promise in the search for possible structural Charcot foot at risk factors.

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O.06-5

Anatomical Charcot reconstruction utilising standardised osteotomies to improve surgical outcomes

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Introduction

Charcot neuroarthropathy is a debilitating condition that frequently leads to skeletal instability, deformity and an increased risk of ulceration leading to infection, often resulting in prolonged periods of immobilisation. However, reconstruction offers limb salvage, and the possibility of weight bearing compared to amputation with increased mortality.

Methods

We report a prospective study of 62 patients undergoing Charcot reconstruction surgery between May 2014- January 2022 by 2 surgeons. Peripheral vascular disease was assessed using duplex scan. When arterial disease was confirmed, it was treated before reconstruction. Utilising 3D modelling and standardised osteotomies (e.g., King's Cut, ARK osteotomy and Lisfranc correction) for anatomical correction of Meary's angle, AP and Lateral talo-calcaneal angle, and calcaneal pitch.

Patients underwent primary or staged reconstruction if osteomyelitis was suspected due to pre-existing ulceration. Definitive fixation was undertaken with internal fixation to specifically stabilise the unstable foot columns. Multivariate analysis was carried out to assess risk factors for failure, and $P > 0.05$ for statistical significance. Survivorship was considered where no ulceration, or catastrophic failure, requiring metal work removal or amputation was observed.

Results

Fifty-nine feet were included (37 single-stage-reconstructions, and 25 two-stage-reconstructions); 3 patients did not progress to definitive surgery and 3 patients had bilateral surgery. 62.7% patients were male with an average age of 56 (range), 88.13% had type 2 diabetes mellitus type, 56% were hypertensive, 14% had chronic kidney disease on dialysis. Twenty (54.1%) single stage reconstructions had pre-operative ulceration, 3 patients had ischaemic heart disease and 36 patients had evidence of peripheral arterial disease in the operated leg.

81% of patients achieved normalisation of the 3 out of 4 angles ($P < 0.05$). Two patients (3.1%) required further surgery from removal of metalwork for infection and limb salvage, 11 (18.6%) had delayed wound healing. Survivorship was 97% at 3, and 94% at 6 years, however if pre-existing vascular disease was present, it was 94% at 3, 85.3% at 6 years. All patients were mobile at final follow-up.

Conclusion

Careful patient selection, multidisciplinary teamwork, and anatomic reconstruction led to predictable outcomes and functional limb salvage. Pre-operative vascular compromise led to slight reduction in survivorship, but no major amputation.

O.07-1

Tissue availability of intravenously administered antibiotics in patients with infected diabetic foot ulcers in the context of circulation status – (DFIATIM study)

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Aim: To assess antibiotic (ATB) availability in patients with infected diabetic foot ulcers (iDFU) in the context of micro- and macro-circulation status.

Methods: Nineteen patients (mean age 61.7±6.7 years; HbA1c 64.1±17.1 mmol/mol, BMI 31±5.2kg.m⁻²) with iDFU of WIfI (2-3)-(0-3)-(2-3) indicated for intravenous ATB therapy were enrolled in the study. Patients were treated with boluses of amoxicillin-clavulanic acid (AMC; 9 patients) or ceftazidime (CTZ; 10 patients) according to the microbial sensitivity of the causative agent. The total duration of ATB therapy was 6-7 days. After induction of a steady ATB state, microdialysis was performed with the insertion of a microdialysis cannula into the peripheral soft tissue near iDFU followed by the application of a sixth ATB bolus intravenously. Tissue fluid samples were taken from the foot within the next 6 hours. Simultaneously, blood samples were taken from peripheral blood for detection of ATB serum levels. ATB serum and tissue concentrations were determined by electrophoresis. The presence of PAD was assessed by triplex ultrasound and the ankle-brachial index (ABI; mean ABI 0.89±0.4) and toe-brachial index (TBI; mean TBI 0.68±0.28) tests; arterial flow was determined by occlusive plethysmography (mean first phase of arterial flow 78.1±33.7ml/s, mean second phase 44.6±22.5ml/s); microcirculation status was evaluated by transcutaneous oxygen pressure (TcPO₂; mean TcPO₂ 47.5±10.8 mmHg).

Results: Serum AMC levels after bolus administration reached a maximum of 79.6±42.7 ug/mL, with CTZ reaching 164.4±70 ug/mL. AMC concentrations in peripheral tissue reached approximately 11-32% of serum levels (from 0.97±1.1 to 7.3±5.3 ug/mL; p=0.0001-0.029) and 10-20% for CTZ (from 4.5±2.1 to 14.5±4.1 ug/mL; p=0.0001-0.003). We proved positive correlations of tissue ATB concentrations with arterial flow (with first r=0.49-0.5; p=0.029-0.032 and second phase r=0.479-0.61; p=0.007-0.0441) and in AMC group negative correlations with BMI (r = - 0.693-0.895; p=0.001-0.038). Other patient characteristics as weight or parameters of macro-/micro-circulation did not correlate with tissue ATB levels.

Conclusion: Our preliminary results showed that tissue ATB concentrations in patients with iDFU were relatively satisfactory, reaching up to 32% of serum AMC and 20% of serum CTZ concentrations. These findings seem to correlate with arterial flow.

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O.07-2

Effect of prior antibiotic use on culture results in people with diabetes and foot osteomyelitis

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Background: Antibiotic use prior to biopsy acquisition in people with diabetes and osteomyelitis of the foot (DFO), might influence bacterial yield in cultures, or induce bacterial resistance. Obtaining reliable culture results is pivotal to guide antibiotics for conservative treatment of DFO.

Methods: We prospectively analysed cultures of ulcer bed and percutaneous bone biopsies of people with DFO and investigated if antibiotics administered prior to (<2 months up to 7 days) biopsy acquisition led to more negative cultures or increased resistance in virulent bacteria. We calculated relative risks (RR) and 95% confidence intervals (CIs). We stratified analyses according to biopsy type (ulcer bed or bone).

Results: We analysed bone and ulcer bed biopsies of 64 people, of whom 29 received prior antibiotics, and found that prior antibiotics did not lead to a higher risk of at least one negative culture (RR 1.3, (CI 0.8-2.0), nor that prior treatment increased the risk of a specific type of negative cultures (RR for bone cultures 1.15, (CI 0.75-1.7), RR for ulcer bed cultures 0.92 (CI 0.33-2.6)) or both cultures (RR 1.3 (CI 0.35-4.7), and neither did it increase the risk of antibiotic resistance in the combined bacterial results of ulcer bed and bone cultures (RR 0.64, (CI 0.23 – 1.8)).

Conclusions: Antibiotics administered up to 7 days before obtaining biopsies in people with DFO, do not influence culture yield, regardless of biopsy type, nor is it associated with more antibiotic resistance.

O.07-3

Outcomes of diabetes-related foot infections over a 3-year-period in persons attending the Liverpool Hospital High Risk Foot Service, Australia

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Background Diabetes-related foot infection (DFI) accounts for approximately 27,600 hospital admissions annually in Australia and has significant impacts on patients. To our knowledge, there is limited reporting on DFI outcomes beyond identification and treatment.

Our aim was to capture individual DFI episodes presenting to the Liverpool High Risk Foot Service (LHRFS). Demographic and microbiological data was recorded, as well as the infection grade (PEDIS 2-4), osteomyelitis diagnosis and duration of antimicrobial therapy. Ultimately, an “outcome” of DFI resolution or failure was given.

Methods LHRFS commenced data entry on a REDCap registry from September 2019. Data was extracted in November 2022. Every DFI was entered as a singular episode, therefore a patient may have multiple episodes. Patients were followed throughout their episode and the registry was updated throughout.

Results Outcomes were recorded as DFI resolution or failure and further categorised by skin/ soft tissue DFI (SST DFI) or diabetes-related foot-osteomyelitis (DFO) +/- SST DFI, and by PEDIS grade. Failure was defined as a lack of resolution from conservative therapy resulting in minor or major amputation, surgical debridement, joint resection, and/or death.

A total of 523 episodes of DFI +/- DFO were extracted, 502 of which were “complete” with a clinical outcome (failure or resolution). About half (n = 269) had SST DFI and 233 were diagnosed with DFO +/- SST DFI.

72.31% (363) DFI episodes resolved and 27.69% (139) failed. Increased infection severity was associated with higher rates of failure, particularly with DFO (61.90% failure of PEDIS 4 DFO +/- SST DFI episodes vs 48.28% failure of PEDIS 4 SST DFI).

Extensive demographical and microbiological data will be presented alongside the overall outcomes of resolution and failure.

Conclusion To our knowledge, there is no single prospective database from >3 years of collection that reports on DFI outcomes. This comprehensive dataset will offer an in-depth insight into not only on the DFI rates within LHRFS, but the outcomes for patients with SST DFI vs DFO +/- SST DFI.

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O.07-4

Re-infection and clinical outcomes in clean vs. dirty resection margin in patients with diabetic foot osteomyelitis

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Aim: To identify the incidence of re-infection and clinical outcomes of residual osteomyelitis (OM) in patients who underwent bone resection as treatment for diabetic foot OM.

Method: This was a post hoc analysis of 194 patients with OM in two randomized clinical trials that were treated for diabetic foot infections. The diagnosis was confirmed with bone cultures or histopathology. The margins of the resected bone were biopsied and cultured. Residual osteomyelitis was defined as positive bone culture or histology. Clean resection was defined as negative cultures and negative histology from the resection margin. We used clinical data from the 1-year follow-up for the outcomes.

Results: (Table 1): 44% (n=86) of patients had residual OM; 56% (N=108) had clean bone resection. There was no difference in rehospitalization (30% vs. 36%, p=0.39), reinfection (20.9% vs. 25.0%, p=0.50), reoccurrence of osteomyelitis (84.6% vs. 65.2%, p=0.21), surgery after initial discharge (17.4% vs. 19.4%, p=0.43,) wounds (53.5% vs. 62.0%, p=0.23) and time to wound healing (median 48 (31,72) vs. 46 (25,79), p=0.98) in patients with residual OM and clean bone resection. Patients with residual OM had significantly longer hospitalized days (median 14 (12,19) vs. 11 (9,14), p=0.01), days of antibiotics (48 (30,56) vs. 19 (12,24), p=<0.01).

Conclusion: Patients with residual OM are hospitalized longer and use antibiotics longer compared to clean resection. Besides this, residual OM did not affect the outcomes for re-infection, recurrent OM, rehospitalization, and surgery. Finally, residual osteomyelitis did not make difference in wound healing time and failure compared to clean resection.

Table 1: Clinical outcomes in clean resection vs. residual osteomyelitis.

	Clean resection (n=108)	Residual osteomyelitis (n=86)	p-VALUE
Patient factors			
Hospitalization duration, days	11 (9,14)	14 (12,19)	<0.01
Antibiotics duration, days	19 (12,24)	48 (43,55)	<0.01
Amputation index hospitalization	96 (88.9)	47 (54.7)	<0.01
Acute kidney injury	36 (33.3)	33 (38.4)	0.47
1 Year Outcomes			
Healed	67 (62.0)	46 (53.5)	0.23
Time to heal, days	46 (25,79)	48 (31,72)	0.98
Reinfection	27 (25.0)	18 (20.9)	0.50
Rehospitalization foot	39 (36.0)	26 (30)	0.39
Osteomyelitis at Reinfection	15 (65.2)	11 (84.6)	0.21
Surgery After Initial Discharge	21 (19.4)	15 (17.4)	0.43
Amputation After Initial Discharge	12 (11.1)	9 (10.5)	0.89
Length of stay, days	14 (10,19)	15 (12,24)	0.24
Total antibiotic days	21 (14,32)	48 (30,56)	<0.01
Descriptive variables are presented as N (%). Continuous variables as median (Q1, Q3). Duration is presented as days. Outcomes are clinically collected within a year after initial surgical treatment.			

O.07-5

Short versus long postsurgical antibiotic treatment for operated diabetic foot infections – interim analysis of four parallel randomized-controlled single-center trials

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Background: Minimal duration of antibiotic treatment in diabetic foot infections (DFI) is unknown. We investigate open questions in this field of research in real-life situations of adult, operated DFI patients.

Methods: Single-center, prospective-randomized non-inferiority trial, with 1:1 randomization into a short or long postoperative antibiotic treatment group with four stratifications: A) Conservative approach (debridement only) for soft tissue DFIs: 10 versus 20 days antibiotic therapy. B) Conservative Approach for bone infections (DFO): 3 vs 6 weeks of antibiotic therapy. C) Residual post-amputation soft tissue infection: 1 vs. 4 days of therapy; and D) Residual DFO after partial amputation: 1 vs. 3 weeks of antibiotic treatment. The primary outcome is “Clinical Failure” after a minimal follow-up period of six months, defined as the presence of any problem needing re-intervention. Non-inferiority margin is set at 20% for each stratum separately. We compare groups and use a multivariate logistic regression with the outcome “Clinical Failure”.

Results: Among 394 DFIs hospitalized between September 2019 and December 2021, we included 318 episodes (inclusion rate 81%). Among the included cases, 237 episodes completed the Test-of-Cure visit (Per Protocol population), and constitute the base of this 2nd interim analysis (median age 65 years, 27% female patients).

Overall, 40 DFIs (40/237; 17%) failed clinically, and 5 revealed a microbiologically-identical recurrence (2%). A short antibiotic was not significantly associated with a higher failure risk (7/110 vs. 23/127 failures; $p=0.59$). The corresponding stratified results were (5/42 vs. 7/21 failures; $p=0.04$ for a conservative soft tissue treatment (group A); 9/26 vs. 10/42 failures; $p=0.72$ for the conservative DFO therapy (group B); 1/15 vs. 1/28 failures; $p=0.10$) for residual postamputation soft tissue infections (group C); and 2/27 vs. 4/35 failures; $p=0.69$ for residual DFO in the proximal bone stump after amputation (group D). In multivariate logistic regression analysis, a short antibiotic duration did not influence overall failure rate (odds ratio 0.8, 95% confidence interval 0.4-1.7).

Conclusion: A shorter period of antibiotic treatment might be noninferior to longer treatment duration in terms of failure of operated DFI.

O.08-1

Early Complications Following minimally invasive surgery for hallux valgus in patients With and Without Diabetes

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Background It is well known that people with Diabetes mellitus (DM) are more likely to develop complications undergoing foot and ankle surgery. Currently, orthopedic surgery tends to use minimally invasive surgery (MIS), this resource is used to successfully solve forefoot deformities such as Hallux Valgus (HV). So far there is no evidence enough on this type of surgery and its complications in people with DM.

The objective of this study is to determine the types and rates of early complications of elective MIS procedure for hallux valgus in a population of diabetic patients (DBT) compared to a control group of non-diabetic patients (NDBT).

Methods This retrospective study was carried out at our institution between October 2017 and August 2020. During the study period, 874 feet were operated on with MIS technique. All diabetic adults with a diagnosis of HV who underwent percutaneous correction surgery with distal metaphyseal osteotomy and a minimum follow-up of 6 months were included. All diabetic patients who underwent surgery had controlled diabetes with glycosylated hemoglobin less than 7%. For each DBT patient, we randomly selected two aged-matched patients ± 1 year without DM as controls. Complications were recorded and defined as any deviation from the normal postoperative course.

Results A total of 75 patients were analyzed, 25 DBT and 50 NDBT. The follow-up was 10.8 months (6-48). There were no significant differences in demographic characteristics except for the body mass index and the Charlson comorbidity index, both of them were higher in the DBT group ($p = <0.001$). The complication rate was 18% ($n = 9$) in NDBT and 24% ($n = 6$) in DBT patients ($p=0.553$). There were also no significant differences in the different types of complications (infection, osteosynthesis discomfort, pseudoarthrosis, residual pain and metatarsalgia). In the DBT group, superficial infections were successfully treated with oral antibiotics.

Conclusion This would be the first study that specifically evaluates complications in diabetes patients with elective hallux valgus MIS correction. In our results, diabetic patients have not been associated with a higher rate of complications compared to non-diabetic patients.

O.08-2

The correlation of wound healing with pedal acceleration time

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Background/Aim Pedal acceleration time (PAT) is a novel perfusion tool that measures the acceleration of flow within the pedal vessels. (1) PAT classified into four categories being 1 (40–120 milliseconds (msec)), 2 (121–180 msec), 3 (181–224 msec), and 4 (>225 msec). (1,2) Post revascularisation PAT may correlate with limb salvage in chronic limb threatening ischemia (CLTI). (2) However, the association of PAT with healing is not well defined. The aim was to determine the change in PAT post revascularisation and the association with wound healing at one year in patients with peripheral artery disease and diabetic foot disease.

Methods Patients were included that underwent PAT from 1st January 2019 to 31st December 2021 at a single tertiary centre. Demographic information, wound scoring, PAT measurement, revascularisation, and surgical procedures were recorded. Wounds were followed until healed. Paired samples T-test was used to determine the change in PAT, with standard deviation (SD) presented.

Results There were 305 limbs (262 patients) that underwent PAT assessment over this period. The median age was 70.5 years and 65% had diabetes. There was a significant decrease in PAT after percutaneous or surgical revascularisation from 242.6msec \pm SD 62.7 to 126.7msec \pm SD 38.4 ($p < .001$). Wound healing at one year for patients that achieved a post revascularisation category 1, category 2, category 3 and category 4 was 76.2%, 58.3%, 30% and 22.2%, respectively. The proportion of patients undergoing a major limb amputation at one year for patients that achieved a post revascularisation category 1, 2, 3 and 4 was 6.9%, 22.6%, 28.6% and 26.1%, respectively.

Conclusions PAT values respond to lower limb revascularisation and the final PAT category achieved for a limb post revascularisation may be associated with healing and major limb amputation. This novel perfusion tool may provide a valuable assessment in patients with CLTI and diabetic foot disease.

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O.08-3

Timolol promotes wound healing and repair in Bama minipigs with diabetic chronic cutaneous ulcers

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Aims

To evaluate the wound healing and repair effects of timolol on diabetic chronic cutaneous ulcers (DCUs) in Bama minipigs.

Methods

We established DCUs model in Bama minipigs and randomly divided all wounds into the normal saline control group (NSC), timolol low dose group (TLD) and timolol high dose group (THD). Treatment was administered every other day according to the grouping, and the wound area and healing rate were calculated before each treatment. We recorded the wound healing time when the wound was covered by the new epithelium completely. Wound tissues were obtained at different time points before and after treatment to evaluate the wound repair conditions.

Results

The wound healing rate of the TLD group and the THD group were significantly higher than that of the NSC group ($P < 0.0001$; $P < 0.0001$), and there was no statistical difference between the first groups ($P = 0.944$). Compared with the NSC group, the healing time of the TLD group and the THD group were significantly shorter ($P = 0.044$; $P = 0.020$), and there was no statistical difference between the latter two groups ($P = 0.940$). During the treatment, the number of neutrophils and lymphocytes infiltrated in timolol-treated wounds was significantly reduced compared to the NSC group. The number of M1 macrophages infiltrated in timolol-treated wounds was significantly lesser than those in the NSC group, while the condition of M2 macrophages was on the contrary. The thickness of the new epidermis, micro-vessel density, α -SMA positive myofibroblasts, PCNA positive cells, the content of type I collagen and the ratio of type I/III collagen were significantly increased, while the content of type III collagen was significantly reduced in timolol-treated wounds compared to the NSC group. At the same time, the expressions of VEGF- α , FGF-2, TGF- β 1 and TIMP-1 were significantly increased, while the expressions of IL-1 β , IL-6, TNF- α , MMP-2 and MMP-9 were significantly decreased in timolol-treated wounds compared to the NSC group.

Conclusions

Topical application of timolol promoted the DCUs healing and repair in Bama minipigs, possibly by reducing wound inflammation, promoting angiogenesis, granulation tissue formation, collagen deposition, wound contraction and re-epithelialization, and participating in ECM remodeling.

O.08-4

Effects of rocker profiles and self-adapting insoles on plantar pressure in patients with diabetes and loss of protective sensation

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Background Rockers and insoles, used to offload high plantar peak pressure (PP) in patients with diabetes to prevent ulcers, are made manually. This leads to variability in the effectiveness of the product. [1] Additionally, due to changes in foot structure, the position with high PP may change over time, requiring new rockers and insoles. [1] To deal with the variation in effectiveness and foot structure, we introduced a two-way innovative approach, with individualized algorithm based 3D-printed rocker profiles and self-adapting insoles.

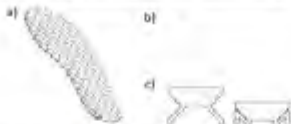
Methods 25 patients walked on a treadmill with standard shoes and insoles while the in-shoe PP was measured. Those with PP >190kPa received rockers and self-adapting insoles during their second visit where 3 conditions were measured (Table 1).

Results Table 1 shows the number of sensors with PP >190kPa and the largest PP per condition for the forefoot and heel. For the forefoot, the rockers with either the standard or self-adapting insoles, show a significantly lower PP compared to the control condition. For the heel, the same condition (rockers & self-adapting insoles) shows a significantly higher PP compared to the control condition.


Conclusions Rockers with or without self-adapting insoles are effective in reducing the PP to <200kPa in the forefoot. The same rockers are ineffective in the heel. This could be either related to the harder material used in the shoes or the pressure increase covering a large heel area, causing too many insole elements to buckle down, leaving limited possibilities to redistribute the pressure elsewhere.

Table 1: Design of the rocker shoe & self-adapting insole and pressure data

Design of the rocker shoe and self-adapting insole



The self-adapting insole (a) which consists of >100 hexagonal shaped elements (b) The elements buckle when pressures exceed about 190 kPa (c).



The rocker shoe (a) which has a 3D printed profile (b), grey layer is 3D printed, yellow layer is the heel padding and blue layer is the outsole.

Plantar pressure data of forefoot and heel area during different conditions (n=21)

	Standard shoes & standard insoles Visit 1		Standard shoes & self-adapting insoles Visit 2		Rocker shoe & standard insoles Visit 2		Rocker shoe & self-adapting insoles: Visit 2	
	Largest PP (kPa & SD)	Sensors > 190 kPa (count & SD)	Largest PP (kPa & SD)	Sensors > 190 kPa (count & SD)	Largest PP (kPa & SD)	Sensors > 190 kPa (count & SD)	Largest PP (kPa & SD)	Sensors > 190 kPa (count & SD)
Left								
Forefoot	227 ± 38	3.8 ± 3.3	232 ± 55	2.7 ± 2.7	188 ± 46	0.7 ± 1.4	188 ± 33	0.6 ± 1.1
Heel	190 ± 37	2.5 ± 3.8	193 ± 43	2.3 ± 3.5	194 ± 35	3 ± 4.3	207 ± 47	3.5 ± 4.6
Right								
Forefoot	231 ± 36	3.4 ± 2.9	213 ± 30	2.4 ± 2.0	190 ± 22	0.7 ± 0.8	182 ± 24	0.2 ± 0.5
Heel	201 ± 28	3.3 ± 3.9	216 ± 42	3.4 ± 3.6	211 ± 29	4.1 ± 4.2	225 ± 42	4.6 ± 4.1

Reference [1] Reints, R. Thesis.

O.08-5

Preliminary evaluation of dual-energy CT to quantitatively assess bone marrow edema in patients with diabetic foot ulcers with suspected osteomyelitis

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Aim: The purpose of this study was to evaluate the value of virtual non-calcium (VNCa) images calculated from dual-energy CT (DECT) to quantitatively assess the presence of bone marrow edema (BME) in patients with diabetic foot ulcers and suspected osteomyelitis.

Methods: Patients with a diabetic foot ulcer and suspected osteomyelitis who underwent DECT (80kVp/Sn150kVp) were retrospectively included. Two observers independently measured CT values in Hounsfield Units (HU) in a region of interest on the VNCa images of the bone adjacent to the ulcer and a reference bone (either the same location on the contralateral foot or, if unavailable, the talus). The patients were divided into two clinical groups, osteomyelitis or no-osteomyelitis, based on the final diagnosis by the treating physicians. Observer agreement was tested using an intraclass correlation coefficient (ICC).

Results: A total of 56 foot ulcers were identified of which 23 were included in the osteomyelitis group. The mean CT value at the ulcer location was significantly higher in the osteomyelitis group (-17.23 ± 34.96 HU) compared to the no-osteomyelitis group (-69.34 ± 49.40 HU; $p < 0.001$). Within the osteomyelitis group, the difference between affected bone and reference bone was statistically significant ($p < 0.001$), which was not the case in the group without osteomyelitis ($p = 0.052$). The observer agreement was good for affected bone measurements (ICC = 0.858) and moderate for reference bone measurements (ICC = 0.675). With a cutoff value of -40.1 HU, sensitivity was 87.0%, specificity was 72.7%, PPV was 69.0% and NPV was 88.9%.

Conclusion: DECT has a potential value for quantitatively assessing the presence of BME in patients with diabetic foot ulcers and suspected osteomyelitis.

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0.09-1

Increasing diabetes foot disease hospitalisations (5 years to Jun 2019) in a tertiary hospital, Aotearoa New Zealand

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Background/Aim Monitoring diabetes foot disease (DFD) hospitalisations can provide information on health system burden and help monitor the effectiveness of foot care services. However, in Aotearoa, amputation is the sole reporting measure for DFD so that outcomes of the majority of DFD hospitalisations are unknown. This retrospective cohort review of hospitalisations for adults with diabetes aimed to describe and determine trends in DFD hospitalisations at a tertiary hospital.

Methods Data were collected on hospitalisations (1 Jul 2014 to 30 Jun 2019) for people ≥ 15 years, including those domiciled inside and outside the hospital district area. Hospitalisations were defined in days from admission to discharge date. Subsequent admissions within 24 hours were bundled and counted as a single hospitalisation. DFD hospitalisations were described by gender, age and ethnicity for amputation, admission type, length of stay (LoS), and mortality rates. Age-standardised rates were calculated for the hospital district resident and diabetes populations.

Results There were 11222 admissions for adults with diabetes, of which DFD was the principal admission reason for 886 people, accounting for 14.3% ($n=1,605$) of hospitalisations and 23.9% ($n=16,992$) of bed days. Amputation occurred in 24.6% ($n=396$) of DFD hospitalisations. DFD hospitalisations increased from 235 per year to 416 over 5 years, were higher in males (68%, $n=1094$), and amongst older age groups (peaking at 60-69 years). From first DFD hospitalisation, mortality at 30 days and 1-year post admission date was 5.4% and 24.7%, respectively. The median LoS for people without DFD was 4 days compared to 7 for DFD hospitalisations.

DFD hospitalisation rates age-standardised against the hospital district resident population were higher for males than for females (3.39 and 1.87 /10000 person-years, respectively), and rates by ethnicity were 4.57/10000 for Māori, 7.78/10000 for Pacific and 1.82/10000 for Other. DFD hospitalisation rates age-standardised against the district resident diabetes population, were 74.92/10000 for Māori, 52.70/10000 for Pacific and 36.59/10000 for Other.

Conclusion 75% of DFD hospitalisations are currently unreported. Prevalence of DFD hospitalisations significantly increased over 5 year and varied by gender, age, and ethnicity. The disproportionate burden of DFD hospitalisations for Māori and Pacific Peoples requires further investigation.

O.09-2

Creation of a 'precision prognostic classification' for diabetic foot ulcer healing with the use of a bottom-up approach

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Background/Aim: Diabetic foot ulcer (DFU) classification systems offer the baseline information to streamline treatment strategy and to audit quality of care. Although SINBAD and University of Texas (UT), the most frequently used prognostic classification systems, were prospectively validated, not all individual parameters were shown to have consistent associations with healing. Moreover, because the parameters used in these classifications were selected based on expert opinion, some important factors might be missing. We have therefore identified which are the prognostic factors of DFU healing by using a bottom-up approach based on nation-wide databases and robust methods.

Methods: Data from 1664 patients with DFU were prospectively collected by all 34 Belgian diabetic foot clinics (DFCs) as part of a national quality improvement initiative in 2013. At presentation 21 patient- and foot-related characteristics were recorded. Patients were followed until healing or for 6 months. We performed multivariable Cox proportional hazard regression to identify the characteristics associated with DFU healing. Multivariable models were developed using backward regression with multiple imputation of missing values and bootstrapping. Models were assessed for their ability of predicting DFU healing (model performance) by computing Harell's c-statistic and compared to models based on previous classifications.

Results: Patients were mainly male (65.6%) with a median diabetes duration of 14.8 years. At 6 months, the probability of DFU healing was 61.5%. The multivariable model revealed five essential variables: presentation delay, history of minor amputation, ulcer location, surface area and ischemia. This 5 variable-model showed a better performance compared to models based on variables included in the SINBAD and UT systems. Unlike SINBAD, loss of protecting sensation, was not revealed as independent predictor. Presentation delay and history of minor amputation have not been highlighted previously.

Conclusions: A bottom-up approach relying on existing databases and robust methodology can be used to build a prognostic classification for DFU healing. Our 5 variable-model achieved a balance between data collection burden and performance. Such bottom-up approach can offer new parameters and allows to tailor the classification to local clinical settings. Our 5 variable-model may offer a 'precision classification' for diabetic foot clinics.

0.09-3

Changes in the microbiology and epidemiology of community-acquired diabetic foot osteomyelitis over two decades: a pilot, multicenter, European cohort study

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Background/Aim: We analyze the changing microbiology of community-acquired diabetic foot osteomyelitis (DFO) in selected European countries.

Methods: We retrospectively studied anonymized cohorts from five centers with academic experience in DFO (Geneva, Zürich, Las Palmas; Barcelona, Istanbul) stratifying the observation time into four periods (2000-2005; 2006-2010; 2011-2015; 2016-2019). We chose the centers arbitrarily, based on the availability of an active cohort and representing central Europe and two edges of the Mediterranean.

Results: Among 1880 DFO episodes, there were small differences in the patient demographics between centers. Most of the patients were men (76%) with a median age of 67 years and the presence of type 2 diabetes (89%) in the last 17 years to the diagnosis of DFO (range, 10-25y). We detected polymicrobial infection in 624 cases (33%), while gram-positive bacteria were the most common (1132 cases; 60%, *Staphylococcus aureus* 34%) and the less anaerobes (4%). There was a higher prevalence of methicillin-resistant *S. aureus* (MRSA) in Spain and Geneva compared to Zurich or Istanbul (14%-12% and 12% vs. 2% and 3%, $p < 0.01$). Overall, the proportion of MRSA was decreasing in last two decades (12%-7% vs. 4%-5%) whereas Enterobacteria increased (14%-21% vs. 21%-25%). Enterobacteria, 70% of gram-negative bacilli (GNB), was more prevalent in Spain and Turkey compared to Switzerland (34%-31% and 44% vs 20% and 13%, $p < 0.01$). GNB quinolone resistance was analyzed in the Zurich, Geneva, and Barcelona cohorts, which was overall 14%, and Enterobacteria accumulated 66% of quinolone resistance. The presence of necrosis was associated with a higher presence of Enterobacteria compared to other bacteria (38% vs 29%, $p < 0.01$). Although no differences were observed in the prevalence of necrosis or average age over the years, a high antibiotic consumption above 49% in all periods were observed. In multivariate logistic regression analysis, necrosis (odds ratio 1.5, 95% confidence interval 1.2-1.9), Spanish cohorts and Istanbul (OR 3.7, 95% CI 2.6-5.4; 3.1, 95% CI 1.5-6.4) and mainly the latter period (OR 2.9, 95% CI 1.8-4.6) remained associated with Enterobacteria.

Conclusions According to this multicenter cohort study, Enterobacteria among community-acquired DFO pathogens are increasing in recent years, the group that accumulates some resistance mechanisms.

0.09-4

Trends and outcomes of Lower limb revascularisations in a multi-ethnic Asian population: a 7-year study observational study

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Aim Rates of lower limb amputations are high in Singapore (1) and the role of revascularisation procedures in relation to the amputation burden is unclear. This study examined the national trends in Lower Limb Revascularisations (LLR) in Singapore between 2012 and 2018; and progression to worse outcomes (repeat revascularization, Lower Extremity Amputation (LEA)- minor and major) after index LLR.

Methods This retrospective observational study used national population data for ages 16-100 years from Ministry of Health Singapore administrative datasets. Age- and sex- standardized LLR rates were calculated per 100,000 total population. Rates were also calculated for population with end stage renal disease (ESRD), peripheral arterial disease (PAD) and cardiovascular disease (CVD) stratified by diabetes status. Trends over time were calculated using joinpoint regression. Progression time from index LLR to each outcome and the factors associated with progression were also evaluated using competing-risk regression.

Results A total of 3.5 million unique individuals, 10.4% of whom had diabetes, were available for analysis. Median follow-up was 43.86 months. Rates of LLR in overall population (2012: 470.60/100,000; 2018: 611.56/100,000, 4.6% annual increase, $p < 0.001$) and diabetes population (2012: 1012.16/100,000; 2018: 1292.10/100,000, 3.9% annual increase, $p = 0.002$) increased while LLR rates remained stable in population without diabetes. Risk attributable to diabetes in total population was 75.65% in 2018. ESRD or PAD increased the risk of LLR by over 40 times in the population with diabetes. Incidence rate of repeat revascularisation, minor LEA, major LEA, and death after index LLR were 208.63, 27.00, 45.00 and 54.15 per 1000 person-years respectively. Median time to repeat revascularisation, minor and major LEA was less than a year, while median time to death was 20.3 months. Presence of diabetes, ESRD, PAD, and HbA1c $\geq 7\%$ were significantly associated with worse outcomes.

Conclusion

Overall rates of LLR and diabetes related LLR have increased over time. Rates were significantly higher in population with diabetes, PAD and ESRD. Equally importantly, rates of repeat procedures and progression to amputation or death were high, and likely to occur within a short span of time after index LLR.

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O.09-5

The use of sodium-glucose co-transporter-2 inhibitors or glucagon-like peptide-1 receptor agonists and the risk of lower limb amputations in Denmark

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Background/Aim: Numerous studies investigated the potential issue of sodium-glucose co-transporter-2 inhibitors (SGLT2-Is) increasing the risk of lower limb amputations (LLAs), but produced conflicting results. Particularly studies comparing SGLT2-Is to glucagon-like peptide-1 receptor agonists (GLP1-RAs) seem to find an increased LLA risk with SGLT2-I use. This raises the question whether the results are driven by a protective GLP1-RA-effect rather than a harmful SGLT2-I-effect. GLP1-RAs could promote wound healing and therefore reduce the risk of LLAs, but the associations between the drug classes and LLA remain uncertain. Therefore the aim of the current study was to investigate the risk of LLA and diabetic foot ulcer (DFU) with SGLT2-I use and GLP1-RA use versus sulfonylurea use.

Methods: A retrospective population-based cohort study was conducted using data from the Danish National Health Service (2013-2018). The study population (N = 74,475) consisted of type 2 diabetes patients aged 18+ who received a first ever prescription of an SGLT2-I, GLP1-RA or sulfonylurea. The date of the first prescription defined the start of follow-up. Time-varying Cox proportional hazards models were used to estimate the hazard ratios (HRs) of LLA and DFU with current SGLT2-I use and GLP1-RA use versus current SU use. The models were adjusted for age, sex, socio-economic variables, comorbidities and concomitant drug use.

Results: Current SGLT2-I use was not associated with an increased risk of LLA (adjusted HR 1.10 [95% confidence interval (CI) 0.71-1.70]). This finding remained consistent after stratification by sex, age, and continuous duration of use. Current GLP1-RA use, on the other hand, was associated with a reduced risk of LLA (adjusted HR 0.57 [95%CI 0.38-0.83]). The risk of DFU was unchanged with both exposures of interest.

Conclusion: SGLT2-I use was not associated with an increased risk of LLA, but GLP1-RAs had a protective effect. Previous studies reporting an increased risk of LLA with SGLT2-I use compared to GLP1-RA use might have been looking at a protective GLP1-RA effect, rather than a harmful SGLT2-I effect.

O.10-1

Changes in corneal morphology in patients after combined pancreatic kidney transplantation: neuropathic diabetic foot and corneal erosion

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Background: Reduction in neurotrophic stimuli induces a thin epithelial layer that may lead to recurrent corneal erosion. DM patients have an increased risk of developing epithelial fragility, corneal recurrent epithelial erosion, abnormal wound healing, and infectious keratitis. The causal relationships between morphological changes of subbasal corneal leash fibers and neurotrophic keratopathy are presented in the patients of diabetes mellitus, refractive surgery, keratoplasty and dry eye.

Methods: The study included 15 patients with combined kidney and pancreas transplantation with a median disease duration of 25 [20-28] years. Using a confocal microscope, the central zone of the cornea scanned with a resolution of 384x384 px, and a microscope field of view of 400x400 μm^2 . Quantitative nerve analysis was performed using ACCMetrics automated software. During the analysis, the following parameters were studied: nerve fiber density/mm² of the cornea (CNFD), morphological composition of the corneal epithelium. The severity of neuropathy was also assessed according to the NDS score, the presence of a diabetic foot.

Results: corneal thickness was significantly less compared to diabetic patients without neuropathy 521.71 ± 27.58 vs 532.2 ± 41.0 μm . 5 patients had a history of corneal erosion. The density of nerve fibers in patients in the study group compared with the control group was 27.1 ± 9.1 fibres/mm² vs 35.5 ± 9.4 fibres/mm². 3 patients underwent laser coagulation of the retina, 12 underwent cataract surgery. All patients had severe peripheral neuropathy, diabetic foot developed in 7 patients. Corneal thickness was significantly less compared to diabetic patients without neuropathy 521.71 ± 27.58 vs 532.2 ± 41.0 μm . Five patients had a history of corneal erosion. All patients had severe peripheral neuropathy, diabetic foot developed in 7 patients.

Conclusions: Diabetic corneal changes, such as delayed epithelial wound healing, edema, recurrent erosions, neuropathy/loss of sensation, and tear film changes, are common but underdiagnosed complications of diabetes mellitus compared to retinal pathology. Pathological changes affect the corneal epithelium, nerve plexus, tear film, and to a lesser extent the endothelium, as well as the conjunctiva. These anomalies may appear or worsen after trauma, as well as various operations, including retinal, cataract, or refractive surgery.

O.10-2

Declining incident rates of distal polyneuropathy in a cohort study, but with distinct age-related patterns between diabetes types 1996-2018

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Background and aims Incidence rates for diabetic complications are decreasing. However, for distal symmetrical polyneuropathy (DSPN) this has not been demonstrated. In this study, we investigated incidence rates for DSPN in individuals with type 1 and type 2 diabetes in a large population-based study.

Design and methods In the period 1996 to 2018 19,342 individuals were identified at a Danish tertiary diabetes center (Steno Diabetes Center Copenhagen). Vibration perception threshold (VPT) was assessed by repeated biothesiometry during the study. Exclusion of individuals with prevalent DSPN or missing data left 9,473 individuals for analysis of DSPN by cut-off >25 Volts and 2,783 individuals by age-sex-height specific cut-offs. Poisson regression analysis was used to model incidence rates of DSPN for both cut-offs and separately for type 1 and type 2 diabetes. Sex, age, diabetes duration and calendar time were included as covariates.

Results From 1996 to 2018 incidence rates of DSPN decreased for both type 1 and type 2 diabetes, when using 25 volts cut-offs. (Figure 1).

Age-sex-height specific cut-off demonstrated similar incidence patterns by calendar time. For type 1 diabetes, decreasing incidence rate were seen with higher age (Not shown).

Conclusion Incidence rates for DSPN are declining in type 1 and type 2 diabetes, possibly due to improved diabetes treatment. This causality remains to be explored. Distinct age-related patterns when using age-sex-height specific cut-off indicate that the pathophysiology of DSPN may differ between diabetes types.

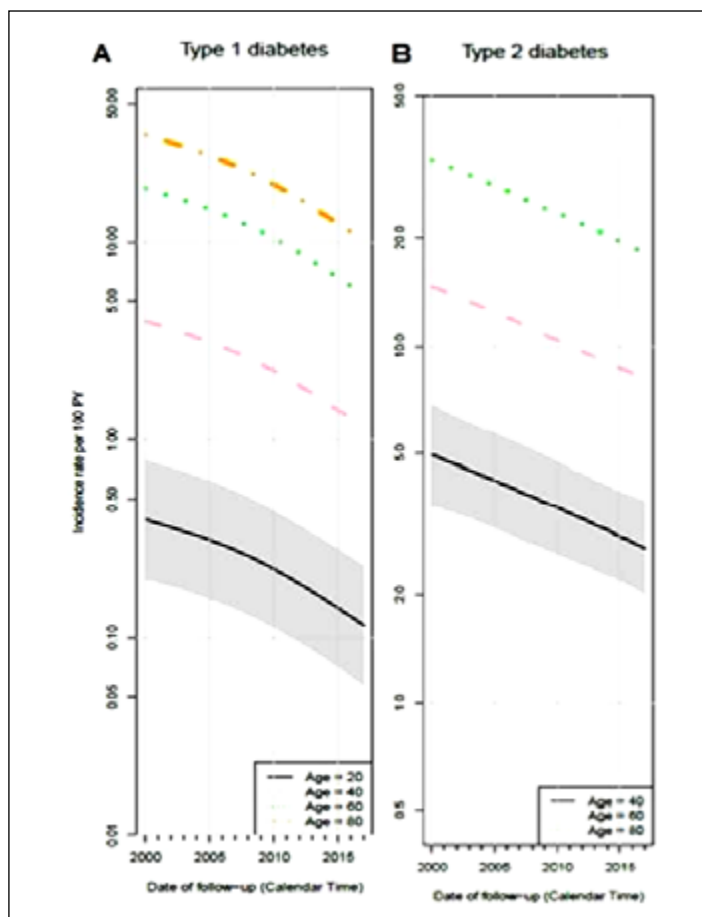


Figure 1

O.10-3

Associations between sensory-feedback in foot and physical activity in frail patients undergoing routine hemodialysis – A randomized double-blinded controlled trial

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Background/Aim: Patients receiving hemodialysis (HD) experience fatigue, limited time availability, and mobility impairments, which all contribute to less physical activity, resulting in frailty. Intradialytic electrical stimulation (E-stim) is recommended as an alternative intervention solution instead of the traditional exercise program. Specifically, E-stim to the plantar region of the feet can have the benefit to activate lower limb muscles, as well as enhancing the sensitivity to somatosensory signals from the foot. The aim of this study was to explore the association between sensory-feedback in the foot and physical activity characteristics to demonstrate the efficacy of plantar electrical nerve stimulation (PENS) during HD process in patients with frailty.

Methods: All participants exhibited pre-frail to frail levels based on the Fried frail criteria, and they were randomized into either an intervention group (IG: n=21, age=55.5 ± 14.3 years, BMI = 28.5 ± 6.0 kg/m², female = 28.6%, pre-frail=38.1%, frail=61.9%) receiving PENS or a control group (CG: n=22, age = 61.0 ± 7.8 years, BMI = 30.7 ± 6.2 kg/m², female = 45.5%, pre-frail=36.4%, frail=63.6%). The IG received 1-hour PENS during the routine HD process (3 sessions/week), and the CG received an identical but non-functional device for 12 weeks. The maximum Vibratory Perceptual Threshold (VPT) value was measured to assess sensory-feedback in foot, and daily life physical activity was assessed using the wearable pendant at the baseline and 12-weeks. The delta values (Δ) between 12-weeks and baseline were calculated to explore the association between VPT and physical activity.

Results: In the IG, Δ walking duration ($\rho=-0.458$, $p=0.037$) and total step numbers ($\rho=0.484$, $p=0.026$) were negatively correlated with Δ maximum VPT value, whereas there was no correlation in the CG.

Conclusions: Our findings suggest the sensory-feedback in the foot in the IG may be improved after 12-weeks of E-stim therapy, which may affect an increase in walking-related activities in HD patients. Therefore, we recommend this practical therapy may be useful, especially for HD patients who have frail symptoms, to increase their physical activity.

Acknowledgements: This study was supported by the Qatar National Research Foundation (QNRF, Award #NPRP10-0208-170400I).

O.10-4

The Ipswich touch test and the 10g mono-filament test – consistency in identifying loss of protective sensation in clinical practice?

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Background / Aim = Loss of protective sensation (LOPS) is associated with the presence of neuropathy and an increased risk of diabetic foot disease. Two such tests for identifying LOPS are the 10g monofilament (10g) and the Ipswich touch test (IpTT). This study considered the consistency of both tests in clinical practice.

Methods = 216 participants were assessed for LOPS utilising both IpTT and 10g. The 10g test was performed at 10 sites and the IpTT at 6 sites across both feet as recommended by IWGDF. Those identified as high risk also had repeat testing with both tests on 2 further occasions within one week. The consistencies of both tests were compared on all three occasions using interclass correlation testing.

Results: Across all time points both tests had good consistency as detailed below

	Baseline (n=216)	Follow-up 1 (n=54)	Follow-up 2 (n=47)	
LOPS on both	47 (22%)	30 (56%)	23 (49%)	
No LOPS on both	148(69%)	23(43%)	19(40%)	
Inconsistency	21(10%)	1(2%)	5 (11%)	
ICC (95% CI)	0.86 (0.81 to 0.90)	0.96 (0.94 to 0.99)	0.79 (0.65 to 0.88)	
Interpretation of Reliability	Good	Excellent	Moderate to good	
Test type 10g/IpTT LOPS at all time points No LOPS at all time points Inconsistency ICC				
(95% CI)	Interpretation of Reliability			
Baseline & Follow-up 1 (n=54)	10g			
IpTT	30 (56%)	IpTT	24 (52%)	
27 (50%)	17 (31%)	22(48%)	18 (39%)	
21 (39%)	7 (13%)			
6 (11%)	0.73 (0.58-0.83)			
0.78 (0.65-0.87)		19 (41%)	4 (9%)	
	Moderate to good	5 (11%)	0.83 (0.71-0.9)	
Baseline & Follow-up 2 (n=47)	10g			
IpTT	26 (55%)	0.79 (0.65-0.88)	Moderate to good	
22 (47%)	14 (30%)	Baseline & Follow-up 1 & Follow-up 2 (n=46)	10g	
18 (38%)		IpTT	24 (52%)	
	7 (15%)	21 (46%)	13 (28%)	
	0.69(0.51-0.81)	17 (37%)	9 (20%)	
7 (15%)		8 (17%)	0.73 (0.61-0.83)	
0.71 (0.53-0.82)	Moderate to good	0.77 (0.65-0.86)	Moderate to good	
Follow-up 1 & Follow-up 2 (n=46)	10g			

Conclusion = There is much discussion in the literature about which test to use to assess for LOPS. In this study it has been shown that neither test has superiority in identifying LOPS. Either test can be used in clinical practice.

O.10-5

Quantifying Gait Impairments Caused by Peripheral Neuropathy in a Large Prospective Cohort of Adults from a Single Tertiary Wound Clinic

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Introduction: Peripheral neuropathy occurs when there is damage to nerves outside of the brain and spinal cord. It is important to quantify the impairments in gait for vulnerable patients since patterns in gait can inform clinicians of surgical recommendations, early intervention, and monitoring. The aim of this study is to quantify the gait changes in patients with peripheral neuropathy.

Methods: Adult patients who could ambulate unassisted and without pain, without open wounds, and without previous lower extremity surgery in the previous three months were offered participation. To reproducibly evaluate gait, participants completed a standardized protocol with wearable Opal sensors (ADPM, Portland Oregon) and completed a 120-second walk test and a 30-second Romberg (sway) test. Data was provided by the Motility Lab software (Hamilton Thorne) and analyzed using unpaired student's t-tests with significance defined as $p < 0.05$.

Results: 190 patients were included with an average age of 57.3 ± 16.7 years and a BMI of 29.3 ± 10.4 kg/m². 84 patients were diagnosed with peripheral neuropathy and 106 patients without peripheral neuropathy served as a control. Peripheral neuropathy significantly predicted a reduced gait speed (0.82 vs. 0.97 m/s, $p < .0001$), increased elevation midswing (1.62 vs. 1.36 cm, $p = .040$), increased step duration (0.62 vs. 0.59 s, $p = .0008$), decreased cadence (97.56 vs. 102.81 steps/min, $p = .0004$), increased double limb support (28.91 vs. 25.07%, $p < .0001$) and decreased single limb support (35.65 vs. 37.84%, $p < .0001$).

Conclusion: To our knowledge, this study has the largest comparative sample that analyzes gait outcomes compared in peripheral neuropathy. We found significant impairments in multiple spatiotemporal aspects of gait. Clinicians should consider incorporating quantitative gait analysis in the risk stratification in patients with or at risk of peripheral neuropathy.

Table 1. Gait Parameters in Non-neuropathic and Neuropathic Adults

Gait Parameter	Control (n=106)	Peripheral Neuropathy (n=84)	P Value
Gait Speed (m/s)	0.97	0.82	<0.0001*
Elevation Mid-swing (cm)	1.36	1.62	0.040*
Step duration (s)	0.59	0.62	0.0008*
Cadence (steps/min)	102.81	97.56	0.0004*
Single Limb Support (%)	37.84	35.65	<0.0001*
Double Limb Support (%)	25.07	28.91	<0.0001*
Stride length (m)	1.13	0.99	<0.0001*
Sway (m/s ²)	0.63	0.41	0.019*

O.11-1

Non-Invasive optical methods to assess Tissue Perfusion in patients with Peripheral Arterial Disease and Diabetes Mellitus – a Systematic Review

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Background: Peripheral Arterial Disease and Diabetes Mellitus continue to increase. Diabetic Foot ulcer (DFU) is a debilitating complication which is burdensome socially, psychologically and economically. It is therefore imperative to be able to continuously monitor local tissue perfusion in high-risk patients for risk stratification, management and prognostication of DFU in a non-invasive, easily accessible and cost-effective manner.

Aims & Objectives: To systematically review the available methods of assessing non-invasive optical tissue perfusion and their use in PAD and DFU, to collate and present details of the technologies, advantages and disadvantages

Methods: A systematic literature review was conducted in accordance with PRISMA guidelines. Embase and Medline databases were searched using Ovid interface, as well as Pubmed and Google Scholar. The articles were reviewed by two independent reviewers.

Results: 625 articles were screened. 26 were included in the final review. The modalities included and discussed include:

- Photoplethysmography
- Spatial frequency domain imaging
- Hyperspectral imaging
- Laser Doppler
- Laser speckle Flowgraphy
- Near infra-red spectroscopy
- Thermography
- Indocyanine green.

Conclusion: Several modalities are available for non-invasive monitoring of tissue perfusion which show promise for use in diabetic foot disease. Further clinical evaluation is required to determine if there is a role for these technologies in widespread clinical use.

O.11-2

Impact of diabetic foot infection on the clinical outcomes of autologous cell therapy in patients with chronic limb-threatening ischemia

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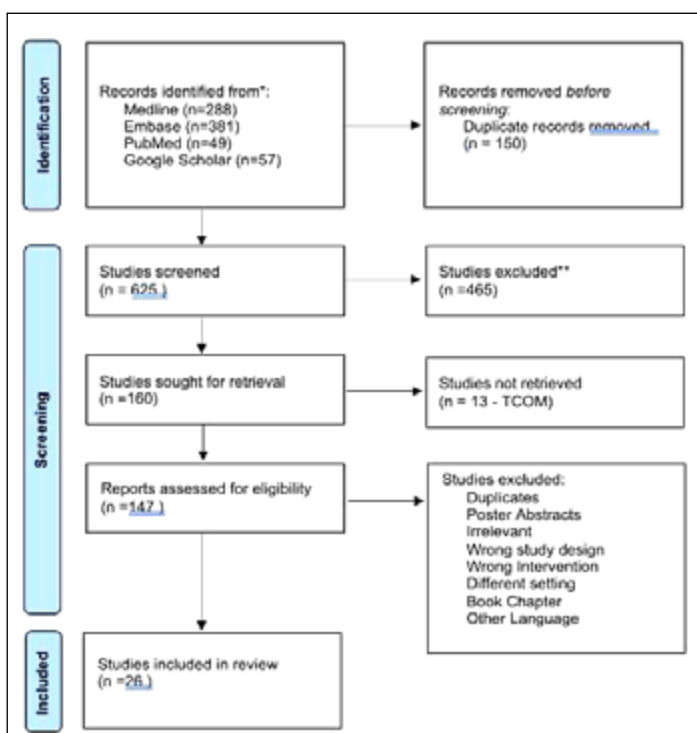
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Aim: Therapeutic arteriogenesis by autologous cell therapy (ACT) is a new treatment method for diabetic patients with no-option chronic limb-threatening ischemia (NO-CLTI). Diabetic foot infection (DFI) might be one of the main causes of major amputation in patients with diabetic foot disease, especially in those with NO-CLTI. The aim of our study was to assess the impact of DFI on the outcomes of cell therapy in patients with NO-CLTI and diabetes.

Methods: One-hundred-forty-nine ACT applications performed in 124 patients with CLTI persisting after unsuccessful standard revascularization treated in our foot clinic over 15 years were included in the study and analyzed. ACT applications were divided into 2 groups – the DFI group with the presence of clinical signs of infection (n=46) and the non-DFI group (n=103). Both groups were compared in baseline values and the changes in transcutaneous oxygen pressure (TcPO₂) were evaluated after 6 months. Major amputation, amputation-free-survival (AFS), and ulcer healing were assessed during the whole follow-up after ACT (3 months to 14.3 years).

Results: TcPO₂ in DFI and non-DFI groups were similar at baseline. At 6 months it increased by 21.7 mmHg CI95=(18.0, 25.3) in the no-DFI group and by 29.8 mmHg CI95=(22.5, 37.2) in the DFI group. The difference between groups was significant (p=0.032). Median AFS in the non-DFI group was 4.6 years CI95=(3.7, 6.3), significantly higher compared to 1.4 years CI95=(0.5, 3.0) in the DFI group. Ulcer healing was significantly better in the non-DFI group with a median time to heal 0.9 years CI95=(0.7, 1.1) compared to the DFI group where less than 40% of ulcers healed and lower bound of mean time to heal CI95=6.6 years.

Conclusions: Our study shows that patients with NO-CLTI and baseline presence of DFI treated by ACT had significantly lower AFS and significantly worse ulcer healing. Therefore, the indication of ACT in patients with clinical signs of infection should be carefully considered. Supported by the project National Institute for Research of Metabolic and Cardiovascular Diseases (Programme EXCELES, Project No. LX22NPO5104) - Funded by the European Union - Next Generation EU and by MZO 00023001.



PRISMA Flow chart

O.11-3

Capillary arterialization associates with increasing muscle damage – a novel view on microvascular pathology of chronic limb threatening ischemia

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Background: Clinical management of critical limb threatening ischemia (CLTI) is focused on prevention and treatment of atherosclerotic arterial occlusions.¹ The role of microvascular pathology on the disease progression is still largely unspecified and more importantly not utilized in terms of treatment. The aim of this study was to characterize microvascular pathology in CLTI-affected human skeletal muscles and establish if and how the microvascular changes could affect CLTI pathology.

Methods: Clinical high-resolution contrast enhanced ultrasound imaging² and amputation muscle samples from CLTI patients were used to describe microvascular pathology of CLTI on the level of resting tissue blood flow² and microvascular structure³, respectively. Furthermore, a chronic, low perfusion pressure -simulating ischemia model in rabbits was developed based on femoral artery denervation⁴ to display the effect of increasing capillary size heterogeneity on muscle survival under low perfusion pressure.

Results: Resting tissue-level blood flow was not depleted but displayed decreased capillary transit time in CLTI muscles ($P < 0.05$). In line with the flow findings, the muscle microvasculature in CLTI was shown to exhibit capillary enlargement ($P < 0.001$) and further arterialization leading to an increase in capillary size heterogeneity ($P < 0.001$) along worsening of myofiber pathology. Furthermore, increased capillary size heterogeneity was shown to worsen tissue outcome ($P < 0.001$) under chronic ischemia in rabbits.

Conclusions: Our findings suggest active, hypoxia-driven remodeling of the microvasculature in CLTI muscles leading to pathology on the level of tissue blood flow dynamics that has the potential to aggravate tissue damage and thus hold importance also for CLTI outcomes. Thus, imaging the microvascular changes hold promise for improving both diagnostics and treatment of CLTI in the future.

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O.12-1

An investigation into the contributing factors to diabetic foot ulcer healing efficacy. A study of the patient and wound characteristics

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Background and aims: Diabetic foot complications are the most frequent cause of non-traumatic lower-limb amputations with a lost leg due to diabetes somewhere in the world every 20 seconds. In African countries, diabetic foot complications, such as ulceration, infection, or gangrene lead to considerable morbidity, disability, and mortality. The healing time and whether an ulcer heals or not vary for each wound both within and between individual patients. Hence this study aimed at investigating the factors that contribute to healing time within and between individuals to understand the characteristics that lead to improved DFU healing efficacy.

Materials and methods: Data from 8198 ulcers from 3922 patients who attended a specialist diabetes service in Dar-es-Salaam, Tanzania during Jan 2014-Dec 2021 were recruited to this study. During the course of treatment, 7777 ulcers were healed and 421 ulcers remain unhealed. All the patients on registration were taken full history, demographic details, and full examination with grading for peripheral neuropathy, arterial diseases, and ulcer classification. Details for micro and macrovascular complications were recorded for each appointment.

A Generalised Linear Mixed Model approach was used to identify the characteristics that affect the DFU healing time as the outcome measure using the mentioned measures as input.

Results: The model showed to be able to identify both the patient and wound related measures with significant effects on DFU healing efficacy ($Z=63.218$, $P=0.000$). Age, delay attending the foot clinic after DFU, Duration of diabetes, Fasting Blood Glucose level, detectable pedal pulse, neuropathy level ulcer history, previous amputation, ulcer wound length, Wagner classification, tissue loss level and University of Texas grade significantly ($p<0.05$) affected the healing time. Among these delay in presentation (Ave: 15 days) showed to have the strongest effect on diabetic foot ulcer healing time.

Conclusion: Certain characteristics related to arterial disease, neuropathy level, wound size and classification, as well as the patient's history and blood sugar level showed to influence ulcer healing efficacy. In treating the DFUs, these characteristics as well as delays in presentation need to be considered to optimise the treatment efficacy of Diabetic Foot ulcers in each individual patient.

O.12-2

Prediction of ulcer outcome for SINBAD ulcer scoring system in Egyptian Tertiary diabetic foot clinic

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Background/ Aim Different available classifications for diabetic foot ulcer (DFU) with no consensus on which one is preferred to use in different situations. International working group of diabetic foot guideline (2019) identified SINBAD score (Site, Ischemia, Neuropathy, bacterial infection, area, depth) as recommended for communication between health care professionals. The study aimed to apply SINBAD scoring to assess DFU and evaluate related outcome in tertiary diabetic foot clinic in Egypt.

Methods Retrospective study from September 2019 to September 2022. Data from all cases with diabetic foot ulcer were classified by SINBAD score on their first day of diabetic foot clinic attendance. Only patients who completed follow up period of 12 weeks were included. Primary outcome included ulcer healing versus non healing during this period. In non healed ulcers at the end of selected period percentage of improvement of ulcer surface area was calculated as secondary outcome.

Results Total number of patients with diabetic foot ulcer was 823 patients, only 288 patients completed 12 weeks follow up and presented with 342 diabetic foot ulcers. According to SINBAD score site of 82% of DFU were Forefoot, 1.8% were ischemic, 98.5% neuropathic, 41.8% showed bacterial infection, 53.2% had surface area > 1 cm² and 5% were deeper than skin and subcutaneous tissue. 184 ulcers (54%) healed during the selected period with median healing duration 55.5 days. Percentage of ulcer healing varied from 100%, 72.8%, 55%, 46.2%, 12.9%, 0% to score 0, 1, 2, 3, 4, 5 respectively. No case presented with score 6. With reference to score 1, odd ratio for ulcer non healing after 12 weeks increased for each additional level of score value (Odds ratio 2.18, 3.11, 18.08 for score 2, 3, 4 respectively). SINBAD score had good prediction of ulcer outcome with area under curve (AUC) 0.685. Percentage of improvement of ulcer surface area in non healed ulcer showed statistically significant negative correlation with SINBAD score ($r = -.285$, $p = .001$).

Conclusion SINBAD, a simple diabetic foot ulcer score, has significant prognostic ability to predict foot ulcer outcome at 12 weeks in Egyptian tertiary diabetic foot clinic.

Keywords Diabetic foot, Diabetic foot ulcer, ulcer classification, ulcer outcome

O.12-3

Prospective randomised placebo-controlled trial assessing the efficacy of silver dressings to enhance healing of acute diabetes-related foot ulcers

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Background/Aim

Silver dressings are used for their antimicrobial properties but there is limited evidence of clinical benefit when managing diabetes-related foot ulcers (DFUs). We aimed to assess whether silver dressings in acute DFUs increased the proportion of ulcers healed compared to non-silver dressings.

Methods

In this open-labelled, randomized controlled trial, consecutive individuals who presented to a tertiary multidisciplinary diabetic foot service with a DFU of <6 weeks duration were randomized 1:1 to receive an antimicrobial barrier silver dressing (Silver Group) or dressing without silver (Control Group) in addition to standard care. Ulcers with tendon in the base or osteomyelitis were excluded. Stratified randomization was performed to ensure the presence of peripheral arterial disease (PAD) and infection were equally managed within the two groups. Primary outcome was the proportion of ulcers healed at 12 weeks. Secondary outcomes included time to heal and 50% ulcer reduction, rates of osteomyelitis, amputation, need and duration of antibiotics.

Results

Seventy-six ulcers (55 participants) in the Control group and 91 ulcers (63 participants) in the Silver group were included. There was no difference in the proportion of ulcers healed by 12 weeks in the Control vs Silver group (75% vs 69%, $p=0.49$). After adjustment for presence of PAD, infection and initial ulcer size, silver dressings were not associated with odds of healing (OR 0.92, (CI 0.26-3.2), $p=0.53$). There was no difference in time to healing, progression to osteomyelitis, need for amputation and duration or need for antibiotic treatment.

Conclusions

In individuals with acute DFUs, the use of an antimicrobial barrier silver dressing did not improve wound healing nor reduce need for antibiotics compared to non-silver dressings.

Reference

Antimicrobial barrier silver dressing used was Acticoat.

Acknowledgements

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O.12-4

Wound healing and health-related quality of life in patients with DFU treated with TLC-NOSF polyabsorbent dressings*: Prospective, multicentre real-life study

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Background/Aim: A prolonged inflammatory phase, high levels of matrix-metalloproteinases (MMP), a delayed healing process and high recurrence rates are well known challenges of chronic wounds, including diabetic foot ulcers (DFU).¹ This clinical evaluation aimed to assess the performances of TLC-NOSF dressings* with polyabsorbent fibres in the local management of patients with chronic wounds in an unselected patient population under real-life conditions in Germany.¹ The results presented were analysed for DFU patients.

Methods: A large, prospective, multicentre observational study with wounds of various aetiologies treated with three different TLC-NOSF polyabsorbent dressings* was conducted in 105 centres across Germany (Jan. 2019 - June 2020; n=961). Thereof patients with DFU were recruited by 55 centres. The main endpoints included: the rate of wound healing, the clinical assessment of wound healing progression, local tolerance and acceptability of the dressings. Changes in health-related quality-of-life (HRQoL) were assessed with the validated Wound-QoL 17 questionnaire and analysed as global score as well as sub scale scores regarding body, psyche and everyday life.

Results: Altogether 217 patients with DFU were treated with the dressings* for a mean duration of 63±30 days. At final visit, 57.6% of the ulcers were healed, 32.3% improved and 4.1% were stabilized. In DFUs ≤ 1 month duration, wound closure was even higher (71.3%). This continuous improvement of wound healing was supported by a remarkable reduction of sloughy tissue (Median 78.9%). A substantial improvement was reported in the majority of the patients on all HRQoL parameters: At the initial visit HRQoL was severely disadvantaged, especially in psychological/everyday life dimensions. At final visit significant improvements were achieved in all dimensions. This improvement in HRQoL was closely related to improvement in wound healing progression. The dressings were 'very well/well tolerated' (97.7%) and 'very well/well accepted' (97.7%).

Conclusion: These results show the good performance of these dressings in rapidly improving wound healing and HRQoL of patients with DFUs treated in real-life setting. They are consistent with previous clinical evidence on TLC-NOSF dressings,²⁻⁴ supporting current guidelines recommending their use for local treatment of DFUs⁵ and confirming that optimal outcomes are achieved when used as first-line treatment.

P01.1-1

Biomechanics and the Diabetic Foot Development of the Torbay Skellen Triage Tool for Diabetic Foot Ulcer Prevention

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Background/aim: The causal pathway leading to plantar diabetic foot ulceration (PDFU) is well documented, primarily associated with diabetic peripheral neuropathy (DPN)^{1,2,3}. Clinically, DPN screening focuses on sensory loss, such as the 10g monofilament⁴. Yet risk factors associated with diabetic peripheral motor neuropathy (DPMN), such as deformity and reduced range-of-motion, are ignored despite their contribution to PDFU.

The Torbay Skellen Triage Tool (TSTT) is an innovative tool to screen for DPMN and assess the risk to prevent PDFU.

Methods: The TSTT was created using a consensus method by a group of podiatrists and orthotists. A training package was designed for clinicians to use the TSTT and screen patients at high risk of ulceration. After 12 months a service evaluation was completed to analyse the TSTT effectiveness. Data was collected from a local NHS Trust diabetic foot ulcer database over 12 months, and an audit undertaken. Outcome measures were DFU prevention, ulcer healing times, and ulcer severity as assessed by SINBAD score. An unpaired t-test was calculated for the skellen triage score for non-ulcerated vs ulcerated patients.

Results: For n=143 patients, initial ulceration prevention rates improved from 64% to 95% at 12 months post TSTT introduction. Re-ulceration rates remained at 55% at 12 months. Average ulceration healing times improved from 17 to 14 weeks. Re-ulceration severity reduced on average from SINBAD = 1.5 to 1.1. The TSTT was statistically significant, $p = 0.0001$, as a score for non-ulcerated vs ulcerated patients.

Conclusions: The introduction of the TSTT showed promise of ulceration prevention when introduced as a screening tool for DPMN. Re-ulceration rates remained high, resulting in the design of a reablement plan. Using the TSTT enables earlier referral for gold standard offloading, including therapeutic insoles and footwear. The TSTT can be used as a measure of DPMN and risk measure of plantar foot ulceration, and a future RCT is recommended.

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P01.1-2

Case series of treatments with a novel, customized, non-removable, stiffened offloading sole for patients with plantar diabetic foot ulcers

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Background: We have standardised the rapid bedside fabrication of a non-removable offloading device by the wound care team[1]. It provides a pressure-optimised support surface (felt) and a stiffened, rocker bottom sole (cast material). This sole is easy to make, is attached to the foot, is reusable and allows access to the ulcer for wound treatment. It offers many of the features of a total contact cast and is easy to learn. As part of the treatment policy for diabetic foot ulcers (DFU) at our centre, we do not recommend that patients limit their steps. To evaluate the method, we reviewed patient careers when using this novel offloading device.

Method: Patients starting a treatment of DFUs between 01.01.2021 and 31.12.2021 with the novel sole fabricated within the first 7 days were included in a retrospective single-center case study. Data of the following year were used to analyse the results.

Results: 20 patients met the inclusion criteria. Another 16 patients started this method later than 7 days after the start of ulcer treatment and were excluded. 2 patients died due to heart failure. Another 2 patients were hospitalised during treatment for surgery on their foot (1st tenotomy FDL D2 and D3 and distal metatarsal minimal invasive osteotomy, 2nd resection of the pip joint D4). The median time to wound closure for the 18 survivors was 173 (+153) days, median 103 days. One patient had a transfer lesion that healed before the target ulcer closed. No patient had an amputation. The treatment with the fixed sole was well accepted and continued in all cases until wound closure.

Conclusion: The sole made of felt and cast material is new a safe and effective causal therapy for people with plantar pressure ulcers. It allows patients to continue walking as much as they want to.

1. Hochlenert, D., FiFi!-mobil® Sole, in DFS-Blog. 2021.
<http://cid-direct.de/blog/fifi-sohle/> access date 12.12.2022

P01.1-3

Different pattern of foot structural changes between diabetic and non diabetic patients: a consequence of weight loss in severe obesity

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Aim: To compare modifications in foot structure and shape in obese patients with or without type 2 diabetes mellitus (DM) after weight loss.

Methods: we studied all patients admitted for bariatric surgery in our Hospital between January and March 2019 with body mass index (BMI) between 40 and 48 kg/m² before and after the planned weight loss, dividing them into two groups according to presence (Group 1) or absence (Group 2) of DM. We compared between groups changes in: skin temperature (ST) at first (ST1) and fifth (ST5) metatarsal joint, ultrasound skin and subcutaneous (US) and fascia (F) thickness and anthropometric measures, in particular dorsal circumference (DC) and ankle circumference (AC).

Results: We enrolled 46 patients: 19 in Group 1 (M/F 11/8; mean age 48.2±10.3 yrs) and 27 in Group 2 (M/F 10/17, mean age 46.8±10.0). Time requested to reach expected weight loss was longer in Group 2 (461.5±131.3 days vs 334.2±106.4, p=0.0011). Foot and leg volumes were significantly reduced in both groups, but reduction was greater in Group 2: ΔDC 1.9±1.6 cm vs 0.7±1.4 cm (p=0.02), ΔAC 2.8±1.9 cm vs 1.2±1.7 cm (p=0.01). Also the amount of reduction of ST was greater in Group 2: ΔST1 3.7±3.1°C vs 1.9±3.1°C (p<0.05) and ΔST5 4.8±3.6°C vs 1.8±3.8°C (p<0.02). On the contrary US reduction was significantly greater in Group 1 both dorsal (0.16±0.14 cm vs 0.04±0.14 cm, p=0.009) and plantar (0.10±0.18 cm vs 0.06±0.19 cm, p<0.05) as well as F (ΔF 0.05±0.01 cm vs 0.02±0.08 cm, p=0.02).

Conclusions: our data confirm structural changes induced by weight loss in severely obese patients, but point out different patterns in patients affected from DM compared to non diabetic ones: a more important decrease in tissue thickness in the former and a greater volume reduction in the latter, probably related to different patterns of oedema reabsorption

P01.1-4

Offloading strategies used for plantar diabetic foot ulcers and their outcomes in real-life clinical practice

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Introduction: International guidelines describe offloading the pressure to facilitate healing as an imperative aspect and cornerstone in the treatment and prevention of DFU in the present-day clinic, for which various offloading devices or other methods can be used. The aim of this study is to describe the most prescribed offloading devices, and to investigate differences in outcome of healing percentages using different off-loading methods in real life clinical practice in patients with a plantar ulcer.

Methods: Prospective cohort study of all patients in one diabetic foot centre of expertise in 2014-2020. Clinical outcomes were determined during a maximum follow-up period of 12 months. Outcomes were differences in offloading treatment devices and differences in ulcer-related outcomes between the different offloading groups.

Results: We included 235 patients with a plantar ulcer from our centre. In this cohort, 39.1% was treated with felted foam alone, and 31.9% were treated with an orthopaedic shoe. Patients who received a Pulman bandage shoe and felted foam as offloading device was much more common in patients with more complex wounds (patients with multiple ulcers, Texas stage C and D, Texas grade 3). The healing rate at 20 weeks in the overall group was 51.5% and at 12 months 76.6% with a recurrence rate of 24.7%. No significant differences remained in multivariate analysis between the different offloading devices.

Conclusion: Total Contact Cast, Removable ankle-high offloading devices, orthopedic shoes, Pulman bandage shoes with felted foam and felted foam alone are used most frequently in clinical practice. Without significant difference in healing outcome in multivariate analysis between the different offloading devices.

P01.1-5

Do persons with diabetes fit in standard footwear?

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Background

In Swedish healthcare more responsibility of the care is transferred to the patient. Patients with diabetes, might have to find shoes by themselves instead of having shoes from the department of Prosthetics and Orthotics (DPO). Is it reasonable to let patients find shoes in regular shoe shops? The aim was to compare foot anthropometrics to conventional lasts.

Method

Patients with diabetes (n=82), mean age 63 years, 36 women, DPOs in Region Västragötaland was measured regarding foot length-width and toe height. Indexes were created: foot width/foot length (FWI) and toe height/foot length (THI). Indexes for the lasts were: last width/last length (LWI) and last toe height/last length (LTI). Conventional lasts for men and women respectively were matched (Thor-last for men; Ortho-last for women, Klaveness, Norway) based on the participants foot length + 10mm. We compared the correlation between FWI and LWI and THI and LTI respectively. The regional ethical board of Gothenburg, (Dnr. 1041-13) approved the study.

Results FWI and LWI showed a moderate positive correlation, Pearson's $r = 0.39$, $p < 0.001$. LTI and THI showed a weak positive correlation, Pearson's $r = 0.21$, $p = 0.06$, Figure 1. On average, the last width was narrower than the feet width.

Conclusion There is a risk that patients with diabetes, buying shoes in regular shops, uses ill-fitting shoes leading to pressure induced ulcer. Patients with diabetes should get help from a DPO having a wider range of shoes to fit each individual.

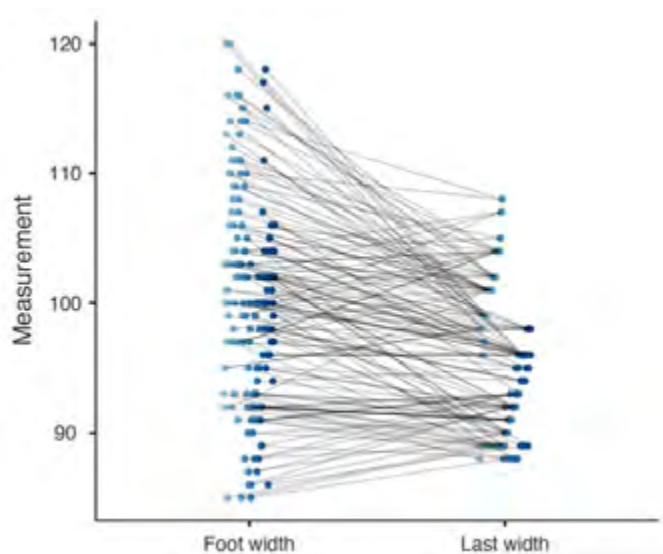


Figure 1: Foot Width and last width (n=82)

P01.1-6

Foot and ankle mobilisation in diabetic peripheral neuropathy: single site, proof-of-concept (PoC), assessor blinded randomized controlled trial (RCT).

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Background: The risk of diabetic foot ulceration increases in feet lacking their protective sensation and exposed to repetitive peak plantar pressures (PPPs). Diabetic glycosylation reducing ankle and 1st metatarsophalangeal (MTP-1) movement may further increase PPP and ulceration risk. Manual therapy could restore accessory gliding of the ankle and MTP-1 joints, and along with stretches, improve function and reduce ulcer risk.

Aim: Investigate if ankle and MTP-1 joint mobilisations combined with a home exercise programme (HEP) of stretches in people with diabetic peripheral neuropathy (DPN), improve ankle and MTP-1 dorsiflexion (DF) and reduce forefoot PPPs.

Methods: A single site, proof of concept, assessor-blinded randomised controlled trial with intervention comprising bilateral ankle and MTP-1 joint mobilisations combined with HEP stretches (gastro-soleus and plantar fascia), delivered over a 6-week period. Participants presenting with DPN and ankle/MTP-1 joint stiffness were randomised to an intervention (n=31) or control group (n=30). Active ulceration, arthritis, fracture, osteoporosis or amputation were excluded.

The primary outcome was ankle DF in stance phase measured using 3D motion analysis (Codamotion). Secondary outcomes included PPP (F Scan), Static ankle and MTP-1 joint DF, postural sway and functional reach test (FRT). Data was collected at baseline (T0), post-intervention at 6-weeks (T6) and 18-weeks from baseline (T18). Data was analysed with intention-to-treat principle and analysis of covariance. Exit interviews explored factors underlying exercise adherence.

Results: There was no difference in baseline characteristics between groups. There was no change in maximum ankle DF in stance phase between T0 and T6 or in postural sway or PPPs ($P>0.05$). At T6, there were significant increases in Left ($P=.001$) and Right ($P=.000$) static ankle DF, left MTP-1 DF ($P=.049$) and FRT ($P=.021$). Changes were maintained at T18 (left and right ankle DF, $p<0.01$, right hallux DF $p<0.01$, FRT $p<0.01$). Intervention adherence was high (80%) and influenced by the physiotherapist, available time and perceived benefit.

Conclusion: Ankle and MTP-1 mobilisations together are effective at increasing static measures of range. They may be useful for improving ankle, hallux joint mobility and anteroposterior stability limits in people with diabetes and neuropathy but not for reducing PPP or foot ulcer risk.

P01.2-1

Footwear and insole design to prevent diabetic and neuropathic plantar forefoot ulcers; - Findings from A series of N-of-1 trials

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Background Foot complications occur in conjunction with poorly controlled diabetes. Plantar forefoot ulceration contributes to partial amputation in unstable diabetics, and the risk increases with concomitant neuropathy. Reducing peak plantar forefoot pressure reduces ulcer occurrence and recurrence. Footwear and insoles are used to offload the neuropathic foot, but the success of offloading is dependent on patient adherence. This study aims to determine which design and modification features of footwear and insoles improve forefoot plantar pressure offloading and adherence in people with diabetes and neuropathy.

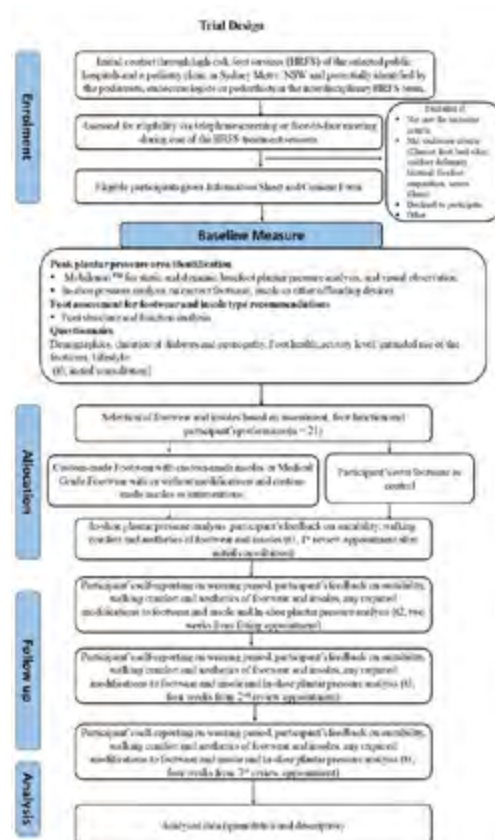
Methods This study, involving a series of N-of-1 trials, included 12 participants with a history of neuropathic plantar forefoot ulcers. Participants were recruited from the high-risk foot services of two public hospitals and one private podiatry clinic in New South Wales, Australia. This trial is non-randomised and unblinded. Mobilemat™ and F-Scan® plantar pressure mapping systems by TekScan® (Boston, USA) were used to measure barefoot and in-shoe plantar pressures. Participants' self-reports were used to quantify the wearing period over a certain period of between two to four weeks during the trial. Participant preference toward footwear, insoles design and quality-of-life related information were collected and analysed. The descriptive and inferential statistical analyses were performed using IBM SPSS Statistics (version 27). And the software NVivo (Version 12) was utilised for the qualitative data analysis.

Conclusion This is the first trial assessing footwear and insole interventions in people with diabetes by using a series of N-of-1 trials. Reporting self-declared wearing periods and participants' preferences on footwear style and aesthetics are the important approaches for this trial. Patient-centric device designs are the key to therapeutic outcomes, and this study is designed and carried out with that strategy in mind.

Walking comfort and ease of use are the two major factors for patient adherence, while the appearance of footwear is the third preference for the patients.

Trial registration

This trial has been registered with the Australian New Zealand Clinical Trials Registry (ANZCTR), and the registration number is ACTRN12620000699965p. Registration date: June 23, 2020



Study design for the N-of-1 Trial

P01.2-2**A systematic review of surgical offloading by digital flexor tenotomies**

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Background: Both prevention and healing of diabetic foot ulcers (DFU) requires offloading sites of concern during weight-bearing activity. Digital flexor tenotomies are a surgical approach to offloading toes with deformities such as hammertoe. The present work is a systematic review of the efficacy of such procedures.

Methods: A validation set of 18 publications was created. The PubMed search string utilized, captured all validation publications. Additional databases searched included: Web of Science, CINAHL and Cochrane Reviews. Searches were initially conducted in July 2021 and a secondary search was conducted for the period of July 2021 – October 2022. Search results were uploaded into Covidence software for assessment. For each of the following processes, two reviewers assessed each piece and a third reviewer served as tiebreaker for any discrepancies between the two initial reviewers: title and abstract screening, full text screening, and data abstraction. Publications that reported metrics on DFU healing, DFU prevention or biomechanical changes following digital tenotomy were eligible for inclusion.

Results: After automated removal of duplicates, 3,068 publications were appraised. Twenty-five (1 randomized controlled trial, 17 non-controlled cohort publications and 7 systematic reviews) were identified for inclusion in the review. Across a collective sample of n=1,036 from 15 studies, 96.5% of active digital DFU went on to heal following a flexor tenotomy. Fourteen of those studies reported on reulceration occurrences across a sample of 872 procedures (follow-up period range: 7-31 months) and there was a collective reulceration rate of 15.6%. Across a collective sample of n=396 prophylactic flexor tenotomy procedures in toes at risk for DFU, 2.0% ulcerated during follow-up (follow-up period range: 0.5-36 months). One study reported on changes in plantar pressure and found the surgery to yield a significant reduction in peak pressure (279kPa; p<0.001). A separate study assessed changes in patients' balance and found no change following the surgery.

Conclusions: The literature to date suggests digital flexor tenotomies are efficacious in treating active DFU and preventing future DFU. However, with the exception of one randomized controlled trial, the level of evidence is weak. Additionally, more studies of the biomechanical impact of the procedure are warranted.

P01.2-3

Cumulative plantar tissue stress and its association with foot ulcer recurrence in people with diabetes

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Background/Aim: To investigate the association between cumulative plantar tissue stress (CPTS), its underlying components (i.e. plantar pressure, weight-bearing activity and adherence) and plantar foot ulcer recurrence in people with diabetes.

Methods: In an observational prospective cohort design, we longitudinally followed 53 participants with diabetes and neuropathy (all IWGDF risk 3) for 12 months. At baseline, we objectively assessed demographics, and: a) barefoot and in-shoe plantar pressures during walking and standing, b) type and extent of weight-bearing activities during 7 days, and c) footwear adherence. These were combined in a CPTS model, which included barefoot and in-shoe pressure-time integrals for walking and standing. We used Student's t-tests in univariate analyses to compare people with and without plantar foot ulcer recurrence during follow-up (significance level $p < 0.05$).

Results: During 12 months follow-up, 17 participants (32%) developed a plantar foot ulcer (metatarsals: 41%, hallux: 47%, digits: 12%). Mean CPTS was not significantly different between the ulcer and no-ulcer group (1313 (SD:1031) vs. 1359 (SD:829) MPa.s/day, respectively, $p = 0.431$). Compared to the no-ulcer group, the ulcer group had equal barefoot peak pressure, lower in-shoe peak pressure, shorter standing duration, lower daily number of steps and lower footwear adherence, although none statistically significant. CPTS was higher at the ulcer location compared to the same region on the contralateral foot ($\Delta 318$ (SD:454) MPa.s/day), while no such left-right difference was seen for non-ulcerated regions ($\Delta 12$ (SD:545) MPa.s/day, $p = 0.023$). Compared to the no-ulcer group, the ulcer group had a statistically significant lower walking speed in the laboratory (0.95 (SD:0.29) vs. 1.14 (SD:0.21) m/s, $p = 0.004$), and used a mobility device more often (35% vs. 14%, $p = 0.073$), although not statistically significant.

Conclusions: CPTS and its underlying components were not different between people who developed a recurrent plantar foot ulcer and those who did not. However, ulcer regions were exposed to higher CPTS level than no-ulcer contralateral regions, suggesting some effect on ulcer development. More generic health-condition related markers indicating patient fragility (i.e. slower walking and use of a mobility device) seem factors in plantar foot ulcer recurrence.

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P01.2-4

Initial trial of a telemetric monitoring system for prosthesis use following lower limb amputation

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Background Prosthesis use leads to ulceration and infection in 74% of amputees annually. Sensory and immunological impairment further affects the 60% of non-traumatic amputees with diabetes. Standard limb care based on self-management only delivers subjective information for use in clinical service assessment. To provide objective real-time information, a multimodal monitoring system (temperature, humidity, activity and mobility) was tested in a Phase I trial.

Methods 20 established amputees receiving a new patella tendon-bearing prosthetic socket with a pelite liner were recruited to a one-month trial. Built into the pelite liner, the wearable electronics sensor had no direct skin contact. The system communicated via Bluetooth to a mobile phone which transmitted data to a remote server for analysis. Participants were requested to provide daily socket comfort scores and report on difficulties concerning system or prosthesis.

Results Of 20 amputees recruited, 4 withdrew participation for logistical reasons. 9 participants had complete data over 3-4 weeks, and two over two weeks. 3 participants discontinued prosthesis use because of skin discomfort or blistering. In 5 participants, overnight data was missing due to interrupted phone communication. Poor cellular coverage affected data transmission on 4 devices. One sensing unit failed due to concurrent silastic liner use. Location data indicated 9 participants sufficiently mobile to travel more than 1km on at least one day during the study.

During active data collection, over 90% of readings correctly transmitted and received.

Comparison of socket temperatures and activity reflected different prosthesis use patterns. Activity, a measure of residual limb movement, would expect to lead to an increase in limb and socket temperature. Ten participants showed temperature rise following activity, which persisted for at least 30 minutes. In contrast, 8 participants exhibited a temperature increase independent of activity. Of these, 5 discontinued prosthesis wear within 48 hrs.

Conclusions Using the system, it is possible for the first time to obtain objective, unbiased information concerning prosthesis wear and in-socket environment. Further developments will focus on applying machine-learning to data collected in a phase II trial to test a new provision of care for amputees.

(Study funded by Innovate UK grant)

P01.3-1

The efficacy of a novel low-cost offloading device (Toa Uzito) in improving the healing time in severe diabetic foot ulcers

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Background/Aim: Diabetic foot ulcer (DFU) disease is common in Sub-Saharan Africa (SSA). Callus formation plays a key role in the pathogenesis of DFU. Offloading remains one of the useful measures to facilitate DFU healing. Prohibitive costs and paucity of personnel with training often preclude this therapeutic option. For all these reasons, we devised an offloading device that requires no special training to use, is easy to implement, and is very affordable. We named this device Toa Uzito (Swahili translation for offloading) and carried out this study to ascertain its utility and effectiveness in the management of DFU in Tanzania.

Materials and methods: We carried out a non-selective study of persons with DFU who attended a specialist diabetes service in Dar es Salaam, Tanzania. From Feb 2021 to Sep 2022 (study period), following informed consent, we identified DFU patients (cases) whose management included the application of the Toa Uzito device. Controls were managed in a similar manner but without the device. Cases and controls were matched with BMI, duration of diabetes, and wound size. Analyses were performed using Mann-Whitney, and Chi-square tests.

Results: 333(M/F:191/142) total matched cases and controls with DFU healed were recruited. 134(M/F:75/59) in the intervention group were treated using the Toa Uzito. 199 control patients (M/F:116/83) were managed without Toa Uzito. The healing time in Toa Uzito device was found to be significantly shorter Md=92 days in the intervention group than Md=116 days in the control ($p=0.039$). The intervention group 89.3% had a significantly higher proportion of bigger ulcers 3 cm² in areas compared to the control group only 69.8% $\chi^2=9.315$, ($p=0.009$). Also, the intervention group had a significantly higher proportion of patients with ulcers bigger than 1 cm² in area, i.e. 99.3% in the intervention group vs 92.0% in the control group $\chi^2=8.794$, ($p=0.003$).

Conclusion: These initial results indicate the efficacy of the offloading intervention in shortening the healing time of DFU. It renders instant offloading and contributes positively towards healing and reduction of amputation rates. Toa Uzito is simple to implement and is easily adaptable for use at the grass root level anywhere in the developing world.

P01.3-2

Use of off-loading fiberglass casting in Kuwait for the treatment of plantar diabetic foot ulceration - A prospective cohort study

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Background/Aims Diabetic foot ulcers (DFU) are common, difficult to heal frequently leading to lower extremity amputations. Successful DFU treatment relies upon arterial supply, infection control and off-loading casts (OFLC). We introduced and assessed the efficacy of OFLC within our DFU clinic. No such data exists for Kuwait or the Gulf region.

Method Patients were prospectively recruited between December 2020 and October 2022. Demographic, medical, ulcer and outcome data were collected. Inclusion criteria was ≥ 18 yrs, inability to detect 10g monofilament or VPT ≥ 24 volts, plantar ulceration, adequate arterial supply (ABI ≥ 0.9 , TBI ≥ 0.75 TcPo2 ≥ 40 mmHg). Exclusion included non-resolving infection, peripheral arterial disease or unwillingness to comply. Patients were seen weekly for wound-care, wound measurements, photographs. OFLC were applied by one clinician. University of Texas ulcer classification (UT) system was used. Due to climatic, cultural and religious reasons we opted to use Fibre-glass boots for fore /midfoot and flexible focused rigidity casts for rearfoot DFU.

Results Over a 22-month period 68 casts were applied to 54 patients (males=32, females =22). Healing occurred in 92.6%(n=63), 7.4% (n=5) remaining unhealed/lost to follow-up. Compliance was excellent at 92.6%. The mean age was 58.6 yrs ± 10.87 (males 57.5yrs ± 10.84 and females 61.5yrs ± 10.98). The mean diabetes duration was 18.96 years ± 7.89 (\pm SD range 1-38yrs); insulin treated 63% (n=43) and oral medication 37% (n= 25). Ulcer sites were forefoot (FF) 64% (n=44), midfoot (MF) 21 % (n=14) or rearfoot (RF) 15% (n=10). UT classification was A1: 26.5% (n=18), A2: 23.5% (n=16), A3: 7% (n=5), B1: 12% (n=8), B2: 20.5% (n=14), B3: 7% (n= 5), C1: 1.5% (n=1) and C2 1.5% (1). The median duration for all precast ulcers was 56 days (range 7-840 days): Interquartile range of 129.5 days. All ulcers mean size was 2.47cm² ± 1.06 , MF and RF were 3.21cm² ± 1.55 , 2.67 cm² ± 1.06 respectively, FF 2.25cm² ± 0.8 . Healing time (days) was all ulcers 44.23 ± 23.12 , FF 41.07 ± 23.83 , MF 53 ± 19.93 and RF 43.5 ± 23.04 .

Conclusion Our data shows similar healing efficacy outcomes with published data and is the first within the Gulf.

P01.3-3

Difficulties and thoughts on the application of decompression measures for elderly diabetic plantar ulcers

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Background: Foot ulcer is one of the common chronic complications in elderly patients with diabetes mellitus, which has the characteristics of high difficulty, long treatment cycle and serious harm. Choosing appropriate decompression measures according to the actual situation of patients can effectively prevent the occurrence and development of foot ulcers, and significantly shorten the healing time of foot ulcers.

Aim: To analyze the application status of plantar decompression measures in elderly patients with diabetic foot ulcers and its effect on the healing time of foot ulcers, and to explore the difficulties and obstacles in the promotion and application of decompression measures.

Methods: The clinical data of 33 elderly patients with diabetic foot ulcer who were treated in the diabetic foot integrated clinic of our hospital from December 2021 to October 2022 were retrospectively analyzed. According to whether decompression measures were used, they were divided into decompression group (17 cases) and non-decompression group (16 cases). The differences in clinical characteristics between the two groups were compared, and the effects of decompression measures on the healing of elderly diabetic plantar ulcers were analyzed.

Results: The average age of 33 patients was (68.24±8.36) years, the average duration of disease was (16.64±6.02) years, and the average BMI was (26.09±3.54). Peripheral neuropathy and vascular lesions were found in both groups. The average healing time was (84.36±23.87) days in the decompression group and (90.41±12.78) days in the non-decompression group. The difference between the two groups was statistically significant ($P < 0.05$). The healing time of diabetic foot ulcer was longer in elderly patients with toe site, higher BMI, higher Wagner grade, longer course of disease, poorer self-care ability and abnormal gait ($P < 0.05$).

Conclusions: Elderly patients with diabetic foot ulcers should actively take appropriate decompression measures to facilitate the healing of diabetic foot ulcers.

P01.3-4

A clinically applicable method for the patient-specific optimisation of cushioning stiffness in diabetic footwear

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Background: The use of appropriate cushioning materials in diabetic footwear or orthoses is very important for their clinical effectiveness. Previous research has shown that optimising cushioning stiffness on a patient-specific basis significantly enhances their capacity to offload(1). Patient-specific plantar loading is highlighted in the literature as a key predictor of patient-specific optimum cushioning(1–3).

Aim: To develop a predictive model for optimum cushioning stiffness that can be used in clinics.

Methods: Sixty-nine adults with diabetes at risk of developing a DFU were recruited from the population attending diabetic foot clinics at the main general hospital of Malta (age=67y±11y, BMI=26.8kg/m²±5.7 kg/m²). Shod plantar pressure (PP) was measured during walking (Pedar®, Novel®) without any additional cushioning material in the shoe (baseline), and after adding flat 10mm thick footbeds. Seven bespoke cushioning materials(3) were used with stiffness ranging from very soft to very stiff. The materials that minimised PP in the toes, metatarsal heads (MetHeads), midfoot and heel were identified for each participant. Multinomial regression analyses were conducted to test whether optimum cushioning stiffness could be predicted based on baseline PP or based on demographic/ anthropometric parameters known to affect PP (i.e., sex, age, weight, height and shoe size).

Results: Using baseline PP as the sole predictor achieved statistically significant prediction of optimum cushioning stiffness at the MetHeads (69% correctly predicted (CP)) and heel (51% CP)). The likelihood of a soft material offering optimum cushioning decreased with increasing PP. Using simple demographic/ anthropometric parameters as predictors achieved statistically significant predictions in the MetHeads (62% CP), midfoot (83% CP) and heel (66% CP). The likelihood of a soft material being optimum decreased with increasing body mass, shoe-size and increased with increasing age.

Conclusions: Stiffer cushioning materials should be used for people who load their feet more heavily. Optimum cushioning stiffness can be predicted for critical regions of the foot using five simple demographic/ anthropometric parameters (i.e., without a need for PP measurements). This finding opens the way for patient-specific optimisation of cushioning stiffness in clinical practice.

References:

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P01.3-5

Offloading diabetes-related neuropathic foot ulcers at Swedish prosthetic and orthotic clinics

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Background Offloading is central for healing diabetes-related foot ulcers (DFUs). The International Working Group of the Diabetic Foot (IWGDF) considers both total contact cast (TCC) and non-removable knee-high walker to be the gold standard treatment of plantar neuropathic forefoot DFUs (1). However, the use of these interventions and other treatment options in Sweden is unknown.

Aim This study aimed to assess 1) the use of different offloading interventions in Sweden for the healing of plantar neuropathic forefoot DFUs, and 2) awareness of gold-standard offloading devices.

Methods An online questionnaire was distributed to 51 prosthetic and orthotic (P&O) clinics in Sweden. It included questions regarding: a) what treatments were used to offload plantar neuropathic DFUs and b) gold standard recommendation awareness.

Results The response rate was 68.6% (n=35). Modified off-the-shelf footwear with an insole was the most frequently provided intervention. TCC was provided by 20% of the clinicians, and no clinicians provided non-removable knee-high walker or felted foam (Table 1a). Only 23% of clinicians were aware that both TCC and non-removable knee-high walker are the gold standard treatment of plantar forefoot DFUs (Table 1b).

Conclusions The pattern of providing offloading interventions was almost exactly opposite to what evidence-based guidelines recommend: clinicians mainly provided footwear with an insole, which IWGDF strongly recommends not to be provided, while gold standards offloading devices were vastly underutilized. The clinicians' lack of awareness regarding gold-standard devices may have contributed to the low use of gold-standard offloading devices.

References 1. Bus SA, Diabetes Metab Res Rev. 2020;36:e3274.

Table 1. Provision of different offloading interventions for healing DFUs, and proportion of clinicians considering total contact cast (TCC) and nonremovable knee-high walker to be gold standard treatments, % (n).

Table 1a. Provision of different offloading interventions for healing DFUs				
IWGDF recommendation	Intervention type	% of clinicians providing intervention (n)		
1 st choice (gold standard)	a) Total contact cast	20 (7)		
	b) Non-removable knee-high walker	0 (0)		
2 nd choice	Removable knee-high cast or walker	49 (17)		
3 rd choice	Removable ankle-high device	71 (25)		
4 th choice	Felted foam combined with footwear	0 (0)		
Do not use	Footwear	86 (30)		
Table 1b. Proportion of clinicians considering total contact cast (TCC) and nonremovable knee-high walker to be gold standard treatment, % (n).				
Nonremovable knee-high walker				
TCC	Yes	23 (8)	0 (0)	3 (1)
	Unsure	3 (1)	23 (8)	11 (4)
	No	0 (0)	0 (0)	37 (13)

Note: Spearman's correlation coefficient was 0.81 (p<0.001).

P01.4-1

Reduction in the prevalence of Methicillin Resistant Staphylococcus aureus in tissue and wound swabs in a diabetes foot clinic 2005-2021

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Aims: To assess annual change in prevalence of Methicillin Resistant Staphylococcus aureus (MRSA) from tissue and wound swab samples from foot ulcers (DFU) in people with diabetes between 2005 to 2021.

Methods: A retrospective analysis of everyone with MRSA positive wound or tissue swabs taken from our specialist multidisciplinary foot clinic over a seventeen-year period, between July 2005 and July 2021.

Results: From 2005-2021 a total of 406 MRSA positive isolates from DFU swabs were identified from 185 individuals attending the foot clinic. The total number of swabs sent was 6312 from 1916 individuals living with diabetes. Annual MRSA DFU prevalence peaked in 2008 at 14.6% (n=38), decreased in 2013 to 5.2% (n=20) and did not exceed 4% (n=6) from 2015-2021. Incidence of MRSA in DFUs followed similar reductions that were observed in incidence of hospital MRSA and hospital MRSA bacteraemia. Hospital MRSA reached a low in 2021 (n=211), a 76% fall from 2007 figures (n=880). Hospital bacteraemia reduced by two thirds from 2006/7 to 2011/12 (from n=48 to n=16), and in 2021/22 a solitary case was reported.

Conclusions: Prevalence of MRSA in DFU infections treated as outpatients is decreasing in line with falls in hospital acquired blood-borne infections and with overall hospital MRSA incidence. This is likely a reflection of the combination of interventions, such as more stringent antibiotic prescribing and decolonisation strategies which have led to a fall in community MRSA. Reduction in prevalence should have positive impact on outcomes in people living with diabetes, reducing the complication of osteomyelitis and necessity for long-term antibiotic administration.

Keywords diabetes mellitus, foot ulceration, Methicillin Resistant Staphylococcus aureus

P01.4-2

Effect of COVID-19 pandemic on patients attending a Multidisciplinary Diabetic Foot Service and incidence of resistant organisms

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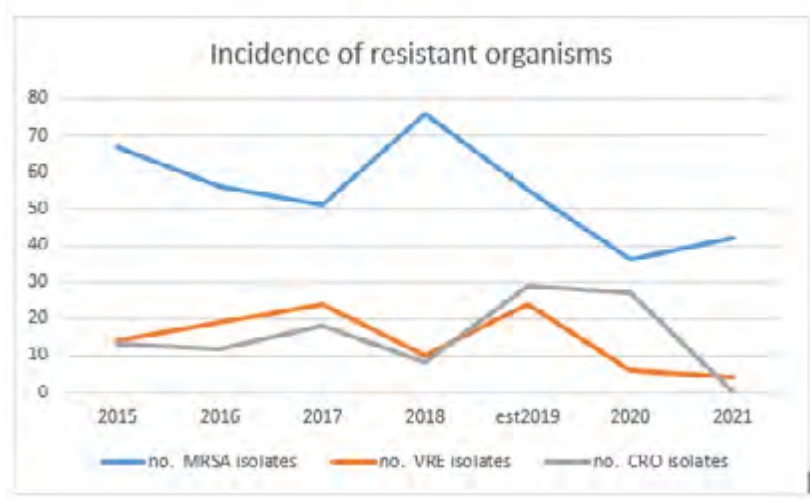
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Background/Aim The COVID-19 pandemic significantly affected health-seeking behaviour as well as widespread use of personal protective equipment and changes to antimicrobial prescribing. It was therefore of interest how this influenced patient attendance at a tertiary Multidisciplinary Diabetic Foot Service (MDFS) and subsequent microbiological results.

Methods We examined data on diabetic foot samples sent to the microbiology laboratory between 2015-2021 by interrogating the Laboratory Information System database and then used Excel to analyse the data. We compared 2020/1 with pre-pandemic data and analysed the incidence of antibiotic resistance.

Results The number of diabetic foot samples sent in 2020 (n=1076) and 2021 (n=1088) was markedly reduced compared to the preceding 5 years when a mean of 2124 samples were sent annually. The number of samples sent per patient also dropped slightly from a mean of 3.5 samples per patient to 3.22 in 2020 and 3.43 in 2021. There was a reduction in the number of isolates positive for methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant *Enterococcus faecium* (VRE) and carbapenem-resistant Gram-negative organisms (CRO) as shown in the figure.

Conclusions The reduction in the incidence of resistant isolates is encouraging but requires further work to determine the main factors leading to this reduction. Staff within the MDFS need to be alert to possible rebound rise in the incidence of resistant organisms in the post-pandemic period.



Incidence of resistant organisms 2015-2021

P01.4-3

Hybrid shared decision-making (SDM) in multi-disciplinary diabetic foot clinic (MDFC): Role delineation and synergy between healthcare professionals (HCPs) and patients

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Background In SDM, HCPs support patients' decisions with the best evidence and what matters most to patients. Patient participation in SDM may be limited in acute care as urgent treatment prevents irreversible sequelae e.g., amputation, whereas chronic care requires ongoing patient engagement in SDM which may be reversible with lower stakes.

Increasingly, an interprofessional SDM (IPSDM) approach is adopted for complex decision-making. Through synergistic efforts of a multidisciplinary care team (MDT), IPDSM adheres to SDM principles to implement healthcare choices agreed upon within the MDT, and with the patients they share.

Aim MDFC care has been shown to salvage limbs in patients with diabetes (DM), a chronic disease, presenting acutely with diabetic foot ulcers (DFUs). We examine SDM approaches found in an MDFC comprising vascular surgeons (VS), diabetologists, and podiatrists in a tertiary hospital.

Methods We conducted a focused ethnography of SDM in an MDFC from February to October 2022 consisting of 55 1.5-hour-long observations, 15 interviews, and discussions.

Results The clinic adopts a hybrid SDM consisting of acute and chronic care approaches as well as IPSDM in one clinical setting to promptly manage patients with DFUs. (Figure)

Conclusions Hybrid SDM in an MDFC involves clear role delineation and mutual role support, smooth transitions and interactions between HCPs, and clear communication with their patients.

Interprofessional Shared Decision Making (IPSDM) in a Multi-disciplinary Diabetic Foot Clinic (MDFC)	
New Diabetic Foot Ulcer (DFU)	
<p>Observation</p> <p>Patient: "I'm anxious."</p> <p>Diabetologist: "Relax, we are here to look after you."</p> <p>Vascular Surgeon (VS) examines wound: "Grade 1. Small wound."</p> <p>Recommendation: wearing the boot.</p> <p>Diabetologist informs VS that Patient dislikes a boot.</p> <p>Patient: Those shoes weigh that VS. Only 1.8kg. VS to Podiatrist: "Stronger shoes. Good circulation. 8. Turns to Patient: "But we must examine this bootage on your right thigh." Patient nods in agreement: "Between the pain in my leg now and a weaker leg just asymptotically, I'd settle for a weak leg."</p> <p>Diabetologist: Her deformed foot... VS: "Ah, the arch is gone. What sort of off-loading can we have?"</p> <p>Podiatrist: TCC</p> <p>Legend: TCC – total contact cast.</p>	<p>SDM Approach</p> <p>Chronic care – establishing an ongoing relationship with patient</p> <p>Chronic care – Footwear adherence is important for wound healing and dependent on patient's preference.</p> <p>Chronic care – clarifying options</p> <p>Acute care – Acknowledging that a clinical decision needs to be made for revascularisation.</p> <p>Acute care – weighing the risks versus benefits offered salvage procedure.</p> <p>IPSDM</p>

Interprofessional shared decision-making in a multi-disciplinary diabetic foot clinic

P01.4-4

Footwear and Offloading Profile of patients with Diabetic Foot Ulcers: A 4 years study of a multidisciplinary clinic in Singapore

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Background: Footwear and offloading interventions are well established within literature and international guidelines to prevent and heal diabetic foot ulcers (DFU). Ill-fitting footwear is a known risk factor of DFU. Yet, there has been no published data on footwear habits and uptake of offloading in patients with DFU. We aim to evaluate footwear choices, preventive footwear and offloading uptake in relation to the wound characteristics in patients presenting to a tertiary multi-disciplinary diabetic foot clinic (MDFC).

Methods: Retrospective data collected from a MDFC between 19 April 2018 to 1 December 2022 involving 905 unique individual attendances for DFU was analysed.

Results: 634 (70%) patients had one DFU and 271 (30%) had multiple wounds. 463 (51%) of the index DFU was sited over the toes, and 339 (38%) were over the weightbearing aspect of the foot. 112 (12%) patients had presented with acute wounds while 538 (59%) are of chronic wounds. SINBAD scoring was implemented in the second half of the clinic audit from 22 Oct 2019 (n=572) and 332 cases (58%) were noted to be severe (SINBAD score of ≥ 3).

Reported aetiologies of the wounds were: 289 (32%) non-footwear related trauma, 237 (26%) overloading, 95 (10%) footwear related trauma, 34 (4%) non-traumatic blisters or skin lesions, 35 (4%) necrosis, 37 (4%) decubitus, 35 (4%) gout and 7 (1%) venous. Majority of them had non-protective, inappropriate footwear choices: 217 (26%) wore slippers, 205 (24%) sandals, 123 (14%) slip-on covered shoes; the rest of which, 87 (10%) wore covered shoes with fixation and 215 (25%) wore prescribed footwear or offloading device. Out of 384 patients who were recommended to change to prescriptive footwear or an offloading device, only 144 (37.5%) accepted the change.

Conclusion: Majority of the patients presenting with DFU has poor footwear choices, and when encouraged to change there was limited uptake. More resources should be put in patient education for selecting appropriate footwear and qualitative studies that looked into factors resisting the footwear change and offloading uptake in an Asian population will be insightful to encourage behavioural change.

P01.4-5

Patient Reported Experience Measures (PREMs) at a Diabetic foot clinic provide a framework for further service improvements

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Background: Multi-disciplinary Diabetic foot clinics provides integrated care for patients. Conventionally ulcer healing and limb salvage are outcome measure of success. Patient Reported Experience Measures (PREMs) are gaining popularity. The aim of this study was to develop and validate a diabetic foot PREM questionnaire.

Methods: PREM questionnaire was developed through consensus. The questions were chosen from pre-validated questions used in a range of other questionnaires. Two pilot versions were trialed on 10 patients each and presented to the Core group and re-trialed before final version was accepted by Trust patient and Public involvement team. The questionnaire consists of 37 questions grouped into 12 sections.

Results: 68 out of 80 patients approached (85%), agreed to complete the PREM questionnaire. 46/68 (60%) had visited the clinic for 6 months or more. Male to female ratio was 1.3:1. Majority of the patients (70%) were aged 41-74 years, less than 10 % were below 40 years of age.

85% of patients filled the questionnaire by themselves. 68% of patient were of white British ethnicity. Responses to all 37 questions in the 12 sections were graded on a scale of 1-7, where 1 was 'never' and 7 was 'always'. Among the 12 domains of patient experience assessed, access to the clinic; information provided to the patient; privacy & dignity; scheduling & planning domains were all rated 7 (highest median score). Medical support; communication with other teams; providing timely information regarding test results; shared decision making and treatment provided were all rated 6 and above. The two domains which scored less satisfactorily (5.5-5.8), were provision of transport to or from the hospital and parking around the hospital.

Conclusion: As clinicians we are more focused on limb salvage outcomes but it is equally important to measure the experience of the person at the centre of our care. The treatment process is long and patients are seen in the diabetic foot clinic multiple times. PREM allows us to measure their experience and provides us with tools for making further service improvements. It should become a standard measure for quality improvement going forward.

P01.4-6

Effects of lower extremity neuropathy and vasculopathy on gait in Chinese type 2 diabetic population

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Background: Diabetic foot disease is one of the most serious chronic complications. The increased local pressure caused by abnormal foot structure and gait is an important basis for the pathogenesis. However, it is still unclear how gait changes in Chinese type 2 diabetic population and the specific relationship between peripheral nerve and vascular lesions and gait.

Method: According to their medical history, blood glucose level and complications related to diabetes, 1861 subjects are divided into normal glucose tolerance group (NGT, n=282), impaired glucose tolerance group (IGT, n=70), type 2 diabetes group (T2D, n=1266) including diabetes complicated with peripheral neuropathy subgroup (DPN, N=144), diabetics with lower extremity vascular disease (LEAD, n=50), and diabetic patients with both DPN and LEAD (DPN+LEAD, n=49). Gait data are measured by a wireless gait analyzer.

Result: People with type 2 diabetes mellitus, lower limb nerve and/or vascular complications results in the decreasing of stride frequency, single stride time and stride speed. Patients only with LEAD shows an increase in the weight-bearing index. Subjects with both DPN and LEAD have lower SDA and SDB. Stepwise multiple regression analysis shows that gender, age and leg length are the influencing factors. Meanwhile, vibration perception threshold (VPT) is an important independent predictor of stride time, SDA and SDB. Ankle-brachial index (ABI) is a significant independent predictor of stride length, weight bearing factor - leg standing phase, SDA and SDB. ROC analysis of the relationship between single stride time and DPN shows that the cut-off point of single stride time is 526.13ms, with a sensitivity of 82.20%. However, severe lower extremity vascular disease (ABI<0.6), the stride length is significantly shortened. After adjusting for leg length, sex, and age, the risk of shorter stride length is still significant in T2DM patients with reduced ABI.

Conclusion: In Chinese patients with type 2 diabetes, lower extremity neuropathy or vascular lesions result in a more conservative gait pattern: reduced stride frequency, speed, and stability. Besides sex, age and leg length, VPT and ABI are independent factors associated with changes in gait parameters. Single stride time of more than 526.13ms is predictive of DPN.

P01.5-1

Are patients safe in their own homes? Preliminary findings of foot loading in association with varied flooring surfaces.

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Background: Adherent use of offloading footwear for prevention of diabetic foot ulcers (DFU) is often suboptimal, particularly in the home environment. The fact that many individuals at risk of DFU engage in more physical activity in their homes than outside of the home further emphasizes the challenge to DFU prevention. One likely factor contributing to low adherence in the home is a perception of protection afforded by carpeting on floors. This study assessed plantar loading in association with varied flooring surfaces.

Methods: Individuals at risk for DFU conducted shod and unshod walking trials on three surfaces: hard tile, low pile carpet + carpet padding, and high pile (plush) carpet + carpet padding. Plantar pressure insoles were affixed to the feet with self-adhesive bandages. Body-worn sensors were used to ensure walking speed differed by <10% between trials. Over the course of 12 strides per condition, peak plantar pressure was assessed across the entire foot as well as four masks (regions) of the forefoot. Peak pressures were assessed as to whether they exceeded 200kPa (a target threshold for prevention of DFU).

Results: Peak plantar pressure data are provided for three study participants (2 female) within Figure 1.

Conclusions: Shod walking yielded consistently lower peak pressures than unshod walking. Within the unshod condition, there was some progressive reduction in peak pressures with the low pile and high pile carpeting. However, even with the high pile carpeting, participants regularly exceeded 200kPa. This preliminary data suggests home carpeting offers insufficient protection for diabetic feet.

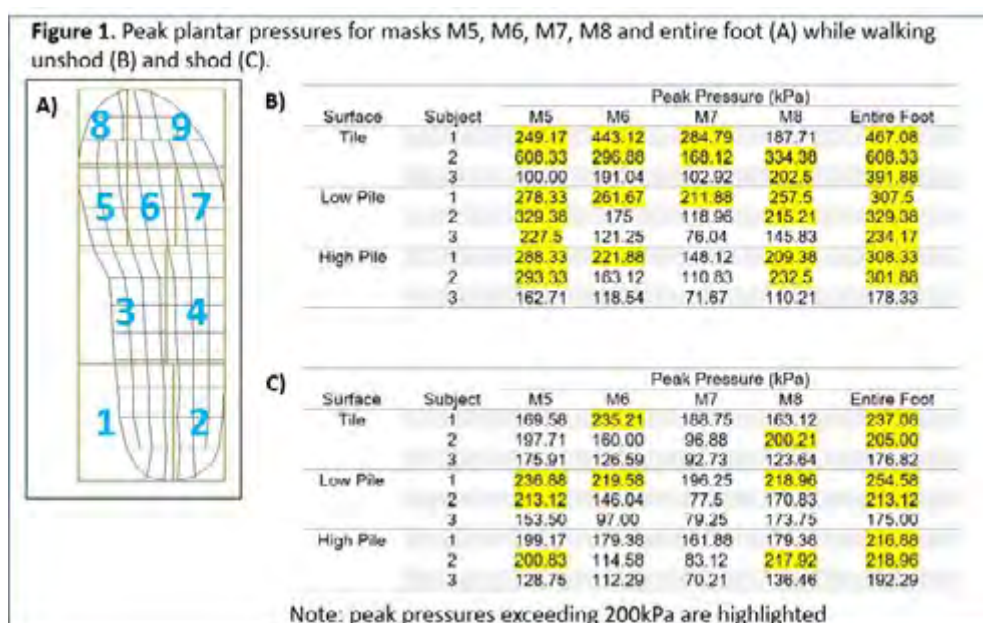


Figure 1. Peak pressures

P01.5-2**A novel offloading device for diabetic foot ulcer reduces plantar peak pressure effectively: a case series***Dr Dirk Hochlenert¹, Ms Mira Mertens¹**¹CID GmbH, Cologne, Germany*

Background: We have standardised the rapid bedside fabrication of a non-removable offloading device by the wound care team[1]. It provides a pressure-optimised support surface (felt) and a stiffened, rocker bottom sole (cast material). This sole is easy to make, is attached to the foot, is reusable and allows access to the ulcer for wound treatment. It is able to offload plantar diabetic foot ulcers (DFU) without limiting steps. It offers many of the features of a total contact cast and is easy to learn. Pedobarography verifies the offloading properties of devices used in the treatment of people with plantar DFU. We used this technique to investigate the effectiveness of the offloading sole at the time of manufacture and after use.

Method: In a prospective case series, all patients with plantar DFU who started treatment with the novel sole between 29/09/2022 and 6/12/2022 were included. We determined the peak pressure by dynamic pedobarographic measurements (Pedar-X System by Novell GmbH, Munich, Germany) immediately after application of the sole, after 1-3 weeks and, if possible, without offloading device after closure of the ulcer.

Results: 9 patients with 10 DFU met the inclusion criteria. In two patients, measurements could not be taken due to technical problems with the pedobarography device. The mean peak pressure at the point of interest (POI) was 47.1 kPa (SD 30.1), at the same point on the opposite foot 148.5 kPa (SD 49.0). At follow-up, the peak pressure at the POI was 47.2 kPa (SD 28.7), at the opposite foot 183.7 kPa (SD 121.8). Wound closure occurred in two patients and the mean pressure at the POI without offloading device was 301.5 kPa (SD 26.2), which corresponded to 100% offloading in one patient and 83.1% offloading in the other.

Conclusion: The FiFi!-mobil sole effectively offloads plantar diabetic foot ulcers 24h / day without limiting steps.

1. Hochlenert, D., FiFi!-mobil® Sole, in DFS-Blog. 2021. <http://cid-direct.de/blog/fifi-sohle/> access date 12.12.2022

P01.5-3

Diabetes foot ulcer healing outcomes and patient adherence comparing ankle and knee-high devices

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Background: Pressure offloading for diabetes-related foot ulcers (DFU) promotes healing, and irremovable knee-high devices, are recommended in guidelines. In practice, it is only a subset of patients who can and will accept wearing them, with a lack of data on the outcomes of other devices. This study aimed to determine what proportion of participants agreed to wear knee-high devices, the level of patient adherence to their use and healing outcomes at 12 weeks.

Method: Data from a recent randomised study of debridement was used, including participants who completed study visits. Inclusion criteria and method are detailed in the original published study (1) including adults with plantar DFU, excluding those with severe ischaemic or infection. Participants from five centres attended weekly for 12 weeks. Clinicians prescribed ankle-high or knee-high devices with a custom or non-moulded insole. Data on device selection, healing outcomes and self-reported adherence to wearing devices were available for reporting. Self-reported adherence was based on participants indicating the average time they spent wearing the device each day.

Results: Ninety-two participants were included, with wearers defined as those who reported wearing the device greater than av.> 6.5 hours/day, and non-wearers defined as those who reported wearing the device for less time than this. Knee-high devices were prescribed to 44 participants (48%), and 77% wore the device >6.5 hours/day. Other participants were prescribed ankle-high devices and 75% wore them av > 6.5 hours/day. Two participants had missing device data. Ulcer size in non-wearers (n=22) was 1.4cm² (median 0.9cm²) and 2.0cm² (median 1.1cm²) in wearers (n=70). Proportion healed by 12 weeks; 58% overall, 57% for the wearers and 59% for the non-wearers, 59% for wearers of the knee-high device and 53% for wearers of the ankle-high device.

Conclusion: These results suggest that in patients with small, plantar ulcers receiving weekly, specialised care, 53-59% will heal within 12 weeks in either ankle or knee-high devices. Poor healing trajectories should be identified early and necessitate optimising all aspects of care, including pressure offloading. The selection of offloading strategy must be based on DFU and patient factors as well as demonstrated efficacy.

NubeVL Diabetes-Care 2021

P01.5-4

The concept of dosing physical activity during foot ulcer remission to prevent recurrence: Early insights from a single center experience

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Background/ Aims: Approximately 40% of patients with diabetes-related foot ulcers (DFUs) will experience ulcer recurrence in the year after healing during a period of DFU remission. Therefore, the aim should be to reduce recurrence yet maintain activity rich days if we are to successfully maintain remission. We discuss a unified strategy developed at the Limb Preservation Consortium at USC and the Rancho Los Amigos National Rehabilitation Center in Los Angeles to treat patients in the DFU remission period with appropriate patient recommendations based on best available evidence and expert opinion.

Methods: Advancements in remote monitoring technologies have seen the development of several approaches to assist in the prevention of recurrence of foot ulcers. Implementation of trial evidence on these areas is slow and lacking. These advancements may assist patients in identifying impending signs of foot deterioration and to seek care promptly to reduce the delays seen in timely care. We present insights on the use of a three-pronged strategy during DFU remission; 1) implement best offloading of high plantar pressure; 2) monitor physical activity and for impending signs of foot ulcer recurrence and 3) dose physical activity using an individualized approach.

Results: Figure 1 (below) demonstrates the proposed algorithm.

Conclusion: Here we report on some recent developments related to the importance of considering gradual return to physical activity in foot ulcer remission. Further research is needed to evaluate this concept further.

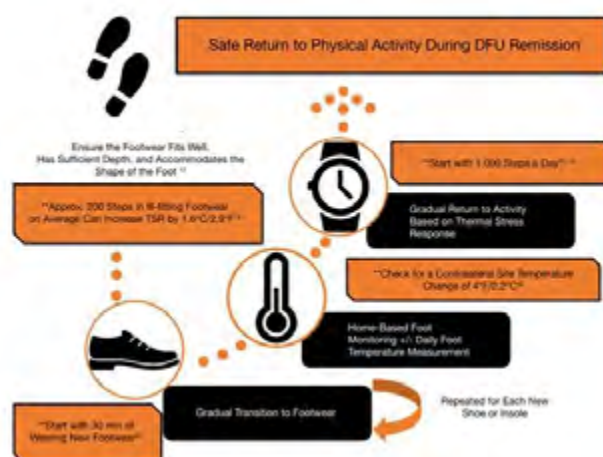


Figure 1: A proposed plan of return to activity during foot ulcer remission

P01.6-1

An exploration of lower extremity amputation before and after covid-19 in an urban tertiary referral centre

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Introduction The COVID-19 pandemic has had an impact on curtailment of ambulatory care services and non-critical hospital services. In areas where multi-disciplinary diabetic foot teams (MDfTs) have been curtailed, the rate of lower extremity amputation (LEA) and poor outcomes have been noted to increase (Casciato et al 2020). In the current study location the MDfT services were not reduced or curtailed throughout the COVID-19 pandemic. Patients who preferred to use telemedicine were encouraged to do so although face-to-face appointments continued as necessary.

Methods The rates of LEAs were collected both in total and secondary to diabetic foot disease were collated for the years 2019, 2020 and 2021 as is standard practice. These were analysed against EHR to identify those occurring subsequent to intervention of the MDfT. The rate of all-cause amputations was also analysed.

Results The rate of both major and minor amputations remained unchanged between the three years. This was true for all cause amputation (table 1) and those related to DM (table 2) Anticipated spike in rate of amputations after the pandemic did not materialise. In 2021 the rate of minor amputations actually reduced.

Type of Amputation	2019	2020	2021
Major	22	27	24
Minor	59	68	56

Table 1 – all cause amputation

Type of Amputation	2019	2020	2021
Major	6	6	6
Minor	42	47	39

Table 2 – DM related amputation

Discussion The MDfT is an effective method of amputation prevention and management of DFD and should be maintained at all times. We note that throughout the pandemic as services were maintained, no increase in the rate of LEA was observed. The anticipated rise in amputations as suggested following the pandemic did not occur in this centre either for those with DM related amputation or for overall amputation rates supporting the need for continuity of service.

P01.6-2

Eastern Health High Risk Foot Service Inaugural Database Audit and Access to Service

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Background In Australia, there are over 27,000 hospital admissions every year for diabetes-related foot disease.¹ Furthermore, diabetic foot complications significantly impact a person's quality of life, and they are a significant burden to morbidity and mortality. Delay in treatment is a risk factor for lower limb amputation and is associated with longer treatment times, increased wound size and worse health outcomes.² How does Eastern Health's (EH) High Risk Foot Service (HRFS) stack up large geographical size and service parameters?

This report marks the first audit (1/9/22 – 19/2/22*) since the establishment and participation in the Australian Diabetes HRFS Database.

Majority of our patients (69%) enter our HRFS via emergency department and are presenting with ulcers that have been present for >28 days.

Methods Australian Diabetes High Risk Foot Service Database.

Results 73 patients with 119 ulcerations within the cohort. 69% of the cohort entered the service via emergency department, with a Wifl score as Moderate or High (58%). SINBAD score of ≥ 3 63% and 67% of the cohort presented with infected wounds.

Conclusions Access to the EH HRFS is via emergency due to barriers such as requiring medical referrals. EH has now implemented an emergency podiatry triage outpatient service to combat patients presenting to emergency. The target is promoting the community health service podiatry referral via this where a EH HRFS podiatrist will review and triage within 24-48 hours of the referral.

Further development of a coordinated diabetes high risk foot unit, including established team goals and service specific KPIs and national benchmarking, is required to meet the National Association of Diabetes Centres (NADC) Collaborative Interdisciplinary Diabetes High Risk Foot Service Standards and improve patient outcomes.

P01.6-3

Werner's Syndrome: A Case Series on a Rare Cause of Complex Foot Pathology

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Aim: To report a case series of three siblings with complex foot disease who have been diagnosed with Werner's syndrome (WS), a rare autosomal recessive progeroid syndrome.

Methods: Three siblings who attend the Complex diabetic foot clinic were consented to partake.

Results: The patients were diagnosed with WS in 2014 by formal genetic studies. They exhibit the classical phenotype with short stature, hoarse voice, scleroderma-like skin, hair and subcutaneous tissue loss and type 2 diabetes. All 3 have developed complex foot problems including longstanding painful peripheral neuropathy and malodorous ulcers significantly impacting their quality of life.

Case 1 is a 45 year old female who initially presented with a fracture to her 5th metatarsal. A 1st MTPJ fusion & ORIF of the 5th metatarsal was performed. Wound breakdown over the metal work and osteomyelitis ensued. She then had a left MTPJ fusion. She developed a post-operative stress fracture at the base of her 5th metatarsal. Treatment was attempted with a boot, a fitted cast, ultrasound therapy, plating, grafting and further surgery. Union was finally achieved in 2018.

She developed an ulcer and subsequent cellulitis of her right 3rd digit. She then developed ulcerations of the right medial hallux and right dorsal third digit. This was debrided and a trans-metatarsal amputation is scheduled.

Case 2 is a 44 year old male who presented with a non-healing ulcer over the left Achilles tendon area approx. 2-3 x 0.5cm. Ulcers on his right 1st metatarsal head, left 1st and 5th metatarsal heads followed. His Achilles tendon ulcer did not respond to antibiotics, hydrofiber, mesh or offloading hydrocolloid dressings or enzymatic debridement.

Case 3 is a 41 year old female who presented with an ulcer under her right 1st MTPJ. She subsequently developed an ulcer of her third right digit which now has bone protruding, followed by an ulcer of her left 5th lateral MTPJ. She has had 3 admissions with recurrent osteomyelitis.

Surgical options aren't felt to be viable for cases 2 and 3 given their comorbidities.

Conclusion: This case series highlights the challenges in treating Werner's syndrome (diabetic) foot disease.

P01.6-4

Decreased Time in Target Glucose Range Rises the Risk of DPN in Chinese Type 1 Diabetes Patients

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Objectives Our study aims to clarify which one, the blood glucose fluctuation or the time percentage in target glucose range, determines the occurrence of diabetic peripheral neuropathy (DPN) among Type 1 diabetes patients.

Methods In this cross-sectional study, a total of 326 Type 1 Diabetes (T1D) inpatients was recruited. All patients were screened for DPN and then divided into two groups, DPN group (n=121) and non-DPN group (n=205). Information regarding BMI, smoking and drinking habits, medical history, glycemic control, insulin function parameters were collected and compared. A 72-hour Continuous Glucose Monitoring System (CGMS) was conducted on each patient, and mean glucose, time percentage in target glucose range (TIR), SD, MAGE was derived from the CGMS reports.

Results Compared with non-DPN group, DPN patients are older, have longer duration, higher BMI, waist circumference, HbA1c, mean blood glucose, but lower TIR ($p < 0.05$). The prevalence of carotid artery plaque, percentage of hypertension, current drinking and smoking were higher in DPN group ($p < 0.05$). Logistic regression analysis revealed that TIR, age, duration, and smoking habit were independent risk factors of DPN, the prevalence of DPN increased steadily with the decreasing of TIR, from 25.6% in Q1 to 55.7% in Q4, and after adjusting for age, disease course, BMI, smoking, hypertension and other confounding factors, TIR was still found to be independent contributors to DPN (OR, 0.62; 95% CI, 0.47-0.83, $p < 0.01$). ROC analysis further demonstrated that the cut-off point of TIR was 47.5%. For indicating the occurrence of DPN in T1DM (AUC=0.6401; 95% CI, 0.578-0.702; $p < 0.001$), and the 5% increase of glucose in range decreased the 11.3% risk of DPN ($p < 0.01$).

Conclusions Except for age, duration, smoking, and hypertension, TIR, but not glycemic variability, is a key risk factor for DPN in T1D population.

P01.6-5

Initiation of GLP-1 receptor agonists at a brief regular diabetic foot clinic visit is feasible and efficient

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Background/Aim: People with diabetic foot ulcers (DFU) have an increased risk of cardiovascular complications and death. High glucose levels drive microvascular complications, and high glucose levels impair ulcer healing. GLP-1 receptor agonists lower glucose levels significantly, and several of these drugs have also been shown to reduce cardiovascular risk in a non-glucose-dependent way. One of these, dulaglutide, is injected subcutaneously once weekly by the patient. The device is self-instructing and easy to use.

This pilot study aimed to elucidate the feasibility and effectiveness of introducing dulaglutide to patients with DFU and impaired metabolic control during brief DFU visit.

Methods: Patients with an HbA1c level >65 mmol/mol and, if an insulin user, a c-peptide level above 0.5 were accessible for GLP-1 receptor agonist treatment if clinically judged so. A physician at the DFU clinic initiated the treatment during a regular visit to the DFU clinic. The initiation was followed by short information emphasizing a high probability of initial adverse effects and long-term benefits.

Results: Twenty-one patients (5 women) with type 2 diabetes aged 68.5 (range 33-79) years, of which nine were insulin users, were prescribed 0.75 mg dulaglutide once weekly. Initial HbA1c was 88 (66-108) mmol/mol with a non-fasting c-peptide level of 1.1 (0.6-3.4) nmol/L.

One patient did not begin with the drug due to economic reasons. None of the remaining 20 patients withdrew from treatment. HbA1c decreased by more than five mmol/mol in 19 patients, and in these, the HbA1c decreased by 14 (6-42) mmol/mol during the follow-up period (6-15 months). In insulin users, the total daily insulin dose decreased from 75 (34-255) to 62 (28-106) units.

Conclusion: It is easy and feasible to initiate treatment with dulaglutide in regular diabetic foot clinics. In patients with preserved c-peptide levels, the HbA1c and insulin dose reduction were clinically relevant.

P01.6-6

The Diabetic Foot in Sudan Overview of Care

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Background The rate of transtibial and transfemoral amputation in diabetics admitted to Khartoum Teaching Hospital, the main referral hospital in Khartoum was between 30 – 40% and the mortality was between 8 to 20% during the ninetieth. Jabir Abu Eliz Diabetic Centre was established in response to this in order to reduce these figures.

Patients and Methods In 1998 a health centre building was allocated for this project as a multidisciplinary out patient including medical, surgical, ophthalmic, dental and all relevant clinics. Four young surgeons and 10 nurses were sent to Kings College Hospital in London Foot Clinic for 4 weeks under the care of the late podiatrist Ali Foster who later visited the Centre several times giving lectures and practical demonstration and we named our main wound care after her. Three wound care rooms were allocated for dirty, infected and clean wound in addition to Foot care clinic and a shoes factory to make a proper foot ware and limb prosthesis.

In order to reduce the inflow of patients from other regions to Khartoum A 3 weeks residential course was formulated and funded by The World Diabetes Foundation (WDF) in Denmark. Seven foot clinics were established in regional cities. Also several peripheral centres in Khartoum were established with 2 weeks course funded by the local Health Insurance office.

Results The total registered number of all diabetic is 90000 and those in the foot section are 19000. In patients regularly reporting to the centre the mortality in the diabetic foot wound is 4.5% and the major limb amputation is 9.8%.

Reflection from one regional centre in Eastern Sudan (ElGadarif) reported reduction of major limb amputation from 22% to 3.5%. Patients reporting to the Foot Clinic regularly every 3 months for prophylactic foot care reported excellent outcome. In a sample of 600 diabetics the rate of foot ulceration was 4% and amputation 3.5% mostly due major limb ischaemia.

Conclusion Diabetic foot is a special entity that needs special care given by dedicated trained staff. Foot care clinic leads to avoidance of inflicting causes and early presentation when it occurs.

P02.1-1

Medical treatment in osteomyelitis due to KPC - A clinical case in diabetic footN DIABETIC FOOT

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Introduction: Although controversial, the usual approach to chronic osteomyelitis in diabetic foot is surgical treatment, especially if associated with midfoot or hindfoot infection or in the presence of multidrug-resistant microorganisms. Successful cases of medical treatment of osteomyelitis due to multidrug-resistant agents, namely carbapenemase-producing *Klebsiella pneumoniae* (KPC), are scarce.

Clinical case: Forty-six-year-old female, diagnosed with type 1 Diabetes Mellitus at age 15. Poor chronic metabolic control (HbA1c 8.9%) and established microvascular complications, namely panphotocoagulated proliferative retinopathy, diabetic kidney disease – stage G2A2, distal peripheral sensory-motor polyneuropathy with bilateral Charcot's foot and history of hallux amputation due to infected neuropathic foot.

History of recurrent antibiotic use and hospitalizations in the last 2 years due to infected neuropathic foot (infections of plantar ulcers). The patient was always very resistant to surgical treatment.

In July 2021, during an evaluation at the Diabetic Foot Clinic (CHUPorto), the patient presented an infected plantar ulcer in the right midfoot, with bone exposure and plantar phlegmon, in need of urgent drainage (PEDIS classification 4). The patient was hospitalized and antibiotic therapy with ceftazidime/avibactam was initiated, due to the identification of KPC only susceptible to gentamicin and ceftazidime/avibactam in the microbiological study of bone collected on admission. Magnetic resonance of the foot showed an extensive process of osteomyelitis involving most of the tarsal bones, namely the talus, calcaneus, medial cuneiform and the 4th and 5th metatarsals, as well as the epiphyses of the leg.

The multidisciplinary team decided on a definitive surgical treatment, which was not carried out due to repeated refusal by the patient. Thus, antibiotic therapy was maintained for 6 weeks, with good evolution. The patient was discharged on the 45th day of hospitalization. Ulcer closure occurred in October 2021, without new recurrence more than a year later.

Conclusion: To the authors' knowledge, this is the first reported case of successful medical treatment of KPC osteomyelitis in the diabetic foot. Infections by multidrug-resistant agents are frequent in individuals with chronic diabetic foot ulcers and surgical treatment remains the first-line treatment in these cases. In this situation, this treatment was not performed due to the patient's refusal.

P02.1-2

Bacterial bioburden characterization of diabetic foot ulcer patients in association with clinical outcomes-an observational study

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Aim The purpose of this study was to analyse the amputation rate of patients who visit our tertiary wound care centre with negative bacterial growth report by conventional tissue culture method.

Materials and Methods: A prospective observational study was conducted among diabetes foot ulcer patients admitted to our tertiary care centre between May 2021 to May 2022.

Results: A total of 721 patients with DFUs with University of Texas Diabetic foot ulcer Classification Grade 2 and 3 ulcers were treated (age group between 20 to 90 yrs), Out of this 531 were male and 190 were female. Deep Tissue Samples were taken during debridement from this 721 patients. Out of this 721 patients whose samples were processed, 501 patients were positive for bacterial growth by Kirby Bauer disc diffusion method and 220 patients were negative for bacterial growth (30.51%) and the commonest isolate was found to be *Pseudomonas aeruginosa* (24.69%) followed by *Escherichia coli* (9.85%) *Enterococcus faecalis* (9.02%) *Acinetobacter baumannii* (8.04%) *Staphylococcus aureus* (6.80%) *Morganella morganii* (4.02%) *Citrobacter koseri* (2.64%) *Klebsiella pneumoniae* (2.91%) *Proteus Spp* (1.53%).

Clinical Outcomes: Total of 220 patients reported negative bacterial growth by conventional technique. In this group we found that 45 patients (20%) underwent amputations (5 major and 40 minor) (82% male and Female 18%).

Conclusion: A negative culture report does not imply a less milder form of infection. As shown in above study a number of these patients with a negative culture report have underwent amputations (20%) and so it would be better to rely on more advanced techniques. Molecular diagnostic techniques 16S rRNA and metagenomic sequencing may provide complete data about bacterial communities which will be valuable to prevent amputation risk and check on rate of amputation. Also, molecular sequencing results may highlight possible associations among certain genera, species, and bacterial functional genes related to clinical outcomes.

P02.1-3

Broad-Spectrum, Potent Activity of Pravibismane Versus Comparators Against Diabetic Foot Ulcer Infection Patient Isolates Collected in a Phase 1b Study

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Background/Aim: Pravibismane is the first drug in a new class of compounds with a novel mechanism of action and potent broad-spectrum anti-infective and anti-biofilm activity. We previously reported safety and efficacy results from a phase 1b clinical study in patients with moderate to severe diabetic foot ulcer infections (DFI). Subjects treated with topical pravibismane (adjunct to standard of care) showed trends towards greater median wound size reduction (85% in pooled pravibismane group vs 30% in placebo group).[1] Herein, we present the antimicrobial susceptibility testing (AST) results from clinical isolates sampled from DFI patients at baseline.

Methods: Wounds were cleaned and debrided prior to specimen collection, which were then processed at a central lab (IHMA, IL) for culture and AST using standard methods.

Results: Pravibismane exhibited lower minimum inhibitory concentration (MIC) relative to a panel of comparator antibiotics against Gram-positive and -negative aerobes and anaerobes. Common pathogens isolated at baseline were: methicillin-susceptible *Staphylococcus aureus* [MSSA (25%)]; methicillin-resistant *Staphylococcus aureus* [MRSA (18.2%)]; *Enterococcus faecalis* (13.6%); and *Pseudomonas aeruginosa* (11.4%). Mean pravibismane MIC (mg/L) for *S. aureus* MSSA was 0.21, *S. aureus* MRSA was 0.17, *E. faecalis* was 2.53, and *P. aeruginosa* was 1.43. Importantly, pravibismane MICs for 12 of the 13 anaerobic bacteria was ≤ 1 mg/L. The data are presented in Table 1.

Conclusion: These data indicate potent broad-spectrum activity of topical pravibismane against clinically-isolated aerobic and anaerobic bacterial pathogens.

References:

[1] Kim, Paul. Presented at the SAWC Fall 2019 Meeting.

Table 1: Mean MICs (mg/L) against select bacterial species sampled from DFI patients at baseline

Baseline organism (n)	Mean MIC (mg/L)	Mean MIC (mg/L) n (% resistant)				
	Pravibismane	Ampicillin	Clindamycin	Ceftriaxone	Levofloxacin	Trimethoprim sulfamethoxazole
Gram- positive aerobic bacteria						
<i>S. aureus</i> (MSSA) (15)	0.21	10.83 0 (0.0)	2.23 2 (13.3)	Not tested	1.5 3 (20.0)	0.13 0 (0.0)
<i>S. aureus</i> (MRSA) (8)	0.17	28 0 (0.0)	10.03 5 (62.5)	Not tested	6.52 7 (87.5)	0.62 1 (12.5)
<i>E. faecalis</i> (18)	2.53	0.97 0 (0.0)	15.56 0 (0.0)	Not tested	2.1 3 (16.7)	4.56 0 (0.0)
Gram- negative aerobic bacteria						
<i>P. aeruginosa</i> (7)	1.43	Not tested	Not tested	29.71 0 (0.0)	0.5 0 (0.0)	7.43 0 (0.0)
Anaerobic bacteria						
<i>Bacteroides thetaiotaomicron</i> (1)	0.25	Not tested	4 0 (0.0)	Not tested	Not tested	Not tested

P02.1-4

Auto-fluorescence Imaging as a Predictor of Contaminated/Infected Diabetic Ulcers' Outcomes

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Aim - To check the efficacy of a auto-fluorescence imaging device (AFI) in providing predictive and quantifiable parameters in the evolution of contaminated/infected diabetic foot ulcers (DFU).

Methods - We studied all consecutive outpatients attending our clinic with a DFU (grade IB-IIB Texas University score), with ABPI ≥ 0.9 and no antibiotic therapy (ATB) May/June 2022 with AFI, before and after surgical debridement and after 3 weeks of ATB, rating the imaging from 1 (100% contamination) to 5 (no contamination), and compared them with Wound Ischemia Foot infection score (WIFI) that goes from 0 to 9 in which 9 is the worse condition and Wound Bed Score (WBS) that goes from 0 to 16 at the improvement of the wound.

Results - We enrolled 20 patients, average age of 64.4 ± 15.1 years, Diabetes duration 15.4 ± 7.3 year, all with type 2 Diabetes, with a ABPI of 0.96 ± 0.1 .

After 3 weeks of ATB the AFI score improved from 2.5 ± 0.7 to 3.9 ± 0.8 ($p < 0.05$), as well as WIFI and WBS [4.1 ± 1.1 vs 2.6 ± 1.1 and 8.2 ± 1.3 vs 11.4 ± 1.9 , respectively ($p < 0.05$)].

Conclusions - Our data, although preliminary, suggest that AFI may predict the evolution of contaminated/infected DFU and help in the decision-making process in their clinical management.

P02.1-5

The long-term impact of “antibiotic stewardship” in diabetic foot infections in two Swiss centers

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Background/Aim: In the last two decades, there have been efforts at various levels of antibiotic stewardship in the treatment of diabetic foot infections (DFI) in Switzerland, including osteomyelitis (DFO). However, we ignore long-term impacts.

Methods: We stratify two large DFI cohorts in Geneva and Balgrist University Hospitals (in Zurich) on DFO and moderate/severe soft tissue infections (ST-DFI), antibiotic-related parameters, and the time periods 2000-2005; 2006-2010; 2011-2015; and 2016-2019. We defined “microbiologic recurrence” as a therapeutic failure involving the same pathogen(s) as in the index episode (excluding new episodes).

Results: Among a total of 1,414 DFI (1,211 DFOs and 603 ST-DFI), the choice of antibiotic drugs did not change substantially. Oral amoxicillin-clavulanate was the most frequent regimen (73%; 66% of all beta-lactams). Overall, the prescriptions for tetracyclines and linezolid were low (5% and 2%, respectively) and higher for cotrimoxazole and clindamycin (40%, 22%). We saw transient excesses of broad-spectrum antibiotic misuse involving carbapenems, piperacillin-tazobactam or antipseudomonal cephalosporins (making up to 40% of all regimens) in the 2011-2015 period in Zürich; and in Geneva during 2000-2005.

There was a clear shortening of the total antibiotic duration. An antibiotic duration of 30 days significantly decreased for both DFO and DT-DFI, respectively (47% to 29% and 44% to 15%, $p < 0.01$). Inversely, the proportions of the 8-15 day group increased from 18% to 25% in Geneva and from 25% to 32% in Zurich, respectively ($p < 0.01$). The very short durations (≤ 7 days) for residual DFO after (partial) amputation phase rose from 18% to 52%, $p < 0.01$. The proportion with a long initial parenteral regimen (> 15 days intravenously) also decreased from 35% to 12%, $p < 0.01$.

Parallely, we did not observe an increase in minor or major amputations or microbiological recurrences with risks of 10%; 8%; 8%; and 7% in the four time periods, $p = 0.35$).

Conclusions: According to two Swiss large specialized centers for DFI with various interventions for antibiotic stewardship in DFI and DFO, we saw a general reduction of the antibiotic use between 2000 and 2019 (with an acceleration since 2010); without a concomitant increase in secondary amputations or infection recurrences.

P02.1-6

Etiological characteristics of diabetes foot with different degrees of renal damage

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Objective To explore the pathogenic distribution characteristics of diabetes foot patients with different degrees of renal damage. Grouped by CKD classification and CKD risk stratification, we compare the difference between the two grouping methods in studying the impact of kidney damage on diabetes feet. **Methods** 368 patients diagnosed as diabetes foot in the Department of Endocrinology of Henan Provincial People's Hospital from December 2017 to May 2021 were included in this study. The patients were divided into groups according to CKD risk stratification and CKD classification. The wound secretions or tissues of patients were collected for pathogenic culture and analyzed. Compare the difference of the results obtained by the two grouping methods. **Results** According to CKD classification, the patients were divided into non chronic kidney disease group, stage 1, stage 2, stage 3, stage 4 and stage 5. The detection rates of bacteria were 44.94%, 44.21%, 44.64%, 48.48%, 60% and 0% respectively. The proportion of gram-positive bacteria was 55%, 54.75%, 56%, 43.75%, 33.33% and 0% respectively. The proportion of gram-negative bacteria was 50%, 52.37%, 52%, 81.25%, 66.67% and 0% respectively. Multiple infections were 5.05%, 11.57%, 8.92%, 15.15%, 20% and 0% respectively. According to CKD risk stratification, the patients were divided into non chronic kidney disease group, low risk group, medium risk group, high risk group, and very high risk group. The detection rates of bacteria were 44.94%, 100%, 42.31%, 42.37% and 50% respectively. The proportion of gram-positive bacteria was 55%, 0%, 61.36%, 52% and 30.76% respectively. The proportion of gram-negative bacteria was 50%, 1, 50%, 56% and 84.61% respectively. Multiple infections were 5.05%, 100%, 11.54%, 8.47% and 15.38% respectively. **Conclusions** The two grouping methods showed that with the aggravation of kidney damage, there was no significant difference in the detection rate of bacteria, the risk of multiple bacterial infections increased, the proportion of gram-negative bacteria increased, and the proportion of gram-positive bacteria decreased. Only 1 patient in both phase 5 group and low risk group resulted in too small sample size, which may affect the results.

P02.2-1

Clinical antibiotics resistance analysis of 241 strains of *Acinetobacter baumannii* from diabetic foot wound

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Aim: With the increase of *Acinetobacter baumannii* (AB) in diabetic foot ulcer (DFU), most of them are drug resistant. We investigated the different antibiotics resistance forms and clinical characteristics of AB.

Methods: culture results were from deep wound tissue of inpatients with DFU for 2 years (January 2020 to December 2021). Antibiotic resistance was analyzed, and its influence on prognosis was followed up.

Results: A total of 1451 strains of bacteria were cultured from 749 patients with DFU, and 241 AB were cultured from 171 patients. AB accounted for 16.61%, accounting for the first in Gram-negative bacteria. Carbapenem resistant AB (CRAB) had 200 strains (82.99%), among which, 191 strains (79.25%) were Multi-drug resistant AB (MDRAB) (resistance ≥ 3 categories), among which 85 strains (35.27%) were XDRAB (only sensitive to colistin and/or tigacycline). The resistance rate of colistin was 0, tigacycline 1.66%, minocycline 11.73%, sulfamethoxazole (SMZ) 31.54%, amtrannan 39.8%, cefoperazone sulbactam 55.61% and cefepime 55.6%. Others resistant rates above 65%. In the case of CRAB, penicillins, second and third generation cephalosporins and cephalomycin were almost resistance, but cefoperazone/sulbactam (36.25%) and cefepime (39.38%) were sensitive or intermediate and could be used. Although the resistant rate of amtrannan was low, there was no sensitive, all intermediate. Minocycline resistant rate was low, oral is convenient and effective. Tigecycline and colistin were not commonly used due to side effects. Electron microscopy showed CRAB would produce biofilm and aggravate antibiotic resistance. However, CRAB generally did not cause severe infection or elevated amputation, but delayed wound healing. Timely debridement combined with cefoperazone/sulbactam with minocycline or aminoglycoside could speed up wound healing.

Conclusions: Most AB in DFU are CRAB, even MDRAB to XMDRAB, easy to form biofilm. But the mortality does not increase. Debridement combined with a variety of sensitive antibiotics can accelerate healing.

P02.2-2

Systematic intraoperative bone sampling increases healing chances in diabetic foot osteomyelitis

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Aim - We aimed to evaluate if a proactive multidisciplinary diagnostic program could improve outcomes in the management of multidrug resistant (MDR) diabetic foot (DF) osteomyelitis (OM).

Methods -We evaluated all the consecutive patients undergoing to minor amputation for OM July-December 2021 in our department (Group A). Intraoperative bone specimens were collected for microbiological and histological analysis on whose results antibacterial therapy was decided. Controls were patients admitted January-June 2021 with same indications (Group B) but with no systematic intraoperative bone sampling. Clinical and demographic characteristics, procedures, healing rate (HR) and healing time (HT), were compared between the groups.

Results - We derived data from 89 patients: 46 in Group A [51.7%; age 68.8±13.5 yrs; diabetes duration (DD) 19.6±11.6 yrs HbA1c 8.7±4.8%;] and 43 in Group B (48.3%; age 70.4±12.9 yrs; DD 18.8±12.1 yrs; HbA1c 8.4±5.1%). No differences in demographic and clinical features, i.e. renal failure (39.1% vs 37.2%, p=ns), ischemic cardiac disease (41.3% vs 39.5%, p=ns), peripheral arterial disease (65.2% vs 67.4%, p=ns) and peripheral revascularizations (56.5% vs 53.4%, p=ns). Group A had a higher healing rate (80.4% vs 60.4%, p=0.0021) and a shorter healing time (67±41 days vs 134±92 days, p=0.020) compared to Group B.

Conclusions – Systematic intraoperative bone sampling for culture and histology, and consequent antibiotic adaptation, increases healing rates and reduces healing times in DF patients submitted to minor amputations for OM.

P02.2-3

Take It Easy: Swab Samplings Superimposable to Intraoperative Bone Specimens in Diabetic Foot Osteomyelitis

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Aim - We aimed to evaluate if swab sampling was trustable and comparable to bone specimen in multidrug resistant (MDR) diabetic foot (DF) osteomyelitis (OM).

Methods - We prospectively evaluated all the consecutive patients undergoing to bone resection in operatory room for OM between July and December 2021 in our Department. From all patients deep swab sampling was collected immediately before the surgery according to guidelines procedures (SS) and intraoperative bone specimens were collected for microbiological analysis (BS). Results were compared, searching for the prevalence of *Staphylococcus aureus* (SA), *Pseudomonas aeruginosa* (PA) and *Enterobacteriaceae* (EB), sorting out Methicillin-Resistant SA (MRSA), PA resistant to Ciprofloxacin (CiproRPA) and Carbapenem (CRPA), EB resistant to Ciprofloxacin (CiproRE) or Extended Spectrum Beta Lactamase producers (ESBL).

Results - We derived data from 46 patients underwent to surgical procedures: SA was detected in 29 patients in SS (63.0%) and 31 in BS (67.4% - p=ns), PA in 21 patients in SS (45.6%) and 22 in BS (47.8%, p=ns) and EB in 25 patients in SS (54.3%) and 26 in BS (56.5% - p=ns). No difference was detected also in microbial susceptibility comparing swab and bone specimens particularly regarding: MRSA (55.1% vs 54.8%, p=ns), CiproRPA (47.6% vs 45.4%, p=ns), CRPA (28.5% vs 31.8%, p=ns), CiproRE (44.0% vs 42.3%, p=ns), and ESBL (56.0% vs 53.8%, p=ns).

Conclusions - When correctly performed, swab sampling is able to detect bacterial strains and susceptibility with results superimposable to intraoperative bone specimens.

P02.2-4

Update of Biomarkers to Diagnose Diabetic Foot Osteomyelitis: A Meta-Analysis

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Aim: This systematic review's aim was to investigate the diagnostic value of biomarkers for diabetic foot osteomyelitis.

Method: We searched relevant literature in November 2022 across PubMed, Scopus, Embase, and Medline for studies who report serological markers and diabetic foot osteomyelitis. Studies must include at least one of the following diagnostic parameters for biomarkers: area under the curve (AUC), sensitivities, specificities, positive predictive value (PPV), negative predictive value (NPV), positive likelihood ratio (PLR) or negative likelihood ratio (NLR). One author then extracted article information for analysis, including authors, publication date, number of subjects, number of subjects with osteomyelitis, osteomyelitis reference criteria, biomarker sensitivity, specificity, positive predictive value, negative predictive value, and area under the curve (AUC). This information was then reviewed and verified by a second reviewer. We then completed a quality assessment by 3 authors using the Quality Assessment of Diagnostic Accuracy Studies tool.

Results: A total of 19 studies were reviewed. PPV and NPV were assessed and ranged from 47-97.8 and 30.5-100 respectively. AUC was reported and ranged from 0.46-0.96. The most common seromarkers were ESR, CRP and PCT (Figure 1). We incorporated them into Forrest and ROC plots. ESR sensitivity and specificity ranged from 0.70-0.96 and 0.5-0.91, respectively. CRP sensitivity and specificity ranged 0.55-0.83 and 0.49-0.83. PCT data was only available for sensitivity and was found to range from 0.79-1.0.

Conclusion: This study suggests biological seromarkers may be valuable in the diagnosis of diabetic foot osteomyelitis.

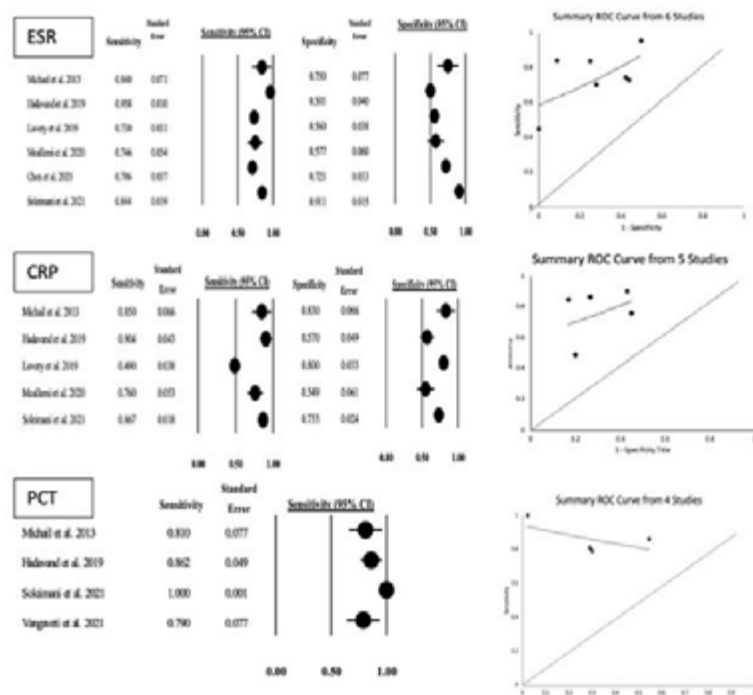


Figure 1: Forrest plot and Receiver Operating Curve for ESR, CRP and PCT

P02.3-1

Lower Limb Sarcopenia on Magnetic Resonance Imaging in patients with Diabetes – a Systematic Review

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Introduction: Sarcopenia is defined by low measures of muscle quantity/quality, muscle strength and physical performance and is associated with frailty and mortality. Individuals with diabetes mellitus (DM) undergo sarcopenia at accelerated rates causing structural changes culminating in limb loss. Early, accurate detection may be of prognostic value.

Aims: To systematically review the available literature on MRI and sarcopenia in lower limbs (LL) in DM.

Methods: A literature review was conducted in accordance with PRISMA guidelines. Embase and Medline databases were searched with Ovid interface, as well as Pubmed and Cochrane. The MeSH terms “sarcopenia” OR “sarcopaenia” AND “diabetes mellitus” AND “magnetic resonance imaging” were employed in the search string. Articles were reviewed by two independent reviewers.

Results: 660 studies were screened initially. 9 studies were included in the study assessing the muscle atrophy component of sarcopenia in the lower limbs of DM patients. There is evidence of early sarco- penic changes in the LL on MRI in patients with diabetic polyneuropathy. There is good inter- and intra rater-reliability.

Conclusion: MRI has merit in assessing skeletal muscle volume and fat infiltration of muscle and is able to detect prior to the onset of symptoms such as diabetic neuropathy. Further research is needed to evaluate its role in grading/risk stratification of patients with diabetes and the evolution of sarcopenia in the context of peripheral arterial disease.

Table of systematic review results

STUDY	YEAR	LOCATION	NUMBER OF PATIENTS	STUDY DESIGN	MEDIAN AGE/RANGE	MRI RATIO	MUSCLES REVIEWED	FINDINGS
ANDERSEN ET AL	1997	Denmark	---	Care Control	32	NOS	Ankle dors and plantar flexors knee extensors and flexors *	FAT cross sectional area reduced in DPN (p<0.001). Muscle volume reduced by 33% (p<0.001), 43% Atrophy mid lower leg (p<0.002) and 67% distally (p<0.002)
JUD ET AL	2002	USA	---	Case Control	16	32/04	Intrinsic foot muscles**	Volume significantly reduced in patients with DPN (p<0.001)
ANDERSEN ET AL	2004	Denmark	---	Case Control	46	32/14	Intrinsic foot muscles**	Volume reduced by 28% in DPN (p<0.001) Interspers most affected
GREENMAN ET AL	2005	USA	---	Case Control	31	22/09	Foot Muscles NOS	Small muscle atrophy present before clinical manifestation of DPN (p<0.001)
ANDREASSEN ET AL	2009	Denmark	36 (T1DM)	Cross sectional	55-81	36/08	Ankle dors and plantar flexors knee extensors and flexors *	Annual loss of muscle volume loss higher in DPN > Non DPN > Control (p<0.001). Average 10% muscle volume loss annually in DM patients (p<0.001)
ALIZAI ET AL	2012	USA	62 (26 with DM)	Case Control	---	62/01	Lower Limb Compartments***	Correlation between clinical grading and fat fraction values (p<0.0001) Higher Dualphase grades (p<0.001) than non DM. Intra and inter-rater correlation 0.85 and 0.83 ICC >0.95. No differences in the reliability values between the two groups using different MRI sequences
CHEUY ET AL	2013	USA	19 (12 with DM)	Case Control	53-57	58/10/0	Forefoot, Midfoot, Hindfoot NOS	
FRITCHARD ET AL	2015	Canada	59 (29 with DM)	Trans sectional	70	58/01	Soleus, Gastrocnemius	MMT higher in DM (p= .002) but reduced to 37% vs 53 in non-DM when adjusted for confounding factors (p= 0.515). ICC 0.99 for intra-MMT 0.98 for inter-MMT
MOURI ET AL	2016	Canada	17 (5 with DPN)	Case Control	65	5/04	Tibialis Anterior	Lower MTR and proportion of contractile tissue 28% lower. Longer T2 relaxation time. (p<0.05)

P02.3-2

Ten kilohertz spinal cord stimulation can improve foot sensory function in patients with painful diabetic neuropathy

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Background/Aim: In a large randomized controlled trial, sensory function was assessed in patients with painful diabetic neuropathy in response to 10 kHz spinal cord stimulation and conventional medical management (10kHzSCS, n=87) or conventional medical management alone (CMM, n=91)¹. Sensory function, and in particular protective sensation of the feet, is critically important in preventing ulceration and amputation².

Methods: Neurologists trained investigators to perform neurological examinations based on American Diabetes Association (ADA) Standards of Care³ on all subjects at baseline, 3-month, and 6-month visits. Sensory function was assessed by guided subject response to a 10g monofilament at 4 locations on each foot. Each response was categorized by the subject as either "Absent" or "Non-Absent". The lowest ADA category of risk includes patients who have no absent sensory responses, whereas any absent sensory response increases the risk category⁴.

Results: At baseline, 21.8% of 10kHzSCS and 17.6% of CMM patients had no absent sensory responses and may belong in the lowest risk category. At the 3-month visit, 40.2% of 10kHzSCS and 18.7% of CMM patients had no absent sensory responses ($p < .001$), and at the 6-month visit, 40.2% of 10kHzSCS and 14.3% of CMM patients had no absent sensory responses ($p < .001$, Figure 1).

Conclusion: The observed disease modification from 10kHzSCS merits further research. Patients in the 10kHzSCS group nearly doubled their likelihood to have no absent sensory responses at 3- and 6-month visits compared to baseline.

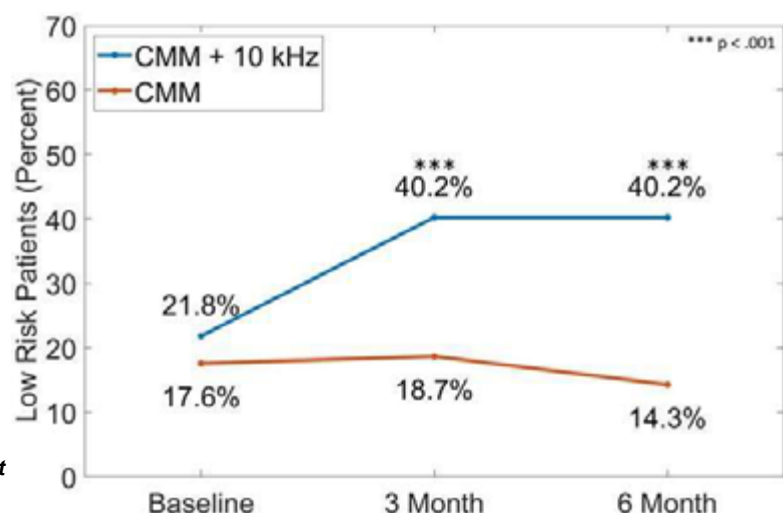
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²Margolis, Wound Repair Regen. 2013;21(1):17–24.

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⁴Boulton, Diabetes Care 2008;88:1679–1685.

Funding provided by Nevro Corp.



Patients receiving 10 kHz SCS were significantly more likely to have no absent sensory responses.

P02.3-3

Peripheral nerve entrapment is associated with an increase in neuropathy symptoms in patients with diabetes.

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Background: Earlier studies provide evidence for the role of superimposed entrapment neuropathy in diabetes-related neuropathy. The aim of this study is to further validate these findings in a large group of diabetic subjects with neuropathic complaints.

Methods: Patients eligible for inclusion were diabetic subjects with an age >17 years and complaints of the feet. Data on demographics, comorbidities, the Michigan Neuropathy Screening Instrument (MNSI) score, protective sensation (10 g monofilament) and palpable arteries were collected. Tarsal tunnel syndrome (TTS) was defined as a positive Tinel sign at the tarsal tunnel and a neuropathic symptom.

Results: 792 patients (67.7% male, 77.3% type 2 diabetes) were included with a mean age of 65 years (95%CI: 64-65), a mean BMI of 28.8 kg/m² (95%CI: 28.5-29.2) and a mean duration of diabetes of 19.4 years (95%CI: 18.5-20.3). 95.6% of participants had a MNSI score >3, indicating peripheral neuropathy, which was significantly associated with a positive Tinel sign ($p < 0.01$).

TTS was found in 459 (58.0%) patients. Patients with an unilateral (10.4%) or bilateral (47.6%) positive Tinel sign reported significantly more frequently signs of neuropathy versus patients without a positive tinel, with an observed clinically meaningful difference (≥ 5 percent) of 0.4 and 0.6 point on the neuropathic subscale for the Tinel-positive subjects, respectively (Table 1). Also, a positive Tinel sign was significantly associated with palpable arteries and intact protective sensation ($p < 0.01$).

Conclusion: Superimposed TTS was found in more than half of diabetic patients, resulting in more neuropathic complaints compared to patients with diabetic neuropathy alone.

Table 1: Complaints of Neuropathy in Diabetic Tinel-Negative and Tinel-Positive Subjects Assessed with the Michigan Neuropathy Screening Instrument

	Group 1: Tinel- negative	Group 2: Tinel- Positive unilateral	Group 3: Tinel- Positive bilateral	P value
No. of patients	333 (42.0)	82 (10.4)	377 (47.6)	
Neuropathic symptoms, N (%)				
1. Are your legs and/or feet numb?	235 (70.1)	73 (89.0)	319 (84.6)	0.03*
2. Do you ever have any burning pain in your legs and/or feet?	223 (66.8)	60 (73.2)	296 (78.5)	0.00*
3. Are your feet too sensitive to touch?	128 (38.2)	34 (41.5)	203 (53.8)	0.00*
5. Do you ever have any prickling feelings in your legs or feet?	239 (71.5)	69 (84.1)	329 (87.3)	0.00*
6. Does it hurt when the bedcovers touch your skin?	80 (23.9)	27 (32.9)	128 (34.0)	0.01*
Mean subscore \pm SD	2.8 \pm 1.2	3.2 \pm 1.2	3.4 \pm 1.2	0.00*
Nonneuropathic symptoms, N (%)				
4. Do you get muscle cramps in your legs and/or feet?	241 (71.9)	66 (80.5)	283 (75.1)	0.25*
7. When you get into the bath or shower, are you able to tell the hot water from the cold water?	93 (27.8)	25 (30.5)	89 (23.6)	0.24*
8. Have you ever had an open sore on your foot?	23 (6.9)	12 (14.6)	24 (6.4)	0.03*
9. Has your doctor ever told you that you have diabetic neuropathy?	226 (67.7)	64 (78.0)	268 (71.1)	0.00*
10. Do you feel weak all over most of the time?	113 (33.7)	28 (34.1)	123 (32.6)	0.94*
11. Are your symptoms worse at night?	128 (38.3)	48 (58.3)	212 (56.2)	0.00*
12. Do your legs hurt when you walk?	146 (43.8)	41 (50.0)	184 (48.2)	0.35*
13. Are you able to sense your feet when you walk?	80 (23.9)	18 (22.0)	38 (10.1)	0.02*
14. Is the skin on your feet so dry that it cracks open?	92 (27.7)	29 (35.4)	130 (34.5)	0.12*
15. Have you ever had an amputation?	241 (71.9)	66 (80.5)	283 (75.1)	0.02*
Mean subscore \pm SD	4.1 \pm 1.8	4.8 \pm 1.8	4.3 \pm 1.8	0.04*
Total MNSI score \pm SD	6.9 \pm 2.5	8.0 \pm 2.5	7.7 \pm 2.4	0.00*

Scores of question 7 and 13 are reversed so that negative responses indicated an abnormality and counted as 1 point in the sum score.
*analyses done using Pearson Chi-square test; analysis done using one-way ANOVA; significant between groups 1 vs. 2, 1 vs. 3 and not between groups 2 vs. 3; * analysis done using one-way ANOVA; significant between groups 1 vs. 2, 2 vs. 3 and not between groups 1 vs. 3

P02.3-4

10 kHz spinal cord stimulation provides durable pain relief and improved sensory function for patients with painful diabetic neuropathy

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Background: Approximately 537 million adults have diabetes worldwide [1], with ~25% experiencing painful diabetic neuropathy (PDN) [2]. The objective of this study was to evaluate high-frequency (10 kHz) spinal cord stimulation (SCS) for the treatment of PDN.

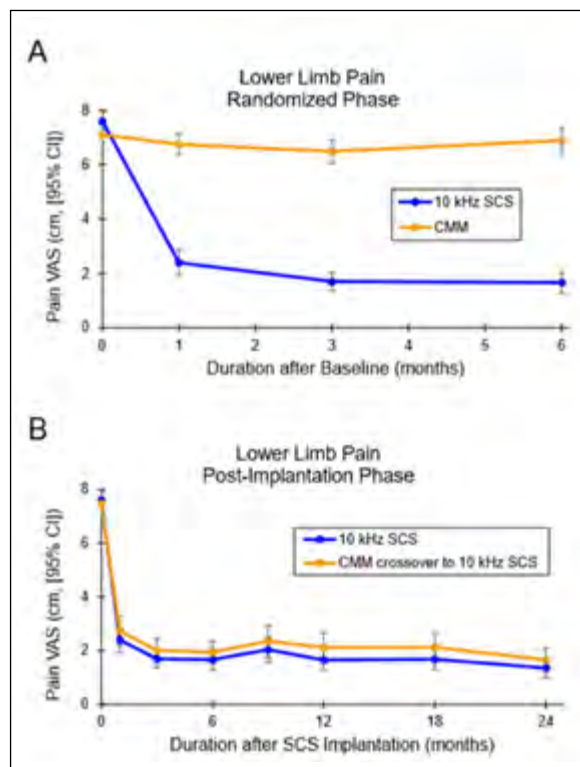
Methods: This RCT evaluated 10 kHz SCS in patients with PDN symptoms refractory to medications ≥12 months (12M). Patients (n=216) were randomized 1:1 to 10 kHz SCS plus conventional medical management (CMM) or CMM alone, with optional crossover at 6M.

Results: At 6M, patients randomized to 10 kHz SCS and CMM alone experienced average pain relief of 76% and average pain increase of 2%, respectively (Fig. 1). After 6M, 93% of eligible CMM patients crossed over to 10 kHz SCS, while no 10 kHz SCS patients crossed over to CMM. At 24M, 10 kHz SCS provided durable pain relief, averaging 80% relief. At 6M, clinician-assessed sensory improvements were observed in 59% and 9% of patients in the 10 kHz SCS and CMM arms, respectively. At 24M, 10 kHz SCS provided durable sensory improvements, with 65% of patients experiencing improvement. Of the 154 patients who received an implant, there were eight (5.2%) study-related infections (5 (3.2%) required explant), which is within the range for SCS across patient populations (2.5-10%) [3]. There were no explants due to loss of efficacy.

Conclusions: The results demonstrate that 10 kHz SCS provides safe, durable pain relief for PDN patients. Sensory function improvements highlight the disease-modifying potential of 10 kHz SCS.

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Lower Limb Pain: 10 kHz SCS provides marked, durable reductions in pain through 24 months. (A) Lower limb pain intensity (10 cm VAS) during the 6-month randomized phase (subjects received 10 kHz SCS + CMM or CMM alone). (B) Lower limb pain during the 24-month post-implantation phase. For CMM arm subjects who opted to cross over to 10 kHz SCS, (B) includes only the post-implantation phase after crossover. Data are presented for complete case cohorts at each time point, with SCS data only for subjects who received a permanent implant (10 kHz SCS: n=90, 88, and 84 at 0M, 6M, and 24M, respectively; CMM alone (in A): n=103 and 95 at 0M and 6M, respectively; CMM-to-SCS crossover (in B): n=64, 59, and 58 at 0M, 6M, and 24M, respectively).



P02.3-5

Study Protocol For Neuromuscular Electrical Stimulation For The Treatment Of Diabetic Neuropathy: A Multi-centre, Double-blind, Pilot, Randomised, Sham-controlled Trial

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Background and Aim: Diabetic neuropathy (DN) has a lifetime prevalence of over 50% among people with diabetes [1]. Lower limb symptoms range from numbness to unsteadiness and pain. Sequelae include foot ulceration and Charcot neuroarthropathy, which are risk factors for amputation and mortality [2]. Neuromuscular electrical stimulation (NMES) is a potential non-invasive, nonpharmacological adjuvant treatment for DN. By depolarising neurons and evoking muscle contraction it may improve peripheral nerve conductivity. The aim is to assess the potential efficacy signal, feasibility and safety of a NMES device as an adjunct to standard of care in people with DN.

Methods: This is a multi-centre, double-blind, pilot, randomised, sham-controlled trial for adults with DN randomised to either best medical therapy (BMT) and a sham device (control group) or BMT and a NMES device (intervention group). A positive nerve conduction study (NCS) and a Michigan Neuropathy Screening Instrument score of ≥ 4 will confirm DN. The primary outcome measure is sural nerve conductivity measured using a NCS at 6 months. This includes conduction velocity (m/s) and sensory nerve action potential (SNAP) amplitude (μV). Patient and public involvement work informed the methods.

Results: The target sample size is 100 participants (50 per group). As research in this area is limited and the treatment effect is unclear, a sample size could not be determined using a power calculation. The difference in change in sural nerve conductivity, between the two treatment groups at baseline, 6 months and 9 months will be analysed using Analysis of Covariance (ANCOVA) models. As there are two sural nerve conduction parameters of interest (two primaries), conduction velocity and SNAP amplitude, separate ANCOVA models for each parameter will be performed and a Bonferroni-Holm step down procedure will control for type I error.

Conclusions: The trial is ongoing, and it will serve as the foundation for future powered, randomised controlled trials investigating NMES in DN.

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P02.3-6

First ever ulcer onset in a diabetic population with loss of protective sensation- is pain perception the game changer?

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Aim: Ulcer risk for neuropathic patients without a history of a first ever ulcer (FEU) is according to IWGDF ulcer risk stratification 2019 low to moderate but incidence is so far unknown. The aim of this study was to evaluate FEU onset and to estimate the time to FEU in a diabetic population with loss of protective sensation (LOPS) and preserved or loss of protective pain (LOPP).

Method: Newly presenting diabetic patients with LOPS in the regular foot check and no history of an ulcer were included between January 2017 and September 2018. LOPS was diagnosed by vibration perception <4/8 (tuning fork), pain perception by a 512 mN pin prick simulator. Baseline parameters and pedal pulse palpability, foot deformity, comorbidities and IWGDF ulcer risk stratification were recorded. Patients were followed up by routine foot checks, phone interview or by letter until occurrence of a first ulcer, death or the end of observation period.

Hazard ratio (HR) of an FEU in patients with compared to those without LOPP was estimated using Cox regression, adjusted for age and sex. Survival functions were compared by logrank test. Time to first ulcer was estimated in the framework of an accelerated failure time (AFT) model.

Results: 130 Patients were followed up for a median of 48.3 month (Range 2.4-62.8 month). 15 patients died (12 without an ulcer). FEU occurred in 24 patients, 106 remained ulcer free. Pain perception was lost in at least one foot in 72 of 130 patients. Eighteen patients with LOPP developed a FEU (25%) as well as 6 (10%) in those with no LOPP. Adjusted HR for FEU was 3.0 (95%-KI [1.23, 7.6]). Logrank test for comparison of Kaplan-Meier curves in pain perception strata resulted in a p-value of 0.02. Estimated median time to FEU was 80 versus 158 months, respectively.

Conclusion: Hazard ratio for FEU was three times as high and estimated time to FEU was almost half as long in patients with LOPP compared to those without. LOPP should be implemented into the IWGDF risk stratification because of its high predictive value for a first ever ulcer.

P02.3-7

Microvascular dysfunction and the IWGDF diabetic foot risk classification

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Background/Aim The IWGDF diabetic foot risk classification is mainly based on the presence of sensory neuropathy (grade 1) ± associated with arterial disease and/or deformity (grade 2). However, the risk to develop an ulcer appears to be much higher in patients with a history of diabetic foot ulcer (grade 3)(1). Other microvascular components contribute to the risk of ulcer. The aim of this study was to assess microvascular function according to the diabetic foot risk classification.

Method A total of 172 type 2 diabetic patients with neuropathy (grade 1/2) or a history of foot (grade 3) ulcer were included. They underwent a neurological assessment (thermal sensitivity, vibration perception threshold, neuropathy symptom score, neuropathy disability score), a vascular assessment (skin microcirculatory reactivity to acetylcholine, heating and pressure, TcPO₂) and plantar sudomotor function assessment by Sudoscan. Statistical analysis were performed to compare these different parameters between Grade 1/2 group and Grade 3 group.

Results Most of the patients were male (74%), aged 68.3±8.4 years (mean±SD). There was no difference between the two groups in term of age, diabetes duration, TcPO₂ level, skin microcirculatory reactivity, NDS, NSS and thermal sensitivity. Retinopathy was more frequent in Grade 3 group compare to Grade 1/2 group (69 vs 39%, p=0.005, OR=3.359). Grade 3 compare to Grade1/2 group had more frequently a sudomotor dysfunction (63 vs 37%, p=0.002, OR=4.031) and less frequently an impairment of vibration perception threshold (76 vs 93%, p=0.01, OR=0.109).

Conclusion This study shows a more pronounced alteration of the sudomotor function in Grade 3, which may contribute to the increased risk of ulcer observed in this group. The measurement of sudomotor function by Sudoscan and the integration of the presence of retinopathy could be useful in clinical practice to better assess the risk of diabetic foot ulcer.

P02.4-1

Concordance between culture, MolecularCulture and Illumina 16S-rRNA-gene-amplicon sequencing of bone and ulcer bed biopsies in people with diabetic foot osteomyelitis.

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Background: In clinical practice the diagnosis of diabetic foot osteomyelitis (DFO) relies on cultures of bone or ulcer bed (UB) biopsies, of which bone biopsies are the reference standard. The slow growth or fastidious nature of some bacteria hampers expeditious detection and identification. Rapid molecular techniques may solve both issues, but their additional value for everyday practice is unknown.

We investigated the concordance between conventional culture, the Molecular Culture (MC) technique and Illumina 16S rRNA gene amplicon (16S) sequencing in people with DFO.

Methods: In the BeBoP trial, bone and UB biopsies were obtained from people with DFO who visited Amsterdam UMC. These biopsies were analysed using 1) conventional culturing, 2) MC, a rapid broad range PCR analysing the 16S-23S ribosomal-interspace-region and 3) 16S sequencing. Concordance among these techniques was evaluated.

Results: We analysed 20 samples (11 bone and 9 UB) of 18 people. A total of 84 species were identified, 45 (53.6%) by all techniques, an additional 22 (26.2%) by both MC and 16S (MC and 16S have an overall concordance of 79.8% %), and the remaining 16 species by culture and MC or 16S, or by a single method only. MC and 16S identified anaerobes not detected by culturing in 5 samples, and the presence of bacteria in 7 of 8 culture-negative (6 bone, 2 UB) samples.

Conclusion: The high level of concordance between MC and 16S and the additional ability of molecular techniques to detect various bacteria not detected by culturing opens up prospects for routine use of fast molecular techniques, in clinical settings including DFO.

P02.4-2

New approaches in treatment of diabetic foot osteomyelitis: surgery vs antibiotic therapy

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Diabetic foot osteomyelitis (DFO) is a consequence of the spread of microbes from the ulcer to the underlying bone structures. The diagnosis of DFO does not currently have a consensus definition¹.

Aim of study: Our main objective was to find the best approach in the treatment of DFO, the shortest treated time and with the least recurrences.

Materials and method: This is a prospective study with homogenous cohort. All DF patients presented in the REHA Albania clinic from January 2019 to May 2022. There were studied 131 patients with diabetic foot and 61 of them had DFO. All the patients were evaluated for the glycemic control, risk factors like neuropathy or peripheral arterial disease. Tissue samples were collected from all patients diagnosed with DFO.

Results: Out of 131 patients enrolled aged from 43 to 92 with a mean age of 63,5. Mean diabetes duration was 11.3 years. We isolated a total of 30 strains. Among them 10 were the most alert pathogens identified (Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Enterococcus faecalis, Staphylococcus spp, Proteus vulgaris, Proteus mirabilis, Streptococcus b-haemoliticus, Klebsiella pneumoniae, Acinobacter baumannii). In the histological examination 58/61 patients (95%) resulted positive for osteomyelitis (presented acute inflammation, micro-abscesses, necrosis of trabeculae). In 3/52 patients (5%) resulted in absence of osteomyelitis (presence of fibro productive process without infection). There were no cases of amputation. In 70% of the patients resection of the infected bone (sequestrectomy) was performed and were also treated with antibiotic therapy mostly systemic. 30% of the patients were treated only with antibiotics (topical and systemic) according to the result of the samples. 34 patients presented complete healing of the wound with a mean healing time of 54 ± 28 days. Antibiotic therapy was given orally for a mean duration of 22 ± 9 days. The patients who had sequestrectomy performed healing time was shorter. No relapse of wounds or osteomyelitis was observed at the site of previous lesions in the follow up of 6 months.

Conclusion: Resection of the infected bone resulted more efficient treatment of DFO, compared to only antibiotic treatment.

P02.4-3

Severe Diabetic Foot Disease Devastating Onset Among Elderly Patients

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Background and Aim: Performance of plausibility of severe diabetic foot disease in combination of acute respiratory tract infection rapidly progressing into respiratory insufficiency.

Methods: During the period of time September-October 2022, 37 patients were hospitalized between ages 68-87 y. o., 25 female, 12 male. All suffered sub-compensated T2 Diabetes Mellitus mostly insulin demanding. Neither critical ischaemia, nor osteomyelitis revealed. Patients selected suffered from co-morbidities like chronic coronary artery disease with medical history of myocardial infarction with/without revascularization of coronary arteries. All of them developed sudden random severe diabetic foot infection including necrotizing fasciitis during first 2-3 days and rapidly ascending soft tissue bacterial gangrene of 1-2-3 toes of one foot. Acute respiratory tract infection parallel was common for all of them. These patients rapidly developed different stages of acute respiratory distress syndrome (ARDS) (32) and/or bilateral pneumonia (28) with/without hydrothorax (12) with desaturation. Symptom-complex was developed on the background of seasonal flu or cold. Generalization of multiorgan disorders including sepsis specific symptoms, like ARDS, microvascular changes, high CRP, D-dimer, procalcitonin levels, extremely high leukocytosis and abrupt left shift in leukoformula were due to both severe respiratory and foot disease mutual aggravation.

Results: Multidisciplinary approached intensive therapy started including adequate oxygenization, thromboembolism prevention, three component rational antibacterial and infusion therapy started. The patients were negative for COVID-19. Severe intoxication syndrome and high temperature registered for all the patients 37, 3-38, 3 C.

Treatment included early minor amputations of the affected toes, meticulous repetitive necrectomies. and aggressive local treatment including negative pressure, ozonoe therapy. All the patients survived after prolonged hospitalization 10-60 days.

Conclusions: Classically, diabetic foot infections progress much slower if without debut of respiratory infections. As a novel tune of diabetic foot disease in elderly diabetic patients, flu may sound as a possible dramatic trigger for development of unexpectedly severe immunosuppression causing both rapid respiratory tract and foot soft tissue damage. with progressing into uncontrolled local and generalized sepsis During first 0-4 days. Active diagnosis and management of both pathologies can reverse the multifaced disease and preserving a weight bearing foot.

P02.4-4

Genome-based analysis of carbapenem-resistant *Acinetobacter baumannii* in diabetic foot wounds

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Aim: According to the 2021 China Antimicrobial surveillance network report, the proportion of carbapenem-resistant *Acinetobacter baumannii* (CRAB) in China has exceeded 71%. Diabetic foot is a chronic and difficult wound, and infection with CRAB can make treatment more difficult. However, its resistant genome has not been fully reported.

Methods: Six CRAB strains from inpatients with diabetic foot wound in 2020-2021 were selected then carried genome sequencing. Three carbapenem-sensitive AB (CSAB) were selected as controls. Analyzing the characteristics of their resistant genes.

Results: MLST (Pasteur) showed CRAB as ST2, CSAB as ST1014. CRAB carried OXA-66 and OXA-23, CSAB carried OXA-51 and OXA-424. However, the above genes didn't constitute to carbapenem resistance. Analysis using a Comprehensive Antibiotic Resistance Database found that CRAB in diabetic foot wounds had its own characteristics. There were 107±5 antibiotics resistant genes. 34±1 were associated with carbapenem resistance. It is mainly divided into three categories: first, 2 genes that affected the permeability of bacterial cell membrane (membrane pore protein). One is CarO, which specifically affects the entry of carbapenems into bacteria, the other is oprD, which has an effect on all 5 β-lactam antibiotics (monobactam; carbapenem; cephalosporin; cephamycin; penam; penem). Second 2 genes that affect antibiotic target changes, including PBP3 and PBP1a. The above two categories' genes were no different between two groups. Third, 30±2 genes associated with efflux pumps. Related to carbapenem was RND efflux pump. The following genes mexB, mexJ, mexK, mexN, adeK, adeJ, adeI, adeH, adeF, adeG, adeL, adeN, adeS, adeR, adeA, adeB, semS, semR, semF, CRP, AbuO, SoxR were no difference in both CRAB and CSAB. However, AdeC and acrD only belonged CRAB.

Conclusion: The MLST and OXA genes of CRAB in diabetic foot wounds are completely different from those of CSAB. The mechanism of carbapenem resistance is complex, involving efflux pump, target changes, and membrane pore changes. AdeC and acrD are specific resistant genes of CRAB.

P02.4-5

Efflux pumps of multidrug-resistant *Acinetobacter baumannii* in diabetic foot ulcers and their effects

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Aim: Multidrug-resistant *Acinetobacter baumannii* (MRDAB) is mostly found in diabetic foot ulcer (DFU), efflux pumps can pump outward multiple antibiotics. A comprehensive understanding of the efflux pumps for MRDAB in DFU will provide the basis for overcoming antibiotic resistance.

Method: 8 MRDAB strains in DFU were collected, genomes were sequenced. The genes associated with efflux pumps were identified, classified and compared with clinical antibiotic susceptibility test results. They were also compared with the efflux pump genes of MDRAB in the literature to find their unique genes.

Results: MDRAB strains had 40-42 efflux pump-related genes, all from chromosomes and not from plasmid. Five super-family efflux pumps can be found at the same strain. 1. The similarities with the literature were resistance-nodulation-cell division (RND) pump genes: (1) AdeABC, AdeFGH, AdeL, AdeS, AdeR, pump outward macrolide antibiotics (MA), fluoroquinolone (FL), monobactam (MO), aminoglycoside (AM), carbapenem (CA), glycylicycline (GL), tetracycline (TE), rifamycin (RI), chloramphenicol (CH), penem (PE); (2) AdeIJK, AdeN: more pump outward lincosamide (LI) and cephalosporin (CE) than AdeABC pump. We also found other types of RND pumps, such as SmeS, SmeR, SmeF, more CE than AdeABC pump, less RI. MexJ, MexK, MexN only less RI than AdeABC. MexB more peptide antibiotics (PE) and sulfonamide (SU) than AdeABC. There were also acrD, CRP, AbuO. They did same as AdeABC, only AbuO increased CE. 2. Major facilitator superfamily (MFS) efflux pump: abaF, abaQ, AmvA, emrB, emrA, rosA, rosB, tet (B) and mdfA. They added LI, fosfomycin (FO), CE, PE, oxazolidinone antibiotics (OA), nitroimidazole antibiotics (NI) on the basis of AdeABC pump. 3. ATP-binding cassette (ABC) efflux pump: TaeA, msbA, novA, macA, macB, less MO, AM, CA, GL and more CE, PE and NI than AdeABC. 4. Small multidrug resistance (SMR) efflux pump: kdpE only effluxes AM, abeS effluxes MA, AM, TE, CH. 5. Multidrug and toxic compound extrusion (MATE) efflux pump: only abeM was found, which was involved in efflux of FL, GL, TE. Combined with the above efflux pump genes, they were consistent with clinical antibiotic resistance.

Conclusion: The genetic composition of the classic RND efflux pump of MDRAB in DFU is intact, and the other four efflux pumps can increase the categories of antibiotics, and they further reveal the complex mechanism of MDRAB resistance.

P02.5-1

A 13-year retrospective analysis of an admission avoidance strategy using intramuscular antibiotics in treating 'borderline-severe' diabetic foot infections

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Aim: To determine the outcomes of using intramuscular (IM) antibiotics as an admittance avoidance strategy in people presenting with a 'borderline-severe' diabetic foot infection.

Methods: Methods: 122 patients (accounting for 141 episodes) were treated for 'borderline-severe infection' between January 2009 and April 2022. They were followed up to determine whether the use of intramuscular antibiotics had prevented acute hospital admission.

Results: In our clinic we saw, on average, 420 contacts per month during the study period. Approximately 5 people per week were admitted directly from specialist clinics or the emergency department with a severe infection. Of those seen in the specialist foot clinic, only 1 person per month was deemed appropriate to receive IM treatment. These had a mean age (\pm) of 61 years (13.3), and 83% were male, and 25% had type 1 diabetes.

The mean (IQR) number of injections was 5.5 (6.0). Of these, 39/141 subsequently needed hospital admission. The remaining 102 people were successfully treated as outpatients, with 95 ulcers healing. Of the 39 admissions, 20 needed IV antibiotics alone, 14 had a minor amputation, 5 had a major amputation.

Conclusions: Admission avoidance strategies are increasingly important in reducing the pressure on hospital beds. Like others, our hospital increasingly uses outpatient intravenous antibiotic services, but that has its own pressures. We now successfully use either the IV or IM administration to treat borderline-severe diabetic foot infections depending on the capacity of either service.

P02.5-2

Antibiotic resistance of definitive pathogens in diabetic foot patients: three-year experience of a tertiary private hospital diabetic foot unit

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Aim: To assess the causative pathogens of diabetic foot infection (DFI).

Methods: We analyzed 303 tissue samples obtained from 107 DFI patients between May 2019 and October 2022 (65 men; 42 women, mean age 68.12 + 13.28 years, type 2 diabetes - 95%).

Results: Polymicrobial flora was detected in 60 biopsies, monomicrobial in 86 and no growth - in 42. 94% of patients had previous antibiotic therapy.

The facultative anaerobic flora was determined in 7 cases (including 1 of *Aeromonas hydrophilia* which caused fatal sepsis).

Number of *St. aureus* was 66 (25%). MRSA was found in 30 (46%). 60% were resistant to fluoroquinolones. More than 90% were sensitive to main anti-staphylococcal agents (vancomycin, linezolid).

E. faecalis was found in 18 (6,9%); 55% were resistant to fluoroquinolones. 100% were sensitive to vancomycin, linezolid, tigecycline; 85% to ampicillins.

Klebsiella spp. – 28 (10,7%). 100% were resistant to levofloxacin, 63% to carbapenems. It was sensitive to polymyxin in 65%.

Escherichia coli (n=20; 7,8%) was resistant to fluoroquinolones in 60%. 84% carried extended-Spectrum β -Lactamases. 90% were sensitive to aminoglycosides, 100% to piperacillin/tazobactam, carbapenems.

Acinetobacter baumannii (n=16; 6,1%) was sensitive to aminoglycosides in 65-72%, to polymyxins in 100%. It was resistance to fluoroquinolones in 62%, to various carbapenems in 64-75%.

Pseudomonas aeruginosa (n=16; 6,1%) was sensitive to amikacin in 76%, to ciprofloxacin in 75%, to carbapenems in 64%, to polymyxins in 80%. Resistance to levofloxacin was 55%, to cefepime - 47%, ceftazidime - 50%.

Proteus mirabilis (n=17; 6,5%): 98% were sensitive to amikacin, piperacillin/tazobactam, 86% to meropenem, 70% to tobramycin, but only 9% to imipenem. More than 40% of cases were resistant to common antibiotics (cephalosporins, aminopenicillins, fluoroquinolones).

Conclusion: We found multidrug resistant pathogens in more than 50% of cases of DFI. In most cases DFI patients will not benefit from empiric single-component antibiotic therapy. Thus, microbiological analysis of the biopsy and identification of resistance genes should be performed as early as possible for targeted therapy.

P02.5-3

Antibiotic impregnated calcium sulphate beads versus usual care in treating DFI: a randomised controlled adaptive trial

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Background The diagnosis of DFU related osteomyelitis (OM) is complex, with no universally accepted definition and poor diagnostic test reliability. The worse prognosis of OM vs soft tissue infection (STI) means that, when uncertain, clinicians may over- rather than under-diagnose OM. Trials where STI needs distinguishing from OM struggle to recruit sufficient patients.

Aim To assess in a proposed trial if antibiotic impregnated calcium sulphate bead treatment of DFUs complicated by clinically diagnosed STI or OM leads to superior eradication of infection at 2 & 6 weeks post randomisation vs. usual care without the use of systemic antibiotics.

Methods An innovative adaptive trial design including both populations (STI & OM) avoids absolute clinical distinction and mitigates against excluding participants. Efficient recruitment will provide an answer to the primary question for both STI & OM within one trial. Planned interim analyses facilitates decision-making, allowing early discontinuation for efficacy/futility in each group.

Usual practice for STIs includes systemic antibiotics for 7-14 days, and for OM ³ 6 weeks. For the trial, antibiotic beads will be prepared with vancomycin and gentamicin at the point of use. In the STI group, beads will be inserted or laid on top of the ulcer after bedside debridement and held in place with a dressing. No further systemic antibiotics will be given. In the OM group, after debridement, beads will be placed as near to the bone as possible and held in place with a dressing and systemic antibiotics will be given for a further 48 hours.

Outcome A funding application has been submitted.

P02.5-4

Incidence of MRSA infection, reinfection, conversion, and clinical outcomes in diabetic and non-diabetic foot infections

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Aim: To identify the incidence, the conversion rate, and effects on outcomes of methicillin-resistant *Staphylococcus aureus* (MRSA) infection.

Method: This retrospective study reviewed the medical records of 446 patients that were admitted to the hospital with moderate or severe foot infections. The infection was classified using the IWGDF classification system. Tissue and bone cultures were obtained from the index hospital admission. Bone and tissue cultures were used to define bacterial pathogens. We identified MRSA and other pathogens at both time points. MRSA conversion was defined as methicillin susceptible *Staphylococcus aureus* in the first culture and subsequently MRSA when there was a reinfection from the same location. Osteomyelitis (OM) diagnosis was confirmed by bone cultures or histopathology. We used clinical data for the outcomes.

Results: The incidence of MRSA was 7.8% (n=35), with no significant difference between the soft tissue infections (STI) (7.7%) and OM (8.0%). MRSA incidence was higher in non-diabetics (23.8% vs. 3.2%, $p<0.01$). The incidence of reinfection was 40.8% (n=182). Reinfection occurred significantly more in OM (49.1% vs. 32.3% in STI, $p<0.01$). The incidence of MRSA reinfection was 6.0% with no difference between STI and OM. Conversion to a MRSA was seen in 2.2% (n=4) total, occurring in 5.4% of the reinfections in OM. Patients with MRSA had a significantly longer antibiotic treatment (median 49.0 (20,81) days vs. 28.0 (15,60), $p=0.03$). There were no differences found in other clinical outcomes in MRSA vs. other infections (healing (94.3% vs. 80.0%, $p=0.23$), re-infection (28.6% vs. 24.3%, $p=0.11$), amputation (48.6% vs. 52.6%, $p=0.90$), mean days to heal (130 vs. 143, $p=0.51$), rehospitalization (28.6% vs. 42.5%, $p=0.16$), and death (0.0% vs. 3.2%, $p=0.61$).

Conclusion: The incidence of MRSA for the first infection (7.8%), re-infection (6.0%), and conversion to MRSA rate (2.2%) was low. The reinfection rate was higher in OM vs. STI. MRSA was more common in non-diabetics vs. diabetics.

Patients with MRSA were given antibiotics for a longer time compared with other infections for the foot infection. Besides this, MRSA didn't make a difference in outcomes compared to other infections.

P02.5-5

A rare example of antibiotics being a cause rather than a cure for diabetic foot

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Background Diabetic foot infection (DFI) is the most common cause of lower extremity amputation and has a one-year mortality of 15% (1). Multidisciplinary foot clinics are essential in preventing this complication. Beta lactam antibiotics remain first line in the empirical therapy of DFI (1).

Case A 75-year-old male type 2 diabetic with a significant medical history of rheumatoid arthritis was admitted with fever and purpuric skin lesions (figure 1), suggestive of leukocytoclastic vasculitis (LCV). One week earlier, amputation of the fifth toe took place due to a Wagner 4 diabetic foot ulcer. The patient was still on beta lactam antibiotics.

Results Skin biopsy confirmed LCV. Extensive history-taking and clinical work-up could not reveal systemic disease, nor Anti-Neutrophil Cytoplasmic Antibodies (ANCA) or immune complexes as a probable cause for the LCV. Because of its suggestive temporal association with the skin lesions, beta lactam antibiotics were discontinued. Due to the severe and systemic presentation Methylprednisolone 32mg therapy was started. The skin lesions resolved over three weeks and steroids were slowly tapered.

Conclusion Up to 45% of drug induced LCV is caused by beta lactam antibiotics, the most common first line empirical therapy for DFI (1, 2). As this case illustrates, early diagnosis and discontinuation of the culprit is essential for good clinical outcome (2). Therefore, when one encounters diabetic foot with purpuric skin lesions, LCV should always be considered.

1. Lipsky BA, Diabetes Metab Res Rev. 2020;36 Suppl 1:e3280.
2. Ortiz-Sanjuán F, J Rheumatol. 2014;41(11):2201-7.



Purpurative skin lesions seen after amputation of the fifth toe

P02.5-6

Multicentre, prospective real-life study on the performance of antimicrobial wound dressings* for diabetic foot ulcers with risk/signs of local infection

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Background/Aim: In Germany a reduction of medical consultations was observed in outpatient care during COVID-19. This real life study aimed to evaluate the performance of two antimicrobial wound dressings with TLC-Ag matrix* in the local treatment of patients with diabetic foot ulcers (DFU) presenting a risk or clinical signs of local infection in everyday practice during COVID-19 under this difficult conditions.¹

Methods: A large, prospective, multicentre (n=39) observational study with two TLC-Ag wound dressings* was conducted in Germany in the treatment of different wound etiologies over a maximum period of four weeks (May 2020 and May 2021; n=728 patients). Evaluation criteria included description of patients and wound management, changes in wound infection, wound healing outcomes, and a general clinical assessment of their performance, local tolerability and acceptability. Within this abstract the results for patients suffering on DFU were analysed.

Results: Ninety patients with DFU were treated with this TLC-Ag wound dressings* for 28±18 days (interim follow-up after 13±8 days) in 22 centres. At baseline, all patients were at risk of wound infection, 93.3% had clinical signs of wound infection and 80.0% were diagnosed with wound infection. Main parameters of medical history: Obesity, heart insufficiency, reduced mobility and recurrent wounds (27%). All parameters of wound infection decreased steadily. Wounds with surgical sepsis showed the most rapid decrease in wound deterioration, pus and exudate-related clinical signs. At final visit, a decrease of 84.7% in local wound infections and of 78.6% in wounds with clinical signs of infection was observed. 92.2% of wounds healed/improved, 3.3% remained unchanged and 1.1% worsened (3.3% missing data). Antimicrobial efficacy (and handling) were assessed 'very good' (easy)/ 'good' (easy) (96,6%). Both wound dressings were predominantly 'very well accepted' and rated as 'very useful' by clinicians.

Conclusion: These results are consistent with previous clinical findings on TLC-Ag wound dressings.^{1,2} They support the good efficacy, tolerability and usefulness of these antimicrobial wound dressings with TLC-Ag-matrix for therapy of DFU with risk/signs of local infection when used in conjunction with appropriate standard treatment.

P02.6-1

A limb threatening presentation of an infected diabetic foot ulceration with group B streptococcus pathogen

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Background This clinical case report demonstrates the rapid deterioration of infected diabetic foot ulceration (DFU) due to group B streptococcus pathogen. despite improving clinical and haematological markers.

Methods A 49-year-old Caucasian man was admitted with an infected neuropathic non ischaemic DFU at the insertion of his Achilles. There was a small collection of pus and probed to tendon. There were no signs of lymphangitis, lymphadenitis or extending cellulitis beyond the wound margins. This was his primary DFU.

X-ray, MRI and Duplex arterial scan were arranged, intravenous antibiotics were commenced, and he was listed for a debridement and washout within 48 hours. With an improving haematological and clinical picture, he attended theatre for his surgical debridement. The infection which was later confirmed to be group B streptococci had tracked 25cm proximally and 400mls of pus was evacuated from the lower leg.

A second wash out, the use of a negative pressure device with irrigation and hydrating dressings preserved the hydration and asepsis of the Achilles tendon enabling plastics to intervene and reconstruct the area with an antero-lateral thigh flap. The patient had preserved muscle power and a fully healed wound within six weeks of initial presentation.

Results Within 24 hours of the last clinical wound check and an improvement in systemic symptoms and haematological results the infection had advanced significantly along the fascial planes of the lower limb. This case report highlights and illustrates the unpredictable nature of group B streptococcus infection with a rapid deterioration in local infection present that would have been a threat to the limb.

Conclusions The rapid triage and surgical debridement within 48 hours most likely preserved the limb of this patient.



Intra-operative image of debridement and washout of right limb

P02.6-2

Duration of antibiotic treatment for foot osteomyelitis in people with diabetes

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Background: Osteomyelitis of the foot in people with diabetes (DFO) generally requires long-term systemic antibiotic treatment combined with surgery. The optimal duration of antibiotic treatment is unclear. If shorter treatment durations are as efficacious, shorter durations would be preferable from an antibiotic stewardship standpoint.

Methods: For this review, we performed a systematic search according to Cochranes' methodology to compare the effects of shorter (< 6 weeks) systemic antibacterial treatment with longer (> 6 weeks) treatment in people with DFO. We included studies comparing durations using all types, doses, or routes of administration of antibiotics except for topical, with or without additional bone debridement/surgery leaving residual osteomyelitis in situ, and provided data syntheses for the outcomes amputation, clinical remission and antibiotic related adverse events (AE's).

Results: We included 3 studies: Tone 2015, Gariani 2021 and Iranpravar 2019. Tone compared 6 with 12 weeks of antibiotics and reported similar numbers of amputation and remission in both groups, and a higher number of AE's in people treated with antibiotics for 12 weeks. Gariani compared 3 with 6 weeks of antibiotics and reported similar remission rates in both groups. Iranpravar compared 6 weeks of clindamycin with 12 weeks of ciprofloxacin, and reported similar remission rates in both groups. The last 2 studies did not report on amputation. All studies reported higher absolute numbers of AE's in people receiving longer durations of antibiotics.

The studies were too heterogeneous to pool, due to differences in the interventions and follow-up. The studies of Tone and Gariani were rated to raise some concerns of risk of bias, and the study of Iranpravar at high risk of bias. We found the certainty of the evidence of low to moderate certainty based on the low amount of studies that could be included, the risk of bias, the imprecision and indirectness of measuring the outcomes.

Conclusion: Due to the low number of studies that could be included in the review, and the variation among the included studies, it was difficult to determine whether a shorter treatment with antibiotics is as safe as longer treatment for DFO. Larger studies with more comparable study designs are needed.

P02.6-3

Effective Disinfection of Debrided Diabetic Foot Ulcer Tissue by Immersion in 200 ppm of the Electrochemically Activated Solution Anolyte

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Background/Aim: Diabetic foot ulcer (DFU) infections are the leading cause of lower limb amputations and reduced quality of life. Anolyte is a non-toxic, environmentally friendly electrochemically generated hypochlorous acid solution with powerful antimicrobial properties that has shown great promise in wound disinfection. This study evaluates immersion in anolyte as an alternative to antibiotic-based DFU treatment.

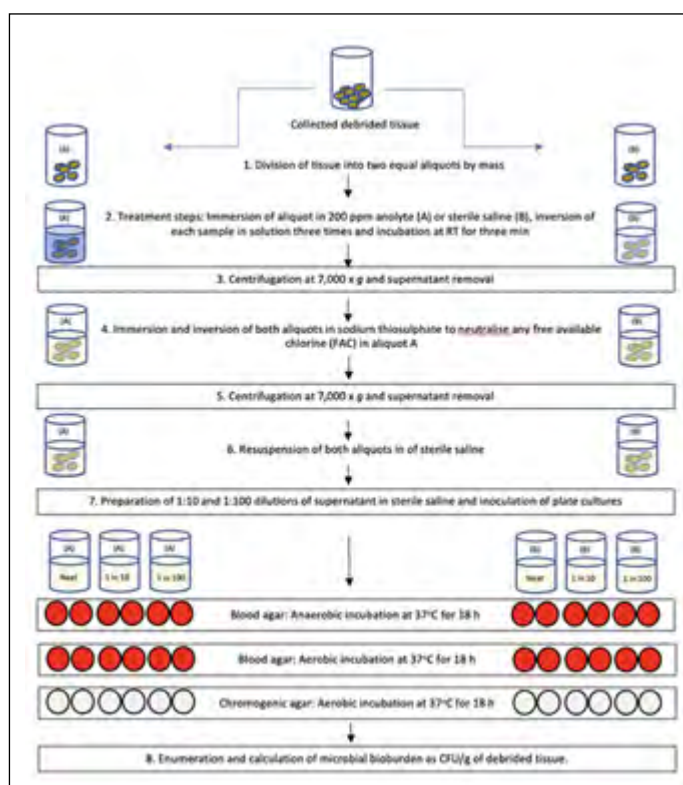
Methods: Tissues were collected from 26 patients with type II diabetes undergoing routine debridement. Clinical ulcer features, graded according to the Texas Wound Classification and any prior DFU interventions were recorded. The microbial bioburden of tissues treated with 200 parts per million (ppm) anolyte or sterile saline were recorded (Figure 1). Bacteria were identified based on 16S rRNA sequences.

Results: DFUs sampled were neuropathic (n=21), neuroischaemic (n=5); 23 of the DFUs were superficial (n=24), or bone deep (n=2). The DFU grades were 1A (n=20), 1B (n=1), 3B (n=1), 3D (n=1), and 1D (n=3). Following aerobic or anaerobic incubation, the average microbial load of saline-treated samples was 1×10^4 Colony forming units (CFU)/g. In contrast, the average microbial load of anolyte-treated samples was 6×10^2 CFU/g, a statistically significant four-log (1773 fold) reduction ($Z = -3.621$, $p < 0.001$). *Staphylococcus aureus* was the most common species recovered.

Conclusions: Immersion in anolyte is highly effective for debrided tissue disinfection and should be pursued as an inexpensive alternative approach for ulcer treatment in situ.

Acknowledgements: This study was supported by Health Research Board grant EIA-2019-002. Ethical approval was granted by the St. James's Hospital and Tallaght University Hospital Joint Research Ethics Committee (2019-12).

Figure 1. Comparative disinfection treatment of debrided DFU tissue samples in 200 ppm freshly generated anolyte or sterile saline.



P02.6-4

DGH experience of using cold argon plasma in treating diabetic foot ulcers and its role in antibiotic stewardship

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Background Antibiotic resistance is a growing concern. Finding effective adjuvants to antimicrobials is vital. Diabetic foot ulcers (DFU) are strongly associated with complex and deep-seated infections, creating a heavy reliance on long-term antibiotic use. This makes DFUs both a contributor to resistance and susceptible to the consequences of ineffective therapy. Argon cold plasma therapy (ACPT) utilizes the production of free radicals to accelerate tissue repair and reduce microbial load, minimizing the application of antibiotics. Here we present our experience of ACPT, delivered through the Adtec Steriplas device, in patients with non-healing infected DFUs.

Methods Conventional therapy including debridement, offloading, glycemic control and vascular optimization was continued. Data from 37 patients over a 40 month period treated with once-weekly ACPT for three minutes/area were collected. Additional metrics included antibiotic use, HbA1c, biochemistry and microbiology. Photos and X-rays were also utilized. All patients were treated in the outpatient setting and admission, vascular intervention and mortality was recorded.

Results Of the 37 patients included in this study, 10 are currently being treated and responding well. 16 patients have completed treatment with successful resolution. The mean length of treatment was 11.2 weeks, with a mean treatment time of 52.5 minutes. Four patients in this group relapsed during treatment, stabilizing with antibiotics. Of the remaining patients who did not complete ACPT, five patients required a change in management plan. Four patients passed away due to unrelated conditions. One patient was treated palliatively due to an unrelated cancer. One patient self-discharged. Incidentally, 13 of the patients who completed successful therapy were non-smokers.

Conclusions Our study sought to illuminate a credible adjuvant to antimicrobial therapy for DFU. Chronic DFU patients prior to use of ACPT had a high incidence of acute readmission and relapse, with repeated antibiotic courses. All patients successfully treated had no relapses over a one-year follow-up. This retrospective analysis provides real world experience with ACPT applied to chronic DFU. We were limited to a small number of patients, treated once weekly. Results may be enhanced with twice weekly ACPT, as recommended. Our report can be substantiated through further study using an RCT.

P02.6-5

Auto-Florescence Imaging Can Detect and Follow Up Multi-Drug Resistant Infections in Diabetic Foot Ulceration

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Aim - To evaluate the use of a auto-fluorescence imaging device (AFI) in providing predictive and quantifiable parameters in the evolution of infected diabetic foot ulcers (DFUs).

Methods - We studied all consecutive outpatients attending our clinic May/June 2022 with a DFU (grade IB-IIB Texas University score), with ABPI ≥ 0.9 and no antibiotic therapy (ATB) with AFI, before and after surgical debridement and after 3 weeks of ATB, rating the imaging from 1 (100% contamination) to 5 (no contamination). We compared these results with the culture results performed before the start of the ATB and after 3 weeks.

Results - We enrolled 20 DM2 patients, (age 64.4 ± 15.1 years, diabetes duration 15.4 ± 7.3 year, ABPI 0.96 ± 0.1). AFI score improved from 2.5 ± 0.7 to 3.9 ± 0.8 ($p < 0.004$) after 3 weeks, the number of multi-drug resistant strains decreased from 57 to 16 ($p < 0.002$) and the number of resistance per strain reduced from 1.16 to 0.52 ($p < 0.0015$).

Bacterial resistance (BR) showed a ΔBR of $-32.42 \pm 13.4\%$ that correlated with the improvement of FID score ΔFID 1.32 ± 0.18 ($p < 0.035$).

Conclusions - Our data, although referred to only 20 patients, show how AFI can be useful in managing of DFU and in evaluating the outcomes of ATB in MDR infections.

P02.6-6

Concordance of bone culture and deep tissue culture during the operation of diabetic foot osteomyelitis

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(Abstract)

Background To retrospectively analyze the consistency of bacterial culture between bone tissue and deep tissue in patients with diabetic foot osteomyelitis (DFO).

Methods 155 patients diagnosed as DFO in the Department of Endocrinology of Henan Provincial People's Hospital were collected and confirmed by histopathology after admission through bone biopsy. During the operation, the soft tissue and bone of the patient's wound base were taken for bacterial culture and drug sensitivity test to compare the consistency of the two. In addition, the differences among DFO patients with different degrees of infection were compared.

Results Among the 155 patients diagnosed with DFO, bone tissue culture and soft tissue culture were performed at the same time during the operation. The positive rate of bone culture was 78.71%. A total of 165 strains were cultured, including 73 Gram-positive bacteria, 83 Gram-negative bacteria and 9 fungus. *Staphylococcus aureus* (33 strains) is the most common bacteria. The overall agreement between bone culture and tissue culture was 42.6%, with *Staphylococcus aureus* having the best agreement (64.3%) and *Enterobacteria* having the least agreement (27.3%). Compared with the moderate infection group, the severe infection group had higher rates of C-reactive protein (CRP), white blood cell count, glycated hemoglobin, platelet to lymphocyte ratio (PLR), neutrophil to lymphocyte ratio (NLR), gram-negative bacteria and drug-resistant bacteria, and lower lymphocyte to monocyte ratio (LMR). The differences were statistically significant ($P < 0.05$). There were no significant differences in total cholesterol, triglyceride and low density lipoprotein cholesterol between the two groups ($P > 0.05$).

The results of drug sensitivity in bone culture showed that *Staphylococcus aureus* was the main gram-positive bacteria, which were sensitive to linezolid and vancomycin. *Proteus mirabilis* was the main gram-negative bacteria, which were more sensitive to biapenem and piperacillin/tazobactam. Fungus were more sensitive to voriconazole and itraconazole.

Conclusion For patients with suspected DFO, bone culture should be taken intraoperatively as far as possible to identify the real pathogen of DFO, and appropriate antibiotics should be selected according to the results of drug sensitivity.

P03.1-1

What constitutes a center of excellence for limb preservation? Framework development from an adapted e-Delphi study

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Background/Aim: An interdisciplinary approach is essential to care for individuals with lower extremity complications related to diabetes and peripheral artery disease. However, there are no optimal and consistent programs for limb preservation. Therefore, we sought expert consensus in the United States on standards and indicators for centers of excellence for limb preservation.

Methods: A 2-step method involving a patient-centered research approach was conducted: 1) a rapid literature review to draft items related to standards and indicators for limb preservation based on the Toe & Flow model using the American College of Surgeons Quality Program Framework, and 2) an adapted e-Delphi study. Experts were members of the American Limb Preservation Society, including podiatric and vascular surgeons, nurses, and others, were invited to contribute to three rounds of the questionnaire using Qualtrics, an anonymous online survey platform. Suggested items were scored on a 9-point Likert scale. Consensus was defined as at least 70% agreement for each item.

Results: A total of 35 experts, mainly podiatrist and vascular surgeons, with at least 2 years of experience in limb preservation were solicited by email. Each questionnaire was open for three weeks. Response rates ranged from 86% (round 1) to 89% (round 2). The third round was unnecessary as all items achieved agreement after two rounds. The experts reached a consensus for all 9 standards and 113 indicators after the first round. In addition, 33% of the items achieved 90% or greater agreement, and only 4% of them were between 70 and 80% agreement. Two indicators were added in the second round and experts agreed. Feedback to the open-ended questions was all favourable toward the initiative, except for one expert who found the questionnaire too long. Nineteen (54%) experts expressed interest in participating in the next phase of the project.

Conclusions: Consensus on standards and indicators for limb preservation can help achieve a more consistent definition of optimal care. The next steps are to define the priority of those indicators and a validation to draft the first framework version. Implementation and expansion of the center of excellence can help maximize ulcer-free, hospitalization-free, activity-rich days.

P03.1-2

A national quality survey of in-patient diabetic foot care reveals significant and disparate gaps in adherence to standard of care

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Background: Among the OECD countries, Israel has the highest rate of major amputations in patients with diabetes. The Ministry of Health conducted a national quality survey in all hospitals assessing the care of patients admitted with a diabetic foot ulcer (DFU).

Methods: National healthcare professionals composed a quality survey reflecting recommended standard of care (SOC) procedures in multiple aspects of in-patient diabetic foot care. The survey was submitted to the participating hospitals for review approximately six months prior to the survey. During May-August 2021, the survey was conducted in 26 hospitals countrywide whereby physicians, nurses and other healthcare professionals visited other hospitals evaluating their peers' performance. Documentation of internal procedures reflecting good SOC was ascertained as well as adherence to these procedures. In each hospital the survey team interviewed the management and staff and reviewed files of patients who were either currently or most recently hospitalized due to a DFU. The proportion of patient files documenting adherence to SOC was calculated for each item. Disparities by hospital size and location were calculated using Chi-test.

Results: While the majority of the hospitals had documented regulations, many prepared in the months prior to the survey, adherence to these varied. Proportion of patient files documenting adherence to major SOC items are shown (table).

Conclusions: A national quality survey of in-patient diabetic foot care increased awareness to the importance of SOC treatment of DFU. While it succeeded in driving hospitals to reinstate internal guidelines of DFU care, implementing adherence to these warrants further effort.

	Size of hospital			Location of hospital		Overall
	Tertiary center	Medium to large	Small	Central	Peripheral	
Number of hospitals	6	11	9	18	8	26
Use of correct diagnostic codes for diabetic foot ulcer	41/54 (75.9%)	73/90 (81.1%)	29/42 (69.0%)	116/145 (80.0%)	27/41 (65.9%)	143/186 (76.9%)
Performing a physical exam of both feet	31/56 (55.4%)	49/92 (53.3%)	26/44 (59.1%)	82/147 (55.8%)	24/45 (53.3%)	106/192 (55.2%)
Palpating foot pulses and documentation of vascular status	39/56 (69.6%)	57/93 (61.3%)	26/44 (59.1%)	95/148 (64.2%)	27/45 (60.0%)	122/193 (63.2%)
Documentation of wound severity according to standard classification	36/56 (64.3%)	57/95 (60.0%)	27/41 (65.9%)	95/152 (62.5%)	25/40 (62.5%)	120/192 (62.5%)
Performing an X-ray of the affected foot	46/56 (82.1%)	73/95 (76.8%)	36/44 (81.8%)	119/150 (79.3%)	36/45 (80.0%)	155/195 (79.5%)
Uploading a photo of the wound to the medical file	31/57 (54.4%)	38/97 (39.2%)	16/44 (36.4%)	61/153* (39.9%)	24/45 (53.3%)	85/198 (42.9%)
Taking bone / tissue culture prior to antibiotic therapy	23/54 (42.6%)	49/93 (52.7%)	20/43 (46.5%)	81/146* (55.5%)	11/44 (25.0%)	92/190 (48.4%)
Glucose monitoring X3/day	54/56 (96.4%)	92/95 (96.8%)	39/41 (95.1%)	141/147 (95.9%)	44/45 (97.8%)	185/192 (96.4%)

* p<0.05

Proportion of patient files fulfilling standard of care criteria

P03.1-3

Experience with the adaptation of the international guidelines on the prevention and management of diabetic foot in the Czech Republic

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Background/Aim: Although the annual incidence of major amputations in the Czech Republic (CR) has been decreasing over the past 10 years (from 2.57 to 2.08/1000 diabetic patients), their prevalence has increased by 22% over the past 5 years. In order to create more awareness, we have translated and adapted the IWGDF Guideline into National Clinical Guidelines– diabetic foot (NCG-DF). The purpose of the abstract is to share our experience with the process of creation of the NCG-DF.

Methods: eight clinical guidelines were subjected to evaluation using the AGREE II tool; five of them were used for our NCG-DF. The main source was the IWGDF Guideline, the following were also used: ESC Guidelines on diabetes, prediabetes and cardiovascular disease developed in collaboration with the EASD, NICE Diabetic foot problems: Prevention and Management, ESVM Guideline on peripheral arterial disease and WHO Surgical Site Infection.

Results: Additional chapters were added to the NCG-DF: personnel and material equipment for diabetic foot clinic and notes for health policy. The literature was unified into one list for the entire publication. As part of the adaptation, we have added e.g.: criteria for diabetes control and for atherosclerosis risk factors, other DF classification systems and neuropathy screening methods used in the CR. We also added as a minimum requirement for the PAD examination systolic ankle and toe pressures and, as appropriate, triplex ultrasonography and transcutaneous oxygen tension. We emphasized that it is necessary to start antibiotic treatment as soon as possible in patients with more serious foot infections. We have also integrated information on hyperbaric oxygen therapy into one chapter on healing diabetic foot ulcers. **Conclusions:** NCG–DF in the CR was published both on-line and in printed version. In order to implement it, the NCG-DF was launched in the annual national diabetic society meeting and presented in several other conferences for various health care workers involved in the diabetic foot.

Acknowledgements: the creation of the NCG-DF was enabled thanks to the Clinical Recommended Practices project and the approval of the IWGDF and its Editorial board; thank you both very much.

P03.1-4

Saving Lower-Limbs: Introducing a New Vascular Wounds Pathway

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Aim Vascular wounds can result in serious complications, including ongoing infection, amputation and death.¹ Best-practice evidence exists for the prevention and management of vascular wounds, albeit awareness is not yet widespread.^{1,2} To increase awareness and as the foundation for a provincial Lower-Limb Preservation Strategy³, Ontario Health's (CorHealth Ontario) Lower-Limb Preservation Advisory Committee collaborated with Wounds Canada to develop a practical pathway for preventing and managing vascular wounds.

Methods The development process involved:

- Review of existing provincial, national and international vascular wound guidelines, standards and best-practice recommendations
- An iterative process to develop Pathway content with Ontario vascular and wound experts
- A collaborative review process with Wounds Canada
- Endorsement of the Pathway by the Advisory Committee and Wounds Canada experts

Results The Pathway for Preventing and Managing Vascular Wounds highlights key care activities for evidence-based best-practice vascular wound prevention and management in a practical one-page infographic. It defines a vascular wound and highlights the importance that every lower-limb wound should be considered a vascular wound until proven otherwise. The Pathway emphasizes the importance of regular preventative screening, patient education, early identification, timely assessment, and best-practice treatment of a vascular wound.

Conclusions The Pathway provides a roadmap for use by lower-limb preservation organizations, administrators, and champions to inform and guide the development and delivery of vascular wound care services. When utilized, the Pathway, together with the Wounds Canada Best Practice Recommendations for the Prevention and Management of Peripheral Arterial Ulcers¹, provide guidance to optimize the delivery of best-practice vascular wound care, reduce health care costs and increase opportunities for desirable patient outcomes including reducing avoidable major lower-limb amputations.

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P03.1-5

Clinical and Economic Outcomes in Diabetic Foot Ulcer Care Re-organization: 18-month Results from an Observational Population Health Cohort Study

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Background/Aim: Diabetic Foot in Primary and Tertiary (DEFINITE) Care is an inter-institutional and multi-disciplinary team (MDT) health systems innovation programme at a healthcare cluster in Singapore. We aim to achieve coordinated MDT care across primary and tertiary care for patients with diabetic foot ulcers (DFU), within our public healthcare cluster - an integrated network of seven primary care polyclinics and two acute care tertiary hospitals (1,700-bed and 800-bed) with total catchment population of 2.2 million residents.

Methods: Results from prospective DEFINITE Care is referenced against a retrospective 2013-2017 cohort, which was previously published. Cardiovascular profile of the study population is compared against the same population's profile in the preceding 12 months. Economic outcomes were derived from direct healthcare costs from a provider's perspective.

Results: Between June 2020 and December 2021, there were 3,475 unique patients with DFU with mean age at 65.9 years, 61.2% male, mean baseline HbA1c at 8.3% with mean diabetes duration at 13.3 years, mean diabetes complication severity index (DCSI) at 5.6 and mean Charlson Comorbidity Index (CCI) at 6.8. At 18-months after the implementation of DEFINITE Care programme, the absolute minor and major lower extremity amputation (LEA) rates were 8.7% (n=302) and 5.1% (n=176) respectively. When compared against a retrospective 2013-2017 cohort, there was a significant 80% reduction in minor LEA (13.7 from 68.9 per 100,000 population, p<0.001) and 35% reduction in major LEA (8.0 from 12.4 per 100,000 population, p=0.005) rates. As compared to the preceding 12 months, there was also a significant improvement in cardiovascular profile (glycemic and lipid control) within the DEFINITE population, with improved mean HbA1c (7.9% from 8.4%, p<0.001) and low-density lipoprotein (LDL) levels (2.1 mmol/L from 2.2, p<0.001). Total economic burden of DFU per year (direct healthcare costs) within the catchment population was S\$36.9 million and via the minor and major LEA avoided per year, there is an estimated healthcare savings (gross cost minimization) of S\$7.4 million per year (20%).

Conclusions: Within DEFINITE care, 18-month data from DFU care re-organization showed a significant reduction in the clinical and economic burden of DFU in the study population.

P03.1-6

Factors contributing to avoidable diabetic foot amputations: systematic root cause analysis of amputations across a regional health economy

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Background/Aim: Despite the establishment of Multidisciplinary Diabetic Foot Teams (MDfT), amputation rates with the UK remains relative static over the last decade. In order to understand the demographics of patients undergoing diabetic foot amputations, a systematic programme of root cause analysis (RCA) was developed to identify contributory factors to amputations across South East London ICS region.

Methods: Over the year prior to the COVID-19 pandemic, all patients having major and minor amputations in the region were identified via clinical coding for procedure and analysis of demographics. An RCA was conducted on a subset via review of patients' clinical records using the London Diabetes Clinical Network Footcare RCA Audit Tool. Data was analyzed and verified with the national Hospital Episode Statistical data - HES and SUS data

Results: For 2018/19, of the total adult population of 1,575,216, 6% (93,320) had a diagnosis of diabetes, of whom 2,806 were seen by the MDfT for active foot disease. There were 36 major amputations and 148 minor amputations performed. RCA was completed for 27 major and 33 minor amputations. A substantially higher proportion of patients were male compared to the local diabetes population (81% vs 54%, $p=0.001$), 75% of patients with major amputations were noted to have a mental health issue and 67% had concordance issues. Of the major amputation patients, 63% (17/27) had PAD, 73-80% of the patients had had a previous foot ulceration. A significant proportion of patients - 17% (9/52) undergoing major amputation and 24% (6/25) undergoing minor amputation – had no footcare provider at the time of the amputation. Delays were identified across the pathway, with 41% of patients presenting after over 2 weeks of being aware of problem. Referral by primary care occurred after a median of 31 days, 44% of minor amputations were carried out as an emergency

Conclusions: Targeted prevention aimed at more vulnerable patients with mental health and concordance issues and greater awareness for the importance of early referral from primary care and community care seems to be the way forward to further reduction of the burden of diabetic foot disease and improve outcomes.

P03.2-1

Patient engagement in diabetic foot ulcer management: a scoping review and a suggested adapted framework

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Background/Aims: Patient engagement is recognized as being a major contributor to improving the quality of health care interventions as well as promoting ideal and personalized health care service delivery and experience. Therefore, we sought to document patients' engagement in diabetic foot ulcers (DFUs) care in five levels (i.e., direct care, organizational, policy level, research, and education), as well as strategies for patient engagement (Figure 1).

Methods: We conducted a scoping review of the literature from inception to April 2022 using the Joanna Briggs Institute framework and a patient-oriented approach. We also consulted DFU stakeholders to obtain feedback on the findings. The data was extracted using PROGRESS+ factor framework for an equity lens. The effects of engagement were described using the Bodenheimer domains for value-based care (i.e., patient and provider preferences, sustainable care, better health outcomes).

Results: Of 4,211 potentially eligible records, 15 studies met our eligibility criteria, including 214 patients involved in engagement initiatives. Very few described patients' characteristics. Engaged patients were typically men from high-income countries, in their fifties, with poorly controlled type 2 diabetes. Most studies were recent and involved patient engagement at the level of direct medical care research. Self-management was the principal way to clinically engage the patients. None of the studies sought to define the direct influence of patient engagement on health outcomes.

Conclusions: We found little rigorous research of patient engagement to promote quality patient-centered care, and therefore new knowledge is needed in this area, especially in organizational, policy, research, and education levels.

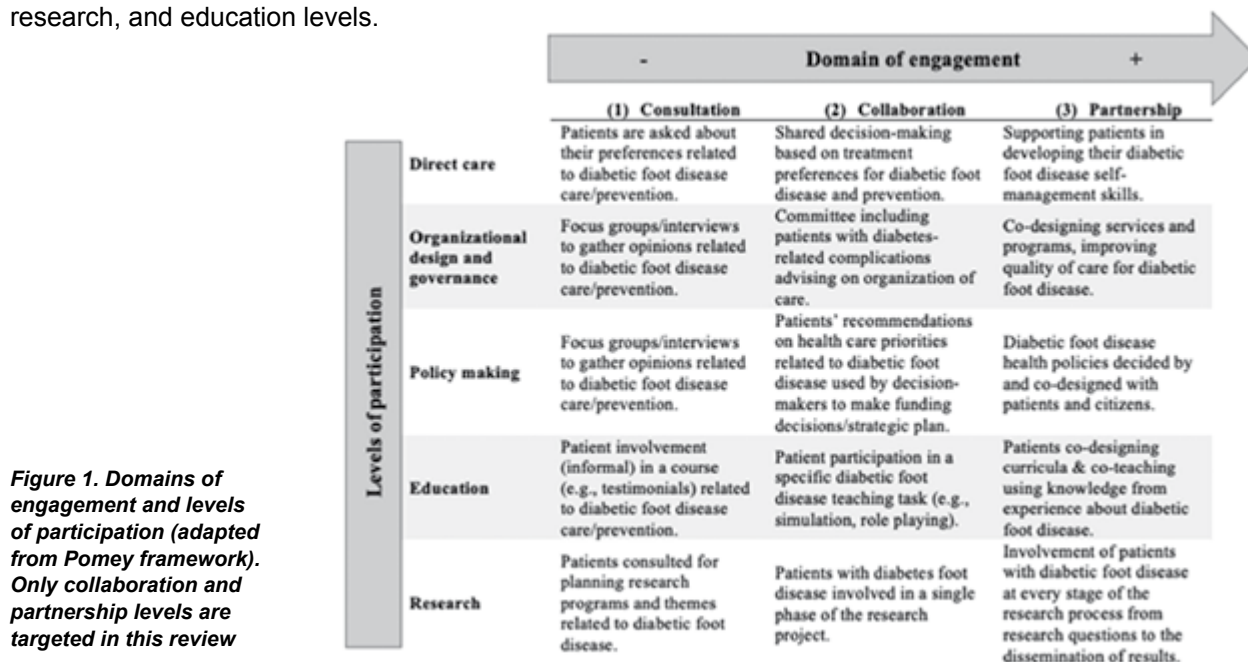


Figure 1. Domains of engagement and levels of participation (adapted from Pomey framework). Only collaboration and partnership levels are targeted in this review

P03.2-2

The Swedish initiative to create clinical person-centered guidelines for persons with diabetes and a high risk of developing foot ulcers

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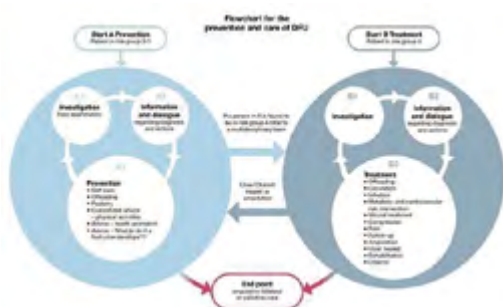
Background/Aim The prevention and care of diabetic foot ulcers (DFU) are unequal in Sweden, depending on differences in allocated resources and competencies. Therefore, the Swedish government commissioned the Swedish Association of Local Authorities and Regions (SALAR) to develop a Swedish person-centred care guideline (PCCG) for persons with diabetes mellitus at high risk of developing DFUs.

This abstract presents the process and outcome of this task.

Method According to a development framework from SALAR, a care flow map was set in consensus by the interprofessional team, consisting of consultants in endocrinology, infectious medicine, orthopedics, general practice, nurses, an orthotist and prosthetist, a patient representative and podiatrists. Then, "patients' experiences and needs" were collected and based on these, a PCCG harmonizing with the guidelines from The International working Group on the Diabetic Foot (IWDF), scientific evidence and best practice was formed. It was then referred for review by healthcare professionals (HCP), the patient's organisations, stakeholders and citizens.

Results Patients with peripheral neuropathy, angiopathy, foot deformities, skin pathologies are included and remain in the PCCG until bilateral major amputation, terminal care or death. All patients should have a written agreement stating their rights and obligations. The prevention and care processes are given in Figure 1. This PCCG focuses more on defining the needs for skills rather than formal competencies. It will be evaluated using pre-defined indicators.

Conclusion This, the first Swedish PCCG, supporting HCP to endorse an equal good care and improve quality of life for persons at high risk of developing DFU, was implemented in 2022.



Flowchart for the prevention and care of diabetic foot ulcers

P03.2-3

MDT or 'Making-Do-Team' - Real-Life-Experience of a Multidisciplinary Team (MDT) Diabetic Foot Round Without Surgical Input in a Tertiary Hospital

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Diabetic Foot Disease (DFD) is a common complication of diabetes associated with significant morbidity and mortality. Optimal management of DFD requires input from a multidisciplinary foot team¹. This study describes the experience of an inpatient DFD Round in a tertiary hospital, without direct input from surgical specialists.

We captured data from the DFD Round in our hospital over a 3-month period (September to November 2022). This weekly inpatient round is attended by Endocrinology and Infectious Diseases specialists, podiatrists, and specialist nurses in diabetes, vascular surgery and tissue viability. No surgical staff currently attend this DFD Round. We collected information on history of peripheral neuropathy/amputation/ulceration, treatment plan, microbiology sampling and culture results, HbA1c, duration of inpatient stay and plan for follow-up on discharge.

Over the study period, 37 inpatients were reviewed on the DFD Round, with a total of 53 patient contacts. 33 (89%) had known peripheral neuropathy. 13 (35%) had a prior history of amputation and 30 (81%) of ulceration. 15 (41%) had active superficial infection; a further 12 (32%) had osteomyelitis. Mean HbA1c was 60.1 mmol/mol. Mean duration of inpatient stay was 20 days. 4 (11%) patients underwent amputation; another 2 patients (5%) are planned for amputation, though further MDT discussion is awaited. 25 (68%) patients were treated with antibiotics without surgical intervention and discharged.

The relatively low number of amputations in the cohort may reflect the fact that the DFD round is primarily providing expertise in medical management. It is possible that amputations were successfully avoided as a result. It is equally possible that there were some delays in necessary surgery due to lack of timely surgical input; two (5%) patients are currently awaiting outpatient surgical input for consideration of amputation – this may have taken place during the inpatient stay if surgical input had been available. We conclude that it is possible to provide a valuable inpatient consultation service to DFD patients without immediate access to surgical input. Once the recommendations of the (national) Model of Care for Diabetic Foot is implemented (with senior surgical input to the DFD service) we intend to re-audit our practice.

¹<https://www.hse.ie/eng/about/who/cspd/ncps/diabetes/moc/diabetic-foot-model-of-care-2021.pdf>

P03.2-4

Validation of the fast-track model: a new diabetic wound assessment for primary care

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Aim: International Diabetic Foot Care Group and D-Foot International developed a fast-track model¹ to define the severity of diabetic foot ulcer (DFU)(see fig.1).

The authors aimed to validate the association between the grade of DFU severity proposed by the fast-track model and outcomes.

Methods: Consecutive patients with a new DFU were included. Patients were managed according to IWGDF guidelines². The fast-track model identifies three levels of DFUs severity: uncomplicated DFUs including superficial, not infected and not ischaemic wounds; complicated DFUs including ischaemic, infected, and deep ulcers (muscle, tendons or bone) and any wound in patients on dialysis or with heart failure; severely complicated DFUs including abscess, wet gangrene, necrotizing fasciitis or patient with fever or sepsis. Healing, healing time, minor and major amputation, hospitalization and survival after 24 weeks of follow-up were reported according to the grade of DFU severity.

Results: Three-hundred sixty-seven patients were included, 35(9.6%) with uncomplicated DFUs, 210(57.2%) with complicated DFUs, 122(33.2%) with severely complicated DFUs. The mean age was 69±13years, 208(56.7%) were male, 344(93.7%) had T2 diabetes with a mean duration of 19±10years. The outcomes for uncomplicated, complicated and severely complicated DFUs were respectively: healing 97.1%, 86.2%, 69.8% (p<0.0001), healing time (weeks) 4.4±3.3, 9.7±6.4, 13.3±8.3 (p<0.0001), minor amputation 2.9%, 20%, 66.4% (p<0.0001), major amputation 0%, 2.9%, 16.4% (p<0.0001), hospitalization 14.3%, 55.7%, 89.3% (p<0.0001), survival 100%, 96.7%, 89.3% (p=0.003).

Conclusions: The study shows an association between the grade of DFU severity and outcomes, and fast-track model may be useful to be assess wound severity in primary care

P03.2-5

The hidden patients - out of sight, out of mind

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Background: The Joint British Diabetes Societies (JBDS) released a guideline document for adults with diabetes on dialysis (2022). Aim, to improve standards of care, highlighting organizational difficulties for the dialysis patient and the need for care to be centered around the individual. Haemodialysis patients were screened at units which treat the local population to look at current care, practice, and deficiencies, evaluating system failures, usage and awareness of pathways which could be a contributing determinant in development of foot ulceration/amputation in this high-risk group.

Methods: A prospective observational cohort study. 51 patients were identified with diabetes from a validated data base from September to December 2022. Podiatry visited the two dialysis units serving locality patients, excluding patients from other NHS Trusts with differing pathways and systems of care. Data collection consisted of participant interview, medical records, hospital information systems, non-invasive foot examination, staff interviews and review of current standards of care.

Results: Ethnicity 24 (47%) Caucasian, 19 (37%) South Asian and 7 (14%) Indian. Mean age was 64.7 (35 – 85), 29 (57%) patients were male, with 88% of all patients Type II with a mean duration of diabetes of 19.8 years (1 – 45). Mean HbA1c 57.3 (34 – 102mmol/L), 45% of these patients were on insulin with 8 (16%) showing HbA1cs over 80mmol/L, 9 (17.6%) of total patients had a named diabetic specialist nurse (DSN) and was under the care of a diabetologist. 95% of patients had eye screening, and access to renal dietician. 23 (45%) patients obtained annual diabetic screening at GP practices, while only 14 (27%) had podiatry. Patients were screened for peripheral neuropathy (24%) peripheral arterial disease (33%) and foot pathologies 18 (35%). Current foot ulceration numbered 5 (10%) and 7 (14%) patients healed wounds. 12 patients only (25%) engaged in foot education. 12 (25%) felt appointment overload was a causal factor for non-attendance at prevention/treatment interventions.

Conclusion: Review by Diabetologist, DSN, integrated Dietetics and Podiatry was lacking. Dialysis staff are an underutilized resource and with education, facilitation of pathways and referral processes could add quality improvement. Further work in patient engagement is needed.

P03.2-6

Lower extremity amputation rates in persons with diabetes mellitus: a retrospective population-based cohort study in region Zwolle, The Netherlands

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ABSTRACT

Objective Lower extremity amputations (LEA) are a major complication of diabetes. Aim of this study was to describe the LEA rates in persons with diabetes mellitus (DM) in the Zwolle region (in the North East of the Netherlands), where preventive and curative foot care is organized according to current guidelines.

Design/Methods Retrospective regional population-based cohort study. Data from all persons with DM treated in primary and secondary care, living in the region of Zwolle were collected. All LEA in the period 2017 to 2019 were analyzed. Comparisons were made between persons with and without LEA.

Results A total of 5915 persons with DM were included in the analysis, mean age was 67.8 [IQR 57.9, 75.9] years, 47% was female and median HbA1c was 53 [IQR 47, 62] mmol/mol. Over the 3-year study period, 68 amputations were performed in 59 persons. This translated into an average annual crude incidence rate of non-traumatic major and minor LEA of 41.5 and 86.9 per 100 000 person-years. As compared to persons without LEA, those who did were more often male, older, mainly had T2DM, were treated in secondary care, had a higher diastolic blood pressure, a worse diabetic foot care-profile, longer DM duration and higher HbA1c. At the end of the follow-up, period 111 persons died: 96 (1.6%) in the group without amputations and 15 (25.4%) in the group with amputations ($p < 0.001$).

Conclusions This retrospective study provides detailed insight in the rate of LEA in the Netherlands. Compared to earlier Dutch data (demonstrating a major amputation rate of 89.2 per 100 000 person-years), the present incidence rate is remarkably lower. However, caution is needed when comparing data, since data sources and definitions were different between these two time periods.

Keywords: Lower extremity amputation, preventive care, diabetes podiatrist

P03.3-1

OPAT is an effective admission avoidance strategy for the management of stable diabetic foot infections

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Aim: The use of intravenous antibiotics is recommended for the management of moderate to severe DFI. In the absence of surgical resection extended courses of intravenous antibiotics are often used thus increasing patient's length of hospital stay. Outpatient antibiotic therapy (OPAT) allows for such services to be delivered to stable patients at home thus reducing the burden on inpatient services.

Method: Data was collected between 2013 and 2021 and retrospectively reviewed for length of treatments; number of patients with DFI; bed days saved and overall cost savings.

Results / Discussion: The results show that using OPAT in conjunction with other standards of care was useful in admission avoidance for DFI during the period. The number of bed days saved and costs are presented in the table below. The average cost saving is € 21362 per patient. No complications were observed in any of the participants related to the OPAT treatment. During the COVID-19 pandemic in 2020 the use of OPAT was increased to ensure vulnerable patients were managed solely in an outpatient capacity. Those in need of surgery during this period were managed in the private hospitals utilising public funding. The use of OPAT facilitated a multi-disciplinary team across multiple locations to achieve optimal care.

	2013	2014	2015	2016	2017	2018	2019	2020	2021
Bed days saved	356	472	216	209	213	363	290	589	368
Mean length of OPAT	29.66	29.5	30.8	26.12	21.3	28	32	28	31
Patients treated with OPAT	12	16	7	8	16	13	9	22	12
Cost saving									
@ €895 per night	318620	422440	193320	187055	190635	324885	259550	527155	329360
Mean cost saving per patient (€)	26551	26402	27617	23381	11914	24991	28838	23961	27446

Conclusion: The use of OPAT for stable moderate and severe infections is an effective admission avoidance strategy in those with DFI and yields significant cost savings.

P03.3-2

Mapping the risk and benefits of population based diabetic foot screening against the Wilson and Jungner principles of screening

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Background & Aim: Evidence-based and quality assured organised screening programmes have the potential to improve public health outcomes, prevent disease, and reduce disability and mortality. The introduction of organised diabetic retinopathy screening programmes has been attributed as one of the reasons why diabetes is no longer a leading cause of vision loss in some regions. In contrast, diabetic foot screening is often carried out opportunistically resulting in people either not receiving annual screening for risk factors or not being followed up appropriately. Moving diabetic foot screening (DFS) into a structured population health screening programme has the potential to reduce diabetes-related ulceration and amputation. However, before an organised screening programme can be introduced, it should meet specific criteria. We aimed to examine and map the evidence for DFS using the Wilson and Jungner (1968) principles of screening.

Methods: A scoping review methodology was conducted in line with Arksey & O'Malley and the Joanna Briggs Institute. Comprehensive searches based on principles of screening were conducted on Medline (EBSCO), Scopus, ScienceDirect and EMBASE databases.

Results: As outlined in Table 1, diabetic foot screening meets many of the Wilson and Jungner criteria for a successful screening programme. However, evidence is lacking in areas relating to screening tests and the effectiveness and cost-effectiveness of screening programmes.

Conclusion: Screening reduces diabetes-related foot ulceration and amputation, and it's clinical usefulness is evident in diabetic foot guidelines internationally. However, further evidence is needed to explore whether the introduction of an organised population-wide DFS programme is warranted.

Table 1. Assessment of diabetic foot screening against the Wilson and Jungner principles of screening

Table 1. Assessment of diabetic foot screening against the Wilson and Jungner principles of screening	
1. The condition should be an important health problem	DFUs are associated with poorer QoL, increased mortality and high costs towards health services when compared to those with diabetes but no DFUs.
2. There should be an accepted treatment for patients with recognised disease	The need for a multidisciplinary approach towards treatment and management of the at-risk foot, and active foot disease is widely recognised. However, there is no one simple treatment for DFUs, and not all patients will respond to treatment equally.
3. Facilities for diagnosis and treatment should be available	Where not already established, facilities for treatment can be expensive to establish.
4. There should be a recognisable latent or early symptomatic stage	Risk factors for ulceration are clearly defined. In addition, there are different stages to diabetic foot ulcers as illustrated by the availability of wound classification systems.
5. There should be a suitable test or examination	Appropriate screening tests are clearly outlined within guidelines internationally. However, currently recommended screening tests for peripheral arterial disease and diabetic peripheral neuropathy have poor sensitivity and specificity, when assessed gold standard reference tests. In addition, they have poor inter-rater reliability.
6. The test should be acceptable to the population	There are no reported adverse consequences of screening tests. In addition, where examined they have been found to be quick and non-invasive to administer. However, there are no available studies that have explored patient and healthcare professional's perceptions of screening tests.
7. The natural history of the condition, including development from latent to declared disease, should be adequately understood	The pathophysiology and risk factors that lead to ulceration is clearly defined within the literature.
8. There should be an agreed policy on whom to treat as patients	Once risk factors have been identified, guidelines (national and international) clearly define which patients require treatment and management for both the at risk foot and active foot disease. However, health systems will need to make decisions relevant to their local context, and availability of resources.
9. The cost of case finding (including diagnosis and treatment of patients diagnosed) should be economically balanced in relation to possible expenditure on medical care as a whole	In hypothetical models, preventing diabetic foot ulcers have been associated with cost savings for healthcare systems. However, we identified no studies that reported on the cost of diabetic foot screening programmes, and whether they are cost effective.
10. Case finding should be a continuing process and not a "one for all" project	Guidelines recommend annual screening for the foot with no previously identified risk factors. Guidelines also recommend that frequency of screening increases if risk factors are identified

P03.3-3

Podiatrists' experience of implementing Ireland's National Model of Care for The Diabetic Foot

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Background and Aim: A Model of Care (MOC) outlines the way health services should be delivered in line with best practice for a population group as they progress through the stages of a condition. In 2011, a MOC for the Diabetic Foot was first published in Ireland, outlining the roles of GP practices, and hospital and community-based podiatrists in the management of the diabetic foot. This study explored podiatrists' work activities and experiences since introduction of this MOC.

Methods: A cross-sectional survey of podiatrists working within their own private clinics, and Ireland's public healthcare system was conducted between October 2017 and April 2018. Only data relating to those working in the public health system is discussed here. It comprised closed and open-ended questions, which were analysed using quantitative descriptive statistics and qualitative content analysis, respectively.

Results: As multiple sources were used to recruit participants; the response rate could not be calculated. Total number of respondents was fifty, working across hospital (n=23 (46%)), community (n=19 (38%)) and both settings (n=8 (16%)). Most hospital-based reported carrying out annual reviews of those at high-risk (56%), seeing patients with active ulceration within 24 hours of receiving referrals (78%) and seeing them weekly (70%) until wound healing. Most community-based podiatrists carried out annual review of those at moderate-risk (63%) and high-risk (57%). Few referred those at high-risk to hospital podiatrists (32%). Respondents noted challenges towards implementing the MOC, including lack of podiatry managers, lack of awareness on the role of podiatry amongst other healthcare professionals (HCPs), lack of referral pathways and lack of resources, including insufficient number of podiatrists to meet the demand on both community and hospital podiatry services.

Conclusion: A MOC aims to improve service delivery through effecting change. Therefore, creating a MOC must be considered as a change management process, and development must also encompass implementation and evaluation of the model. This is the first study to evaluate Irish podiatrist experiences and identifies gaps and challenges (e.g., increased training for allied HCPs on the roles of podiatrists and employing more podiatrists) needing to be addressed to enable successful implementation of the MOC.

P03.3-4

Australia's national report card on achieving the goals of the national diabetes-related foot disease strategy 2018-2022

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Background Diabetes-related foot disease (DFD) is a leading cause of national disease burdens. To reduce these burdens, national disease strategies including consensus goals with actions are recommended. In 2018, Diabetes Feet Australia (DFA), launched the Australian DFD Strategy 2018-2022: The first step towards ending avoidable amputations within a generation. This paper aimed to review Australia's progress towards achieving the strategy's goals.

Methods The 2018-2022 strategy outlined nine key goals (Figure 1), with actions to achieve each goal. In May 2022, the DFA steering committee rated by consensus the nation's report card on achieving each goal, defined as completed (achieving >75% actions), partially completed (25-75%) and not completed (<25%).

Results The committee rated 3 goals completed, 4 partially and 2 not completed (Figure 1). Those completed included new national accreditation system (Goal 4), national guidelines (6), and national research agenda (7). Those partially completed included new national screening pathways (1), state-based DFD service funding (3), national database (5), and national clinical trials network applications (8). Those not completed were no new government funding for preventative services (2) and limited government funding to make national DFD research funding proportionate to national DFD burdens (9).

Conclusions Australia's national report card suggests Australia has achieved or partially achieved most of the 2018-2022 goals and not achieved two. This approach to setting and examining strategic national plans can inform DFD agendas internationally, and the findings are helping develop the new Australian DFD strategy 2023-2030: The next step towards ending avoidable amputations.

Acknowledgements Australian Diabetes Society

Figure 1: Australia's national report card toward achieving the 9 key goals of the Australian DFD strategy 2018-2022: The first step towards ending avoidable amputations within a generation.



P03.3-5

Advancing Public Health Policy for Diabetic Foot Complications in Ontario

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Background/Aim: Advancing public health policy to provide universal funding for people living with diabetic foot ulcers in the province of Ontario

Background Every four hours in Ontario, someone has a lower limb amputated due to a diabetic foot ulcer. These ulcers are the leading cause of all non-traumatic amputations below the knee, with an estimated cost to the health-care system of \$320-420 million per year in direct costs.

Methods For years, the Canadian wound-care community recognized and understood the importance and value of pressure redistribution for persons with diabetic foot ulcers and financial barriers to delivering evidence-based care. We utilized the advocacy coalition, social movement action, and knowledge-to-action frameworks, to leverage policy change. Our coalition efforts targeted increased public awareness and mobilized political support for the universal funding of offloading devices and advancing diabetic foot as a health priority.

Advocacy coalitions were formed by leading organizations to advance health policy. Wounds Canada, the Registered Nurses' Association of Ontario, Diabetes Canada, and the Nurses Specialized in Wound, Ostomy and Continence, increased public and political awareness by making public an economic analysis that demonstrated a cost savings of \$75million. The Ontario Health Technology Advisory Committee's further verified, the need for publicly funded offloading devices.

Results Ontario became the first province in Canada to announce funding for offloading devices, providing \$8 million for these devices over three years.

Conclusion As a coalition, and a Canadian Diabetic foot network, we continue to urge all provincial and territorial governments across Canada to act to improve the population health of people living with diabetes and diabetes related foot complications.

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P03.3-6

Getting a foothold of diabetic foot disease. Outcomes of a multidisciplinary inpatient clinical pathway: A Seventeen-year Institutional Review from Asia

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Background: Globally, diabetes foot contributes to poor quality of life, clinical and economic burden. It is known that multidisciplinary diabetes foot team (MDFT) management provides prompt access to specialist teams thereby improving limb salvage, yet literature on the long term outcomes of inpatient MDFT is scarce. Herein, we present a 17-year review of a multidisciplinary clinical care path (MCCP) for diabetic foot disease (DFD) in a tertiary hospital in Southeast Asia.

Methods: This is a retrospective cohort study of diabetic limb salvage attempts at a 1,700-bed university hospital from 2005 to 2021. Data was obtained from our multidisciplinary clinical pathway for inpatient diabetic foot care.

Results: There were 9,279 patients admitted with DFD with a mean of 545 (\pm SD) admissions per year. The mean age was 64 years old and there was an increased proportion of Indian and Malay patients compared to the resident population. A third of the patients had end stage renal disease and prior contralateral minor amputation. There has been an increasing proportion of patients with 4 or more comorbidities over the period of review.

There was a reduction in inpatient major LEA rate from 18.2% in 2005 to 5.4% in 2021 which was the lowest ever since inception of the pathway (Figure 1). The mean time from date of admission to date of first surgical intervention was 2.8 days and mean time from request for revascularisation to procedure was 4.8 days. The major-to-minor amputation rate was reduced from 0.50 in 2005 to 0.11 in 2021, reflecting diabetic limb salvage efforts to preserve a functional foot. Average and median Length of Stay (LOS) for patients in the pathway was 7.4 (SD = 1.9) and 6.4 days respectively. There has been a gradual trend of increase in the mean LOS from 2005 to 2021. Inpatient mortality and readmission rate was stable at 1% and 11% respectively.

Conclusions: Since the institution of a MCCP, there was a significant improvement in major LEA rate. Our review revealed that the inpatient multidisciplinary diabetic foot care path for limb salvage results are in keeping with literature and international data.

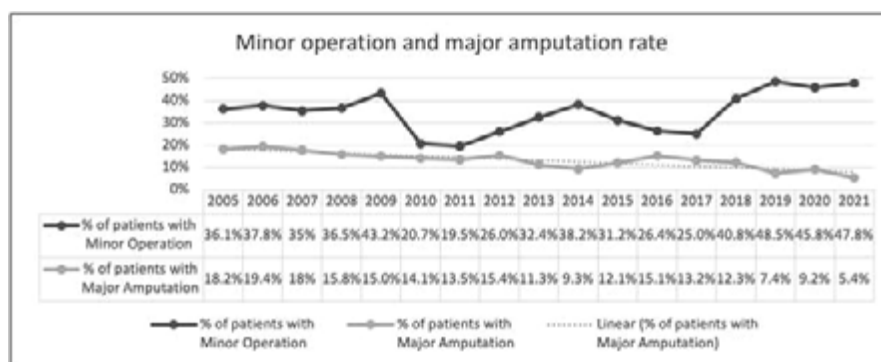


Figure 1: Minor operation and major amputation rates

P03.4-1

The Voices of Canadian Skin and Wound Care Clinicians during the Pandemic: A Qualitative Study

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Background/Aim: We explored how wound care clinicians adapted delivery of patient-centered wound care services and how they identified gaps in healthcare during the pandemic.

Methods: Participants completed a semi-structured, open-ended qualitative online survey. Individuals in the Wounds Canada data-base were sent a survey e-link. Participants were individuals who: deliver wound care services. The study had a multiphase data timeline. Over 18 months, five surveys were distributed. We compared, contrasted and analyzed the data thematically.

Results: Participants (n=392) described:

- 1) Participants described lack of foot and wound education specifically related to lower limb wounds, lack of nursing knowledge of foot ulcers.
- 2) Clinician flexibility remained and grew in relation to advocating for diabetes related wound visits, clinic appointments, and urgent care. They described distress when patients with foot ulcers progressed to amputation, and burden of caring for persons with diabetic foot ulcers, who due to the coronavirus declined nursing visits.
- 3) Increased use of virtual-care technology for persons with wounds. Technology was viewed as an asset/barrier.
- 4) The constant changing of specific policies related to opening and closing of wound clinics, wound services had impacts on the wound care delivery in all care settings and for all wound types. Participants stated they needed clear and detailed policies that supported keeping diabetes focused wound care services open.
- 5) Patient-centered issues were described as unequal patient access to, and expertise using, virtual care technology in homes (internet access, computer equipment capable of managing e-visits).

Conclusions: This pan-Canadian study focused on wound care clinicians' perspectives. Notably, persons with diabetes were described as proceeding to a worsening state or amputation. Wound care education was a significant gap in relation to basic and intermediate wound care training, including relevant technologies across care settings. This gap laid the framework for policy development and provincial wound training initiatives.

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P03.4-2

Building a Canadian Limb Preservation Community of Practice (CoP)

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Background/Aim: Develop a Canadian limb preservation CoP to: tackle rising diabetes-related amputations; and, advance research, training, advocacy, and awareness through knowledge networks linking research and practice projects.

Method: An inter-professional committee was established between Wounds Canada and several Canadian organizations. To strengthen the impact and outcome of this work, we utilized a few overlapping theoretical frameworks, including Communities of Practice — outline how people can collaborate across organizational boundaries¹ Social/Organizational/Expertise Networking — explain how individuals and groups develop and utilize relationships to share successes/failures, evidence/initiatives across expertise domains², ³ Knowledge to Action framework⁴

Results: An active Community of Practice has been established. Members are engaged and participate in various activities. Active involvement has produced:

Limb Preservation Journal (three published) and National interprofessional professional limb preservation symposiums (four annual),
Quarterly diabetic foot committee meetings
Annual social media awareness campaigns

Conclusion: This CoP conducts ongoing initiatives collaboratively. It provides a framework for knowledge creation, sharing, development and transfer. We are currently extending this across North America and the Caribbean. This approach (CoP and Network) can be replicated in other regions globally.

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P03.4-3

The Status of Wound Care Research in Canada

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Aim: To identify the characteristics of Canadian research on wound healing and prevention through a systematic approach using a scoping review methodology.

Methods: We searched Medline, Embase, Cochrane Central, CINAHL and SCOPUS from inception to July 2021 for studies analysing wound care in the Canadian population by Canadian institution-affiliated authors. Interventional, observational cohort studies, pre-clinical or animal studies were also eligible. Study characteristics, outcomes and subcategories, and important findings were collected from each article and summarised. Thematic analysis was performed to identify wound care priorities.

Results: Five hundred and sixty-five articles were included in our study. Physicians co-authored 86.7% of studies (n=490) and nurses contributed to 32.4% of studies. The top five themes identified were: wound prevention, management and treatment (n=241, 43%); surgical site infections (n=105, 19%); vascular and wound healing biology (n=100, 18%); healing apparatus and devices software (n=84, 15%); and models of follow-up care (n=83, 15%). Differences were found between authorship themes. Nurses more likely to co-author articles exploring themes related to direct patient wound care prevention, management, and treatment (Physicians: 147/241 [61.0%] vs Nurses: 154/241 [63.9%]). Physician specialties were more likely to co-author publications on surgical site infections (Physicians: 91/105 [86.7%] vs Nurses: 5/105 [4.7%]), wound healing milieu (Physicians: 79/100 [79.0%] vs Nurses: 7/100 [7.0%]) and advancing technologies (Physicians: 52/85 [61.2%] vs Nurses: 37/84 [44.0%]).

Conclusions: We mapped the scope of wound care research in Canada. Surgical wounds, pressure-injuries, diabetic foot ulcers and burns were the most reported exposures. Wound prevention, management and treatment was the most common priority followed by surgical site infections management and vascular and wound healing biology. We have provided data that supports potential high-yield themes. Our results will inform a Delphi process for a national consensus of stakeholders on wound care research priorities to accelerate improved patient outcome.

P03.4-4

Evidence-based quality indicators in diabetic foot care: the Belgian multidisciplinary expert panel opinion

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Background/Aim: Monitoring quality of care is an essential approach to optimize healthcare, but valid quality measures to study quality of care in diabetic foot clinics are scarce. When developing quality indicators (QIs), existing evidence from the scientific literature and the care experience from various stakeholders play a key role. In this study, we aimed to describe a selection of evidence-based QIs in diabetic foot care by a multidisciplinary expert panel, using a modified Delphi method in Belgium.

Methods: An expert panel including caregivers from primary care and specialized disciplines active in diabetic foot care was recruited. A list of 42 candidate QIs addressing the IWGDF domains was developed from a literature search between 2011 and 2020 and submitted for evaluation to the panel. By using a modified RAND-UCLA Appropriateness Method, experts were asked to rate each indicator for its appropriateness through a 9-point Likert scale. QIs were classified based on the median ratings and the disagreement index, calculated by the inter-percentile range adjusted for symmetry.

Results: The selection of QIs occurred in 3 phases, which consisted of an individual rating of evidence-based indicators and two panel meetings each followed by a rating process. During the panel meetings, the experts suggested refinements to QIs which resulted in a set of 32 candidate QIs. At the final phase, 17 QIs were judged as appropriate without disagreement. This set of appropriate QIs included 4 indicators addressing the domain of organization of care, 7 addressing the domain of wound healing, 1 addressing the domain of peripheral artery disease, 1 addressing the domain of offloading and 4 indicators addressing the domain of secondary prevention.

Conclusions: Based on their scientific and clinical experience, a national group of experts issued from various disciplines identified 17 evidence-based QIs appropriate for studying quality of care in diabetic foot clinics. A modified RAND-UCLA approach was used to stimulate a discussion on proposed evidence-based candidate indicators and to provide an objective measure of the collective opinion. This set of QIs provides valid and useful information for implementing an audit-system for monitoring and improving quality of diabetic foot care.

P03.4-5

Co-creation of a digital health intervention for people at high risk of developing diabetic foot disease

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Background/Aim: Diabetic foot disease (DFD) is associated with significant morbidity, mortality and healthcare expenditure. Self-care is an important part of diabetes management but people with diabetes often do not feel empowered to actively engage in self-care. Digital health interventions (DHIs) may promote patient engagement, but they must be relevant and designed in a manner that reflects the experiences of people living with diabetes. The aim of this study was to undertake early co-creation activities with patients and healthcare professionals (HCPs) to identify relevant issues that can be targeted as part of a future digital health intervention (DHI) for people at risk of developing DFD.

Methods: This study used a mixed qualitative approach that involved 1) a review of the literature and, 2) semi-structured interviews with patients with prior history of DFD and HCPs that specialise in DFD management. Patients and HCPs were identified from two teaching hospitals in London, United Kingdom. The Corbin-Strauss model, a validated theoretical framework for managing chronic illness, was applied to help determine patient needs and propose solutions that could feature in a DHI. It evaluates three key domains; 1) Illness-related work, detailing the aspects of managing the disease itself, 2) Everyday-life work, which describes how chronic illness impacts daily living and, 3) Biographical work, which focusses on the emotional burden of chronic illness.

Results: Findings from the literature review, and interviews (patients, n=19; HCPs, n=7) illustrated the considerable impact of DFD on patients' health, quality of life, and emotional wellbeing. Thematic analysis revealed four key problem areas that could be included in a potential future DHI: 1) access to simple and personalised information, 2) an interactive daily footcare routine, 3) the ability to ask questions to HCPs and 4) access to wellbeing support. Collecting individual sensory data and gamifying the experience were some participant suggestions that may enable the design of a personalised interactive DHI.

Conclusions: This theory-based and co-creation methodology holistically identified needs that should be addressed as part of a future DHI to promote selfcare and ulcer prevention.

P03.4-6

Does the Role of an Integrated Diabetic Foot Coordinator help improve outcomes?

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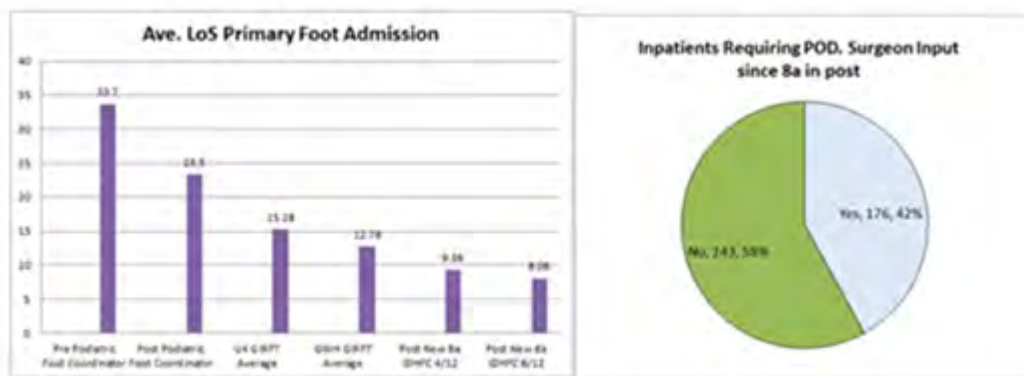
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Background Ensuring patients with complex diabetic foot complications have access to the right care at the right time is key to improving clinical outcomes. A non-surgical coordinator was appointed to aid admission avoidance and improve discharge within the diabetic referral pathway.

Methods Data from an established data base was used to review time to assessment, length of stay, surgical oversight and healing rates.

Results During a 15 month period 459 patients were reviewed, 271 inpatients, 108 in ambulatory care and 80 virtual. An average 98 % of referrals were triaged within 24 hours, improving to 100% by December 2021. The average length of stay reduced from 12.78 days to 8.06 days and those needing surgical oversight changed from 100% to 42%, with NDFA reporting 68.9% healed at 12 weeks (UK average 48.7%).

Conclusions The introduction of the IDFC has supported patient care, ensuring the right care at the right time. Shortening our inpatient length of stay. The use of robust local data collection is helping us to evidence our clinical effectiveness.



Length of stay and surgical input required

P03.5-1

Clinician perspective of the provision of care for active diabetic foot ulceration COVID-19 pandemic. Comparative study

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Aim: COVID-19 pandemic has been a concerning time for those living with active diabetic foot ulceration (DFU), who rely on regular consultations with their foot protection team. The study aimed to establish the clinician's perspective on the changes to the provision of care in this population during the government imposed pandemic restrictions, establish their opinion on how this impacted infection, ulceration, mortality rates, as well as gain their thoughts on care allocation, any barriers faced and prioritisation of high risk patients.

Method: An online national survey was distributed using purposive and snowball sampling to all members of the diabetic foot multi-disciplinary team. This survey was initially distributed during Spring of 2021 when the COVID-19 pandemic was still at a high level of national concern and service provision was still being subsequently impacted. A repeat survey is currently in circulation (Winter 2022/2023) to capture the perspective's of this same clinician cohort in a world post COVID-19 pandemic.

Results/Discussion: As the repeat survey is still in circulation no findings or comparative data has been completed to date. The initial survey yielded 36 responses with input from 5 different clinical roles that are involved in the care of active diabetic foot disease. No sophisticated data analysis has been completed until both surveys are concluded however, findings from the initial study portray frustration at service allocation, staffing, and the need for a triage system. Differing methods of triaging were used at varying hospital groups/regions.

Conclusion: Lack of communication was a recurring theme throughout, clinicians felt there's a greater need for a link between community and hospital care among clinicians, as well as communication between the patient and clinician to ease the added psychological burden and fear they were experiencing during this worrisome time. Over one year on, but has anything changed? Or have any plans been made in the event of this recurring?

P03.5-2

Charcot neuroarthropathy is missing from European Diabetes and Diabetic Foot Guidelines: A Scoping Review

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Background/Aim Evidence based management and clinical guidelines are tools used to assist clinicians in making decisions around diagnosis and clinical care. The aim of this study was to critically evaluate current national diabetes guidelines from across Europe on the diagnosis and management of acute Charcot neuroarthropathy (CN).

Methods A systematic search was performed on the Pubmed, ScienceDirect, Scopus and CINAHL databases. National guidelines from Europe were collated by two methods: a systematic review and through known diabetic foot associations and local contacts. Guidelines published after 2000 were included while any research or review articles were excluded. Guidelines were rated on five criteria: definition of acute CN and remission and for guidance on diagnostic tests, treatment and monitoring. Two independent researchers rated the criteria on quality and clinical applicability. Guidelines were rated as adequate, inadequate or missing.

Results The systematic review identified three publications which met the inclusion criteria. Intra-rater agreement was 92% at abstract screening and 74% at full text screening. A further twelve guidelines were identified through contact with people working in diabetic foot clinics. In total, 15 guidelines were assessed. Following review, 53% (n=8) of the guidelines were missing a definition of CN, and 20% (n=3) did not provide information on how to diagnose acute CN. 60% (n=9) of guidelines provided inadequate or no information on monitoring acute CN and 80% (n=12) provided inadequate or no definition of remission. 80% (n=12) recommended offloading and 20% (n=3) made recommendations on pharmacological treatment. In addition, 27% (n=4) recommended surgical intervention for chronic CN.

Conclusions European national guidelines for diabetes and diabetic foot provide inadequate advice on the management of acute CN. Definitions for diagnosis and remission of acute CN were absent or poorly recorded in the guidelines. There is limited information on the diagnosis and monitoring of acute CN. The majority of guidelines provided advice on how to off-load acute CN but there was no consistent approach to off-loading. This scoping review has identified a need to improve guidelines to better support clinicians managing acute CN.

We would like to acknowledge the support of the DFSG.

P03.5-3

Diabetic foot syndrome: assessment of the course of the disease depending on the social and family status of patients

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Aim. To evaluate the impact of the social and family status of patients on the constant overcoming of the type 2 diabetes mellitus (T2DM).

Method. A 264 patients were identified from 3 DFclinics with follow-up for 1 year. These patients were divided into groups according to their social status: Living in family (Group1, n=154), periodical care (Group, n=132), living alone (Group 3, n=110).

Of 264 patients, 135 (51%) were women, 129 (49%) were men with mean age 59.2 ± 2.7 years. Mean HbA1c was $8.7 \pm 1.7\%$. 56 (21%) patients had HbA1c $< 7.0\%$, whereas 256 (97%) patients had HbA1c $> 8.0\%$.

We estimated quantity of patients with ulcers at time of primary visit, after 6 and 12 months.

Results. At beginning there were difference between Group2 and Group1 and Group2 vs. Group3 ($p < 0.05$). At DFclinic a fear management strategy was applied to patients. However, emotional reaction of "single patient" was weak and sceptic. Reaction of patients' relatives was productive with multiple questions. From Group2 on 2nd visit 28 relatives out of 35 came for the first time. At follow-up for 1 year, we detected decreasing of ulcers in Group1 from 16 to 10%. Among Group2 a relative increasing of ulcers was detected from 12%, but 13 were "new" ulcers (11 patient admitted clinic along). In Group3 was increasing ulcers frequency from 20% to 28.5%. 5 patients underwent amputations (4 low-amputations, 1 high-amputation).

Analyses of patients who were accompanied by relatives at time of visit to DFclinic showed decreasing of ulcers frequency (0-6 months – 1 year) from 17.4-36.2-18.8%, as compared to patients "not-accompanied with relatives" for 8-34-31%, respectively.

Conclusions. Living in family even under partial care have better benefit for diabetic patients. Visit relatives together with patient to DFclinic scientifically improves effect of treatment. Alone patients have higher level of amputation and complications. A fear management strategy has a higher impact on relatives, but not on the patients. Patients are skeptical for the doctors' advices due to long-term treatment and progression of T2DM

P03.5-4

Consensus priorities for wound care research in Canada

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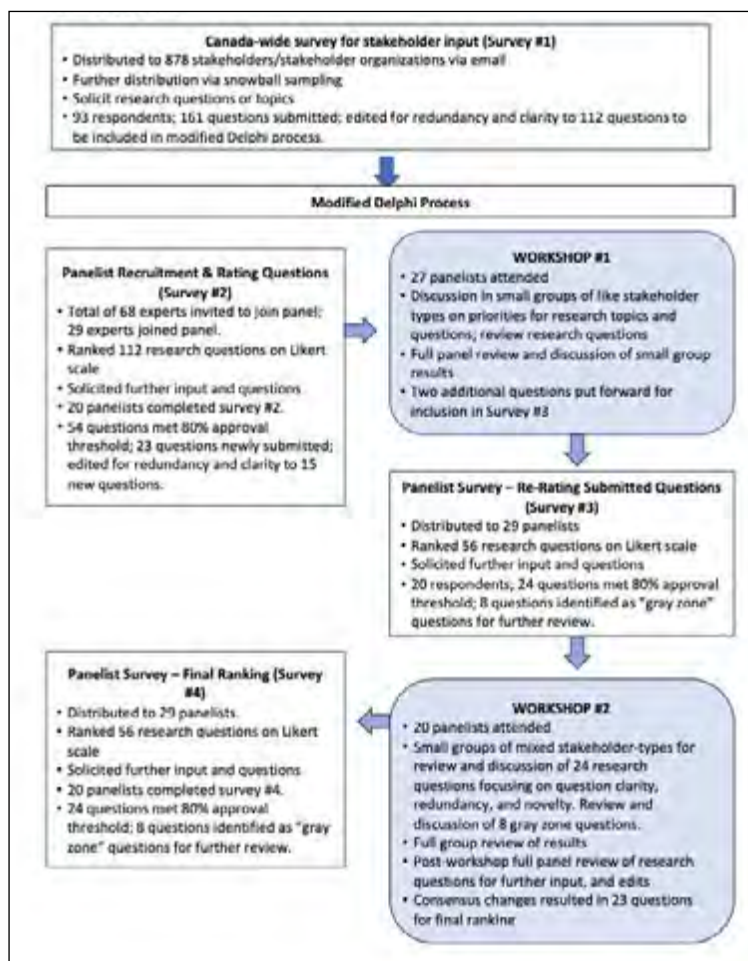
Aim Despite prolific wound care publications by Canadian researchers, there is no consensus among stakeholders on priorities for wound care research. Our objective is to identify consensus priorities for wound care research in Canada.

Methods A Canada-wide survey of wound care stakeholders was conducted to solicit priority research questions and topics. A modified Delphi consensus-building approach was then carried out involving three rounds of voting, and two virtual workshops for panelist discussions.

Results Key steps of the process and important results are summarized in Figure 1. A Canada-wide survey of wound care stakeholders produced 161 submitted research questions from 93 respondents. Sixty-eight wound and wound care experts were invited to participate as panelists in the modified Delphi process; 29 experts joined the panel. Panelists included patients, caregivers, clinicians of various backgrounds, researchers, industry partners, and Wounds Canada leaders. Through anonymous voting, 54 research questions met the 80% approval threshold to move on for further review. After a workshop discussion, 24 questions met the 80% approval threshold among panelists to move on to a final vote. Following a second workshop, panelists ranked 23 research questions in order of priority.

Conclusions A panel of 29 wound care experts broadly representing Canadian wound care stakeholders identified 23 ranked priority wound care research questions. The consensus research priorities will allow national organizations to direct future funding, advocacy initiatives, and targeted research to reduce the burden of wounds on patients and the healthcare system.

Overview of Methods for Identifying Stakeholder Consensus on Wound Care Research Priorities



P03.5-5

Lean thinking as a problem-solving approach in a diabetic foot (df) clinic

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Aim – Lean Thinking is a certified technique for the quality implementation in complex systems like factories, distribution chain supply etc. Aim of our study was to check if the application of the lean management approach to our DF clinic would produce positive effects in the quality of the work of the podologists.

Materials and Methods – A thorough analysis of working processes was carried out in our DF clinic for six consecutive months and three critical aspects were identified: 1. The supplying of materials and the organization of storage, 2. The pathways for the patients accessing the clinic for being visited or leaving it after the visit and 3. The distant location of the waiting room. The interventions consisted in 1. the implementation of a web-based operative program for the supply of materials and the re-organization of the storage, 2. the creation of separate pathways for patients in and out the clinic and 3. The relocation of the waiting room. we measured before and after the changes for one month respectively: 1. rates of missing materials (RMM), 2. time for patients' changing in the visit rooms (TPC) and 3. rate of occupation of the waiting room (ROW).

Results – RMM significantly decreased after the intervention ($3.2 \pm 1.1\%$ vs $12.4 \pm 3.7\%$, $p < 0.01$); TPC reduced as well (5.2 ± 2.3 min vs 10.8 ± 4.1 min $p < 0.05$), while ROW did not show significant modifications although it improved ($72.4 \pm 16.8\%$ vs $60.1 \pm 22.3\%$ ns).

Conclusions – Lean management is effective in improving the quality of podological work in a DF clinic.

P03.5-6

Changes in self-care skills and nursing needs after in-hospital treatment for foot problems in patients with diabetes: A descriptive study

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Background/Aim: There is limited data regarding changes in patients' selfcare skills and needs for assisted selfcare after discharge from in-patient treatment due to foot ulcer related complications in patients with diabetes. The aim of this study was to examine ability to self-care and needs for assisted nursing interventions at hospital discharge compared to pre-admission for patients with diabetes admitted and treated for foot related complications.

Methods: A retrospective assessment was done of the medical records of patients with diabetes consecutively admitted to a specialist in-patient unit due to foot ulcer complications, between November 1, 2017 and August 30, 2018. Data on daily self-care needs and home situation at admission and discharge were recorded.

Results: 134 patients were included; median age was 72 years (38-94), 103 (76.9%) were male, and 101 (73.7%) had diabetes type 2. Median length of admission was 10 days (2-39). Infection was the most common cause of admission (51%), severe ischemia in 6%, and combination of both in 20%. Surgical treatment was performed in 22% and vascular intervention in 19%. Patients discharged to home without assistance were 48.1% compared to 57.5% before admission, discharge to home with assistance 27.4% vs. 22.4% before admission, and 9.2% discharged to a short-term nursing accommodation vs. 6% before admission. Three patients died during the stay in hospital. Need for help with medications increased from 14.9% of patients at admission to 26.7% at discharge and for mobility assistance from 23.1% to 35.9%. Social services at home were increased in 21.4% of patients at discharge.

Conclusions: Patients admitted for diabetic foot complications showed increased need for daily physical and nursing help after receiving treatment in hospital. Careful planning is necessary before discharge to ensure adequate assistance is provided.

P03.6-1

Distal symmetric polyneuropathy is the most common complication of diabetes and an independent risk factor for development of foot deformities

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Background/Aim: Diabetic sensorimotor polyneuropathy (DSPN) is associated with foot ulcers and amputation. The association between DSPN and foot deformities is poorly investigated. We aimed to investigate the association between various forms of DSPN and the prevalence of foot deformities and possible pressure-induced callosity in individuals with diabetes.

Methods: In this cross-sectional study 109 individuals with Type 1 or Type 2 diabetes were included. Foot deformities were assessed using a novel in-house screening tool covering deformities and callosity. DSPN was assessed by several point-of-care measurement and was categorized in 4 groups; “no DSPN”, “large fiber neuropathy” assessed by Bio-Thesimeter and monofilament (10 g), “large fiber neuropathy by additional measures” assessed by DPNCheck, and monofilament (75 g) and “small fiber neuropathy” assessed by pinprick, Rolltemp™ and Sudoscan™. Bilateral abnormal measurement in one or more measures constituted neuropathy. Foot deformities were stratified into three groups with or without callosity and/or nail deformities.

Results: All individuals included in this study had DSPN. The individuals were normally distributed for diabetes type, diabetes duration, retinopathy, and prior amputation. Individuals with DSPN assessed by Bio-Thesimeter and monofilament (10 g) were older, had a higher prevalence of male sex and a lower mean estimated glomerular filtration rate compared to the other two groups. There were no significant differences in the prevalence of deformities and neither in callosity between neuropathy groups (Table 1).

Conclusion: Prevalence of foot deformities and callosities are not significantly different in individuals with various forms of DSPN. This underlines, that neuropathy assessment cannot replace foot examinations.

Table 1: Classification of alterations in feet (unilateral/bilateral)

P03.6-2

Nerve decompression for superimposed peripheral neuropathy in diabetes: An update on the current literature and awareness among medical professionals

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Background: In 2009, a questionnaire disclosed that most medical professionals involved in diabetes care endorsed the theory of superimposed nerve compression in diabetic sensorimotor polyneuropathy (DSP), although <10% of professionals were aware of the potential value of nerve decompression surgery [Melenhorst, 2009]. Since then, more literature shows promising effects of nerve decompression. Therefore, we reviewed clinical studies on lower extremity nerve decompression surgery to assess the awareness among medical professionals nowadays and whether there has been a learning curve over the past 13 years.

Methods: A nationwide questionnaire was sent to medical professionals (general practitioners, endocrinologists, neurologists, plastic surgeons, vascular surgeons, orthopaedics, neurosurgeons, anesthesiologists, diabetes specialist nurses, podiatrists) involved in diabetes care.

Results: Table 1 shows the questionnaire outcomes for professions involved. 62% (versus 23% in 2009) confirmed to be aware of the theory that nerve compression plays a role in the pathophysiology of DSP and 73% (past: 60%) believes this could be the case, whereas only 17% is aware of current the literature. 77% (past: 45%) explains DSP to be irreversible and only 23% (past: 3%) refers to a surgeon. As questionnaire data is being gathered, more response data is expected in the following months.

Conclusion: In the last 13 years, more clinical studies reported outcomes of nerve decompression surgery, which led to a learning curve and more referrals to surgeons. Though professionals state they are aware of the theory and believe nerve compression may play a role, the majority of professionals explains DPN to be irreversible.

Medical specialists	N	Involved in diabetic care	Aware of theory (%) [*]	Aware of literature (%) [•]	Thinks compression may play a role (%) [†]	Aware of possible value of surgery (%) [‡]	Explains DPN is irreversible (%) [§]	Refers to surgeon (%) [¶]	Refers to other specialist (%) [¶]
General practitioners	15	100	40	0	62	7	93	7	60
Endocrinologists	25	92	71	12	71	33	70	16	68
Neurologists	68	97	57	9	52	29	94	56	44
Plastic surgeons	71	48	93	47	97	91	56	24	19
Vascular surgeons	35	100	60	17	59	33	82	29	43
Orthopaedics	54	26	36	6	66	23	54	26	72
Neurosurgeons	40	30	65	23	62	51	74	17	17
Anesthesiologists	36	100	58	17	57	14	80	19	53
Diabetes specialist nurses	68	100	47	6	81	14	76	18	68
Podiatrists	132	99	68	16	82	18	86	9	29
Overall	544	79	62	17	73	33	77	23	42
2009	172	97	23	-	60	9	45	3	-

^{*}"Are you aware of the theory that nerve compression injury plays a part in the pathophysiology of diabetic peripheral polyneuropathy?"

[•]"Are you aware of the latest literature on nerve compression in of diabetic peripheral neuropathy and suspicion of compression polyneuropathy?"

[†]"Do you think that nerve compression injury may play a role in the development of diabetic neuropathy?"

[‡]"Are you aware of the potential value of nerve decompression surgery in the treatment of peripheral diabetic neuropathy?"

[§]"Do you explain to the patient that peripheral diabetic neuropathy is an irreversible condition?"

[¶]"Do you refer to other medical professionals when considering diabetic neuropathy?" "If yes, to which specialty?"

Questionnaire outcomes

P03.6-3

Neuromuscular Electrical Stimulation as a novel technology in the treatment of Diabetic Neuropathy: A qualitative analysis of patient perspectives.

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Background: There is a need for non-invasive, disease-modifying treatment options for diabetic neuropathy (DN). The efficacy of a footplate neuromuscular electrical stimulation (NMES) device (Revitive Medic Coach, Actegy Ltd, UK) is currently being evaluated in a prospective randomised controlled trial¹. In this study, we aimed to identify barriers and facilitators to using a NMES device for the treatment of DN, to better understand and design protocols for this novel therapy.

Methods: Twelve semi-structured interviews were conducted (Group 1 n=6; Group 2 n=6). Group 1 participants did not have DN but did have previous experience of using NMES as participants of the NMES-REHAB trial². Group 2 participants had a history of DN with no previous NMES experience and were given the opportunity to trial the device. Interviews were transcribed and thematic analysis based on inductive reasoning was used to code and extract the main themes identified.

Results: Common barriers included a lack of instructions for the device, a lack of understanding of the NMES technology and tolerance of NMES. Barriers specific to people with DN were perception of safety and lack of sensation. Facilitators common to both groups were device usability, independence and potential symptomatic relief. Facilitators specific to people with DN were following a daily routine and potential prevention of diabetic foot complications. Qualitative interview data suggested that tolerance to NMES therapy may be related to severity of DN.

Conclusion: NMES treatment protocols would benefit from including a period of familiarisation and patient engagement, clear safety instructions and an interface that alerts to when the device is active. The novel themes identified in this study can inform the development of future NMES treatment protocols and research, with the aim of improving treatment uptake and adherence, both in patients with DN and other target patient groups.

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P04.1-1

Risk factors for at-risk foot and peripheral artery disease among the population with diabetes: a multicommunity-based cross-sectional study

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Background: Diabetic foot (DF) is common, complex, multi-disciplinary disease and could bring substantial medical and health care burdens. Identifying at-risk foot as early as possible through screening could prevent it in advance and fundamentally reduce the incidence of DF and alleviate patients' pain. This study aimed to investigate the prevalence, characteristics, and influence factors of at-risk foot.

Methods: This multicommunity-based cross-sectional study included 3030 diabetes mellitus (DM) patients from the at-risk foot screening program of Shanghai Zhongshan and Jinshan PROactive prevention of diabEtiC foot study (Shanghai ZIS PROTECT study) between March 21 and April 30 in 2021. Questionnaire survey, physical examination, and fasting blood sample collection were completed for all subjects. T-test and Pearson Chi-square/Fisher exact tests were utilized for descriptive analysis. Multiple logistic regression models were applied to evaluate influencing factors for diabetic foot, peripheral artery disease (PAD), and LOPS.

Results: The prevalence of at-risk foot was 27.8% among DM patients. Those with moderate-high risk of DF were older, and had higher glycated hemoglobin (HbA1c) level, longer duration of DM, higher pulse rate and lower estimated glomerular filtration rate (eGFR). For higher at-risk grade, age, urinary albumin creatinine ratio (UACR) and eGFR were independent influencing factors (OR=1.04, 95%CI=1.02-1.06; OR=1.001, 95%CI=1.000-1.002; OR=0.991, 95%CI=0.899-1.119, respectively). The prevalence of peripheral artery disease (PAD) was 11.1% in all people with diabetes, and age, pulse rate, and low-density lipoprotein (LDL) were independent risk factors for PAD. In contrast, high-density lipoprotein (HDL), eGFR, and LMR were independent protective factors for PAD. HbA1c was not an independent risk factor for increased risk grade or more severe PAD. Different UACR groups were not independent risk factors for mild PAD; however, compared with people with eGFR≥60, eGFR ranges from 30 to 45 significantly increased the risk of mild PAD (OR=3.076, 95%CI=1.454-6.211).

Conclusions: The results found that at-risk foot accounted for a high percentage among DM patients, illustrating the importance of early at-risk foot screening programs. Advanced age and renal dysfunction are independent risk factors for the at-risk foot. Glycemic control does not reduce the risk grade of at-risk foot and the incidence of PAD.

P04.1-2

Engagement of patients regarding diabetes foot protection post covid 19 in Belfast HSC Trust

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Background Post covid 19, rebuild of foot protection services was essential in Belfast. Whilst most patient contacted the service for an appointment, many did not self-refer. As part of the rebuild, we contacted 1489 patient of moderate to low with pathology foot risk to enable a review using special SUPER star (screening to assign risk) clinics.

Aim A group of patient who had not attended within 1-3 years with a moderate or low with pathology foot risk were invited to attend podiatry via a partial booking system. Review outcomes of engagement and risk levels post project. This would allow correct allocation to the diabetes foot care pathway for N. Ireland. 1

Method The group of patient discussed were to attend and post intervention, an analysis of their demographics, attendance and outcomes was assessed via excel.

Results 35% of patient did not engage.

Of the 65% who attended, only 6.6 % moved to High foot risk and 0.2 % to active foot risk.

Demographics Over 70 years old 53% versus 47% under 70.

40 % of the under 70's DNA/No response verses 29% of the over 70's

Highest areas of social deprivation in Belfast had some of the highest levels of non-attendance, levels reaching 41% no response/DNA.

Conclusion Belfast as a city has some of the highest rates of health inequality in N Ireland, with the lowest age of mortality for both males and females in N Ireland. 2

This was a group of patients not actively engaging with our service and missingness in healthcare is linked to multiple long- term conditions, socioeconomic deprivation and appears to be linked to greater risk of mortality, particularly if mental health issues are one of the long-term conditions.3

Lack of engagement due to missingness is of concern as it may lead to complication occurring for patients living with diabetes and they may not contact in an emergency. 1

How we engage going forward with these patient groups is important not only for foot health but from a public health perspective. Further research and review of how we can engage is necessary.

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P04.1-3

Podiatry supply of Flucloxacillin in cases of mild diabetes foot infection – A Review

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Background: The timely treatment of diabetes foot infections is important to prevent the rapid progression of infection, hospital admissions and amputation¹. Antibiotic therapy is necessary for all diabetes foot infections². Podiatrists with HCPC POM-S annotation can supply Flucloxacillin 500mg, one four times a day for seven days, for mild foot infections³.

Aim: The aim of this review was to assess the issue of 500mg of Flucloxacillin, one four times a day for seven days, with patient outcomes within community foot protection teams.

Methods: The records of all patients diagnosed with mild infection according to IWGDF classification¹, and issued 500mg of Flucloxacillin, one four times a day for seven days, between 23/8/19 – 31/8/22, by a podiatrist working in a Community Wellbeing and Treatment Centre within BHSCT were included. All podiatrists were required to adhere to the Safe Operating Procedure for supply of Flucloxacillin to patients. Data analysis was preformed using Microsoft Excel 2016®.

Results: A total of two hundred and thirty patients were supplied 500mg of Flucloxacillin, one four times a day for seven days, by a community podiatrist during 23/8/19 – 31/8/22.

One hundred and sixty one cases of infection completely resolved. Sixty nine cases of infection did not resolve. Thirty seven cases required further oral antibiotics. Twelve cases antibiotic was changed following microbiology results. Thirteen cases required hospital admission for spreading infection. Five cases required hospital admission for deteriorating ischemia. Two cases did not attend follow up.

Conclusions: This review has shown the supply of Flucloxacillin 500mg, one four times a day for seven days, by community podiatrists can improve and resolve mild foot infections. It can also ensure timely access to antibiotics avoiding delays in therapy. Podiatrists with HCPC POM-S annotation should utilise supplying for mild foot infection where appropriate

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P04.1-4

Periosteal distraction combined with nerve release for diabetic foot

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Objective: To analyze the clinical efficacy of the periosteal distraction technique combined with nerve release in the treatment of diabetic foot.

Methods: Seventeen patients with diabetic foot who were admitted to the hospital with a score of 7 or above were selected by the Brief Pain Assessment Inventory (BPI) and the Visual Pain Scale (VAS), and the above patients were treated by the periosteal distraction technique combined with nerve release surgery. Transcutaneous partial pressure of oxygen, skin temperature, Brief Pain Assessment Inventory (BPI), visual pain score (VAS) and observation of wound healing were measured.

Results: The transcutaneous partial pressure of oxygen and skin temperature of the patients were significantly increased; the patients felt significantly less pain and numbness than before surgery and the wound healing was faster.

Conclusion: The periosteal distraction technique combined with nerve release can improve the oxygen content of the patient's skin and affected limb. It also significantly reduced the pain and numbness in the affected limb, significantly improving the patient's quality of life. The combined treatment further promoted the healing of the wound.

P04.1-5

Vascular patients and podiatry referrals, and patient coding of patients reviewed in the vascular multi disciplinary meeting

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Background/Aim: Integrated podiatry services have a pivotal role in the care of patients with peripheral arterial disease (PAD). Podiatry helps to detect PAD (1), deliver prophylactic foot care and manage complications such as foot ulcers, thus reducing morbidity, the risk of lower limb amputation, and mortality (2,3). The identification of these patients is therefore important. Local access criteria help identify patients eligible for podiatric care. However, the number of patients referred to podiatry by the vascular service, and those with a recorded high-risk foot care plan is currently unknown. A weekly vascular multi-disciplinary team meeting (VMDTM) reviews patients with arterial disease who may require vascular intervention. This cohort of patients formed the sample population. This initial audit aimed to evaluate whether patients with PAD were known to the podiatry service, and if the correct high-risk podiatry care plan was recorded in the patients' notes.

Methods: 111 patients were discussed in the VMDTM between January and April 2022; 77 patients met the local criteria for podiatry care. The patient records were manually reviewed; it was noted if the patient was known to the podiatry service and if a high-risk care plan was documented. Recorded symptoms of claudication or ulceration were noted. The data was tabulated and analysed using Microsoft Excel.

Results: 66% of eligible patients discussed in the VMDTM were not known to podiatry. 72% of patients known to podiatry had high-risk care plans. 35% of patients with symptoms of claudication and 25% of patients with foot ulcers were known to podiatry.

Conclusions: Most patients were not known to podiatry. Possible reasons include a lack of clinicians' awareness of how to refer, an unclear referral pathway, the lack of underpinning education. Further research is required, to improve referral rates and encourage the recording of comorbidity data and care plans to improve the management of these vulnerable patients.

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P04.1-6

MicroRNA-34a improves wound healing in diabetes through metabolic reprogramming and macrophage polarization

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Background/Aim: Diabetes foot ulceration (DFU) is a chronic diabetes complication with large impact on morbidity and mortality. The therapeutic possibilities are limited due to incomplete understanding of mechanisms underlying the disturbed wound healing. Recently, aberrant microRNA expression has been suggested to be involved in the pathogenesis of diabetes complications. MicroRNA-34a (miR-34a) is one of the miRNAs which has been observed to be dysregulated in diabetes, and it is known to affect cellular functions important for wound healing. In this study, we aimed to characterize miR-34a regulation in diabetes and its effect on wound healing.

Methods: miR-34a levels were analyzed in biopsies from DFUs and in the wounds from db/db mouse model of impaired wound healing in diabetes compared to wounds from normoglycemic control mice. The regulation and function of miR-34a in diabetic conditions was further analyzed in macrophages (RAW264.7 cells) and db/db mice.

Results: We found that miR-34a was downregulated in DFUs and in wounds from db/db diabetic mice compared to wounds from normoglycemic controls. Hyperglycemia significantly inhibited miR-34a expression in macrophages in hypoxic conditions. The negative regulation by hyperglycemia on miR-34a in hypoxia was found to be exerted on the transcriptional level, mediated by downregulation of upstream regulator p53. Mechanistically, miR-34a reconstitution in diabetic conditions increased oxygen consumption rate (OCR) and intracellular ATP, whilst decreasing extracellular lactate production in macrophages, resulting in a polarization from pro- to anti-inflammatory changes. Local administration of miR-34a significantly improved wound healing specifically in db/db mice. RNA-sequencing data suggested that miR-34a treatment affected the oxidative metabolism and inflammatory response in the wounds. Fluorescent immunohistochemistry confirmed an increase in prevalence of anti-inflammatory macrophages in miR-34a-treated wounds.

Conclusions: Our results suggest that reduced miR-34a expression is pathogenic for wound healing in diabetes, and miR-34a reconstitution can be a novel potential therapeutic strategy for DFU through alleviating hyperinflammation.

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P04.1-7

Correlation between controlling nutritional status score and amputation risk in patients with diabetes foot ulcer in China

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Aim: More than half of diabetes foot ulcer (DFU) patients have moderate or severe malnutrition, especially in elderly people. Previous literatures have reported that malnutrition is related to DFU wound healing. However, there are few reports on the correlation between nutritional status and lower limb amputation in DFU patients. Controlling nutritional status(CONUT) score is an objective screening tool, which is simple and easy to operate. This study retrospectively analyzed the clinical features and outcomes of DFU patients to investigate the effect of CONUT score on amputation risk and hospitalization time of DFU patients.

Methods: A total of 360 inpatients with DFU in our Diabetes Center from January 2016 to December 2018 were enrolled and analyzed retrospectively in this study. Based on CONUT scores, patients were divided into 3 groups: normal nutritional status group(0~1 scores, n=100), mild nutritional status group(2~4 scores, n=164), moderate-severe nutritional status group ≥ 5 scores, n=93). Patients were also assigned into amputation group(n=110), non-amputation group(n=247), and death group(n=3) according to the clinical outcomes. The clinical characteristics, amputation rate, hospitalization days were compared among those with different CONUT scores.

Results: The total amputation rate of DFU patients was 30.6%. Among all amputations, the major amputation rate (above-the-ankle amputation) was 1.8%, and the minor amputation rate was 98.2% (1.7% for below the ankle amputation and 92.7% for toe amputation). The amputation rate in patients with mild and moderate-severe nutritional status were 1.5 and 1.3 times higher than those in the normal nutritional status, respectively. Logistic regression analysis showed that the mild nutritional status(2~4 scores), Wagner classification and C-reactive protein were independent risk factors for amputation. With the increase in CONUT score, the amputation rate gradually increased, the length of hospital stay was gradually prolonged.

Conclusions: CONUT score is closely associated with amputation of DFU patients, improve the nutritional status of patients in the early stage could reduce the risk of amputation.

P04.1-8

Relationships between metrics derived from continuous glucose monitoring and diabetic lower extremity ulcers

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Background: Time in range (TIR) derived from continuous glucose monitoring (CGM) associates with many diabetic complications. However, few reports are on the correlation between TIR and diabetic lower extremity ulcers (DLEU). The purpose of this study was to further explore the correlation between CGM indexes and DLEU, as well as the influencing factors of TIR, coefficient of variation (CV) of blood glucose, time above range (TAR), and time below range (TBR).

Method: A total of 600 people with type 2 diabetes mellitus (T2DM) (including 306 DLEU and 294 non-DLEU) were recruited in this retrospective study. The general clinical data, complications, and comorbidities were collected; a hematological examination and 72-hour CGM were performed. The percentage of glucose range from 3.9-10.0 mmol/L was defined as TIR. Level 1 TAR and level 2 TAR of 3.9-10.0 mmol/L and >13.9-mmol/L were evaluated with CGM, respectively. Logistic regression analyses were carried out using SPSS 26.0 software in different groups.

Results: The average and minimum blood glucose of CGM, TAR, level 1 TAR, level 2 TAR, glycemia risk index (GRI), and HbA1c were higher, while the levels of TIR, TAR, and level 2 TAR were lower in people with DLEU. Among the 306 people with DLEU, 11 people (0.33%) had undergone amputation. Amputees had significantly higher GRI, HbA1c, level 2 TAR, maximum glucose fluctuation range (LAGE), daytime means absolute glucose difference (MODD), standard deviation and maximum blood glucose of CGM. TIR did not affect the risk of amputation in patients with DLEU. Random blood glucose and fasting blood glucose (FBG) were negatively related to TIR whereas serum sodium and diabetic peripheral neuropathy were positively associated with TIR. HbA1c and the absolute value of monocytes had a significant negative influence on TAR. HbA1c level and diabetes course could negatively influence CV.

Conclusion: TIR was negatively associated with DLEU. Glycaemic metrics (TIR and CV) obtained in CGM could be influenced by random blood glucose, FBG, the absolute value of monocytes, HbA1c, and diabetes course in patients with DLEU. Further studies are needed to explore the relationship between metrics derived from CGM and clinical outcomes in people with DFUs.

P04.2-1

The accuracy of the Ipswich touch test to detect loss of protective sensation in an urban outpatient population in India

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Background: Early detection of the loss of protective sensation (LOPS) in the diabetic foot is very important for the effective prevention of diabetic foot ulceration (DFU) and amputations. The Ipswich touch test (IpTT) is a simple screening method that has been previously validated in hospitalised individuals with diabetes (1). However, it remains unclear if it can be deployed in frontline clinics, especially in austere clinical environments and in developing countries, like India. India is currently experiencing an explosive increase in the prevalence of diabetes which makes the need for reliable screening and effective DFU prevention even more acute.

Aim: To assess the accuracy of IpTT as a screening tool for LOPS in India.

Methods: 252 (male:57, female:195) adults with diabetes (Type 1 or 2) who were attending the diabetic outpatient clinic of Sri Ramachandra Medical College hospital were enrolled into the study (mean age= 58 ± 11 years, body mass index= 27 ± 5 kg/m², duration of diabetes= 12.5 ± 9.5 years). IpTT results were compared against the gold standard method for LOPS detection, namely measurements of vibration perception threshold (VPT) using a neurothesiometer (Horwell Scientific, U.K.).

Results: 21% of participants had LOPS based on VPT (i.e., VPT ≥ 25 V at the hallux). Calculation of Cohen's Kappa (k) indicated fair agreement between VPT and the IpTT (k=0.382, p<0.001). The IpTT's sensitivity, specificity, positive and negative predictive value was 71%, 76%, 44% and 91% respectively.

Conclusions: The results presented here demonstrate for the first time the utility of IpTT as a screening tool for LOPS in an urban outpatient population in India. However, the observed sensitivity and specificity were lower relative to the literature (1,2). This deviation from relevant literature may be the result of differences between the tested populations (predilection for barefoot walking etc.). Potential modifications to the test, and direct comparison against the 10gm monofilament would provide additional insight into its effectiveness. Nonetheless, the observed high negative predictive value does indicate that the IpTT is a useful cost-free screening option for LOPS in resource poor settings.

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P04.2-2

Efficacy versus cost of different types of silver dressings in neuropathic diabetic foot ulcers

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Background/Aim: The diabetic foot ulceration risk is 15%-20%. Wound care plays a pivotal role in the management of diabetic foot ulcers (DFU). Different formulations of silver dressing are available in Egyptian market with different prices but there is little consensus on which one of the available products is cost effective for the DFU. This is mostly due to a lack of research-based evidence to support the use of one dressing over another.

As a lower- middle income country, it was important to study the cost effectiveness of available different silver products in neuropathic DFU healing.

Methods: We conducted a single-center, prospective, randomized study involving 60 outpatients with neuropathic DFU. All patients received standard care for their wounds, different offloading modalities divided randomly into two groups according to the type of silver dressing which was applied. A silver foam dressing which costs 240 LE per 10×10 cm sheet and another nanocrystalline silver spray which costs 950 LE per 236 ml bottle during a 12-week treatment period. Follow-up visits were done every 2 weeks. Target was the percent of reduction of the ulcer size after 12 weeks or complete healing if occurs earlier.

Results: Both research groups were comparably composed considering gender, age, and ulcer characteristics. Ulcer surface area before intervention 2.33(0.25-5) in the foam group vs 3.0(0.72-6.0) in nano spray group, p=0.127

Complete healing of ulcer observed significantly in the foam group (20 patients (66.7%) vs 11 patients (36.7%) in nano spray group, p=0.02)

Percent of reduction of the ulcer size after 12 weeks was higher among foam group than nano spray group (43.9% vs 20.3%) respectively, p=0.049

The cost of treatment was significantly lower in the foam group (368.0±121.78 LE) vs (950.0±0.0 LE) respectively, P<0.001

Conclusions: The silver foam dressing was significantly more cost-effective than the nanocrystalline silver spray in neuropathic DFU healing.

P04.2-3

Cost-utility analysis of rhEGF versus NPT in the treatment of complicated diabetic foot ulcers in the Colombian setting

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Aim: The objective of this study is to determine whether intra- and perilesional recombinant human epidermal growth factor (rhEGF) is a cost-effective technology for the management of patients diagnosed with complicated diabetic foot ulcer (DFU) without infection

Methods: A cost-utility analysis was made from the perspective of the Colombian health system, comparing intra and perilesional rhEGF and NPT. The health outcome used was QALY. A Markov model was designed. For the base case, a 5-year time horizon and weekly cycles were adopted. Transition probabilities were obtained from a systematic literature review. The identification and measurement of resources was based on clinical practice guidelines and expert consultation. The cost of drugs, procedures and supplies was obtained from official health information sources. In the base case scenario, negative pressure therapy is an intervention-dominated strategy for the outcome of QALY.

Results: Table 8 show the results of the base case, ordering the alternatives from lowest to highest cost. NPT is the most expensive alternative at \$US213,330, followed by rhEGF with a cost of \$US67,822. The therapeutic alternative of rhEGF is a dominant strategy; its average cost is lower compared to the NPT alternative. Likewise, it contributes more QALYs for these patients (2.64 versus 2.39). This indicates that an additional QALY has a better cost-effectiveness ratio in the case of growth factor.

Conclusions: It was concluded that the use of rhEGF is a feasible option for the management of Wagner grade 3 or 4 DFU due to the higher effectiveness and lower cost compared to NPT. The NPT and the rhEGF are not competing therapies, they are complementary.

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Table 8. Base case results (dollars)

Table 8. Base case results (dollars).					
Alternatives	Cost	Incremental cost	Effectiveness	Incremental effectiveness	ICER*
AVAC ¹					
rhEGF ²	67,822.03		2.64		
NPT ³	213,330.91	145,508.88	2.39	(0.24)	DOMINATED
¹ QALYs: quality-adjusted life years ² rhEGF: intra- and perilesional recombinant human epidermal growth factor ³ NPT: negative pressure therapy ⁴ ICER: incremental cost-effectiveness ratio					

P04.2-4

Implementing an accessible, streamlined, carbon-efficient, Integrated Diabetes Clinic in Kenya- Cornea to callus.

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Diabetes Mellitus, like climate change, is a looming crisis. For every degree Celsius rise in global temperature, there is an increase in the diabetes incidence by 0.31%.[1] It is known that urbanization and consumption of highly processed foods appear to be worldwide vectors for both climate change & diabetes.[2]

This 25-year-old outpatient Eye Hospital provides gold-standard eye care to people with limited resources. The significance of combining a diabetes clinic with eye treatment was recognised five years ago. The triage team's use of fingerstick glucose and blood pressure testing assists in identifying patients who can benefit from Diabetes Care Clinic (DCC) consultation. Upon referral, the diabetes nurse educator then provides education and support to these patients, to facilitate better management of diabetes and prevent complications. The use of conversation cards with hard-to-ask questions can make it easier for patients to discuss sensitive topics with their diabetologist, improving communication and overall care.e.g. sexual dysfunction.

After consulting a diabetologist, a strategy is created, based on history, features suggestive of complications, clinical examination that includes a retina exam via handheld ophthalmoscope or fundus camera, carotid bruit and cardiac auscultation, 3 minute foot examination (dermatological, neuropathic and Vascular), minimum parameters (keeping in mind affordability)- Hemoglobin, HbA1c, Creatinine with UACR, ECG. This is followed by a review with the diabetes educator/nutritionist to reinforce diabetes education & verification that the clinic has consent to contact the patient, and provide access to peer support networks with diabetes caveats.

Subsequently, they visit their clinic with a plan for review in the DCC.

Low-plastic topical oxygen wound therapy and biodegradable wound care items are encouraged in the clinic, which is mostly paperless.

Why adopt a carbon efficient approach? Climate change and diabetes have long been intertwined, but are seldom discussed. The Intergovernmental Panel on Climate Change, has reported worsening of planetary health; to which the healthcare industry is the 5th largest contributor.

Intensive screening for diabetes and its complications ensures early diagnosis and cost effective treatment thereby lowering a person's carbon footprint. When it comes to climate injustice, we're all complicit.

P04.2-5

Cost-utility analysis of foot-ankle exercise programme for musculoskeletal dysfunctions in people with diabetes: Randomised controlled FOOCAre (FOCA) Trial I

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Background: The aim of this study is to estimate the incremental utility cost ratio (ICUR) of a rehabilitation technology, in booklet format, with foot and ankle exercises for the prevention and treatment of musculoskeletal disorders in people with DPN in relation to the usual outpatient treatment for diabetic foot provided in the Brazilian public health system.

Methods: This is a secondary analysis of a clinical trial (registered as NCT02790931 at ClinicalTrials.gov) that evaluated the efficacy of an 8-week foot-ankle exercise program performed with a booklet in people with DPN. 48 DPN-subjects were randomized and distributed between control group (CG) and intervention group (IG). Complete economic evaluation of the cost-utility type, in the piggyback evaluation modality was performed. The utility index was determined by the EQ-5D, and only direct medical costs were included in the analysis. The Quality Adjusted Life Year (QALY) was used as utility measure and was calculated by multiplying the duration of time spent in a given health state, by the quality of life weighted [1]. For the calculation of the incremental cost-utility ratio (ICUR) the equation used was $ICUR = (IG \text{ cost} - CG \text{ cost}) / (IG \text{ QALY} - CG \text{ QALY})$.

Results: The average utility index was 0.626 ± 0.149 for CG and 0.639 ± 0.152 for IG before treatment, and 0.628 ± 0.197 for CG and 0.608 ± 0.148 for IG after 8 weeks of intervention. Nonetheless, there were no changes in the average costs during the study period. The cost per QALY gained was: $ICUR = (R\$809.70 - R\$1253.62) / (R\$0.322 - R\$0.326) = R\$110.98/QALY$.

Conclusions: Although the use of the booklet for the treatment of diabetic foot with the booklet seems to be less profitable than usual care, it remains a tool in the care strategy, which provides an exercise regimen with a personalized progression based on the users' perceived effort that can be used as a preventive strategy for the development of diabetic foot complications.

Acknowledgements: JLV received grant funding from CAPES [financial code 001]. ICNS is a fellow of CNPq (Process: 304124/2018-4).

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P04.3-1

Ankle-brachial index and toe-brachial index in people with and without diabetic peripheral neuropathy

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Background/Aim: The effect of diabetic peripheral neuropathy (DPN) on ankle-brachial index (ABI) and toe-brachial index (TBI) is unclear. We aim to investigate the relationship between ABI and TBI and analyse their difference (ABI – TBI) in people with and without DPN.

Methods: We conducted a retrospective, observational study of diabetic foot screening results from January 2017 to December 2017 at a tertiary hospital. Data collected include ABI, TBI, 10-gram-mono-filament test, Vibration Perception Threshold Test (VPT) and demographic data. DPN was defined as either presence of at least one insensate site with the 10-gram-monofilament or VPT ≥ 25 V.

Results: 1393 patients were included with 724 (52.0%) males and mean (SD) age 62.8 (12.3) years old. We observed 480 (34.5%) patients with DPN and 913 (65.5%) without. There was a moderate-positive correlation between ABI and TBI in patients with or without DPN respectively ($r = 0.43$, CI: 0.35–0.50, $P < .001$, $r = 0.41$, CI: 0.36–0.47, $P < .001$). There were 76/480 (15.8%) patients with a normal ABI ($0.9 < \text{ABI} \leq 1.3$) but low TBI ($\text{TBI} < 0.7$) in the DPN group compared to only 95/913 (10.4%) of patients in the group without DPN. Analysis between patients with and without DPN over a range of ABI values was performed: TBI was significantly lower in patients with DPN for $1.1 < \text{ABI} \leq 1.2$ ($P = 0.023$) while ABI was significantly higher in patients with DPN for $\text{ABI} > 1.2$ ($P = 0.003$). ABI – TBI for $\text{ABI} \leq 0.9$; $0.9 < \text{ABI} \leq 1.0$ or $1.0 < \text{ABI} \leq 1.1$ were not significantly different between patients with or without DPN. However, ABI – TBI was significantly higher in patients with DPN for $1.1 < \text{ABI} \leq 1.2$ ($P = 0.04$) and $\text{ABI} > 1.2$ ($P = 0.002$).

Conclusions: There is a moderate positive correlation between ABI and TBI in people with or without DPN. Our results show that TBI may be less susceptible to be falsely elevated when $\text{ABI} > 1.1$ in patients with DPN. Thus, it may be useful to conduct TBI for all patients with DPN to identify PAD early.

P04.3-2

Fibrinogen function indexes are potential biomarkers for evaluating the occurrence and severity of diabetic foot

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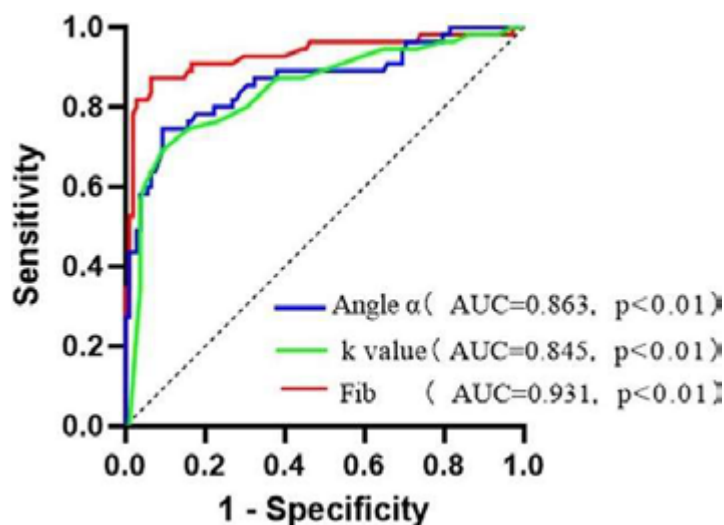
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Background: Research suggests that fibrinogen (Fib) concentrations are used to assess the occurrence and severity of diabetic foot (DF) and to monitor the progression of diabetic foot in patients. However, its correlation with Fib function has not been reported. Here, angle α and k value, reflecting the Fib function, were used to analyse its correlation with DF, and their potential as biological indicators for evaluating the occurrence and severity of DF was explored.

Methods: This clinical study enrolled 163 type 2 diabetes mellitus (T2DM) patients, who were divided into the diabetes with DF (84 cases) group, diabetes with no DF (79 cases) group. Meanwhile, 90 healthy unrelated subjects were enrolled as controls.

Results: Angle α and fibrinogen levels increased greatly in subjects with DF compared with those without. The k value levels greatly decreased in subjects with DF compared with those without ($P < 0.01$). Spearman correlation analysis showed that angle α and fibrinogen were positively correlated with DF grading ($r = 0.635$, $P < 0.01$; $r = 0.616$, $P < 0.01$), k value was negatively correlated with DF ($r = -0.589$, $P < 0.01$). ROC curve analysis showed that the optimal cut-of point for angle α to distinguish patients with DF from those without was 62.85 deg, with a sensitivity of 78.6% and specificity of 78.7%. The optimal cut-of point for k value was 1.75min, with a sensitivity of 82.1% and specificity of 65.8%. The optimal cut-of point for fibrinogen was 3.85g/l, with a sensitivity of 63.1% and specificity of 98.2%. The optimal cut-of point for angle α to evaluate the risk of diabetic foot progression was 70.20 deg, with a sensitivity of 73.2% and specificity of 90.7%. The optimal cut-of point for k value was 1.25min, with a sensitivity of 67.9% and specificity of 90.8%. The optimal cut-of point for fibrinogen was 4.12g/l, with a sensitivity of 85.7% and specificity of 93.5%.

Conclusion: Angle α , k-value and fibrinogen have clinical significance on the risk of occurrence and development of diabetic foot, which can contribute to early diagnosis and early clinical intervention in DF.



ROC curves for the evaluation of severity of DF using angle α , k value and Fib

P04.3-3

Prevalence and associated factors of diabetic foot problems in patients with end stage renal disease receiving renal replacement therapy

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Aim: To study prevalence of foot problems in persons with diabetes (DM) and end stage renal disease (ESRD) receiving renal replacement therapy and associated factors in this population.

Methods: Cross-sectional study was conducted in 2022 at a tertiary hospital in Thailand. 226 patients were assessed and 89 were eligible. Demographic and diabetic foot related information was gathered. Thorough foot examination was conducted to identify loss of protective sensation (LOPS), peripheral arterial disease (PAD), foot deformities, foot ulcers, and lower extremity amputation (LEA). Secondary outcomes include standing/walking time per day, receiving foot care education, accessibility to diabetic foot clinic, foot function index, and EQ-5D-5L questionnaire for quality of life.

Results: 48.3% were males, average age was 69.0 years and BMI 24.5 kg/m². All were type-2-DM and 92.1% had DM for over 10 years. The average HbA1C was 6.7 mg%. 64% had received hemodialysis and 36% peritoneal dialysis, with average duration of 5.3 years. Foot problems found: 83.1% LOPS, 39.3% PAD, 51.7% foot deformities, 30.3% previous foot ulcer, 7.9% current foot ulcer, and 6.7% LEA. Multivariable analysis revealed smoking, HbA1C > 7 mg%, hemodialysis, cerebrovascular disease to be independent risk factors for foot problems. 50.6% did stand/walk 0-1 hour/day. Only 41.6% received DM foot education and 15.7% had access to a diabetic foot clinic. The foot function index revealed pain 0.0/100, disability 35.8/100, activity limitation 22.2/100, and overall score 23.8/100. The EQ-5D-5L revealed calculated utility score 0.836/1 and health status visual analog scale 80.0/100.

Conclusions: The prevalence of most foot problems in DM with ESRD was greater than in a previous study in general DM. Only the prevalence of foot ulcers and LEA were lower, possibly because most of them stand/walk less than an hour/day. History of smoking, poor blood sugar control, hemodialysis, and cerebrovascular disease increased risk of diabetic foot problems. Less than half received DM foot education. Most patients with deformities and ulcers visited the DM foot clinic. Interestingly, patients felt that foot problems had low impact on their foot functions and the average quality of life was good.

P04.3-4

Temporal changes affecting toe-brachial index results during hemodialysis

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Background: Toe brachial index (TBI), the ratio of toe pressure to systolic blood pressure (SBP), helps predict peripheral arterial disease. In patients with kidney failure this may be performed during hemodialysis for convenience. We aimed to determine if the values of TBI would change during and after dialysis compared to a pre-dialysis baseline.

Methods: Using a repeated measures study, TBI were quantified in 31 prevalent hemodialysis patients at baseline (pre-dialysis) and compared to values obtained during dialysis at 1 hour, 2 hours, and 3 hours, and post-dialysis (4 hours).

Results: Mean TBI decreased from pre-dialysis (baseline) at 1 hour (0.72 to 0.63, $p=0.01$) and remained lower at 2 hours and 3 hours, before returning to baseline 4 hours (post dialysis). Mean TBI was lower in those with a history of lower limb ulceration and in females. When analyzed categorically, 16 patients (51.6%) had a 'normal' TBI at baseline, 14 (45.2%) had a mildly low TBI, and 1 (3.2%) had a severely low TBI. Throughout dialysis multiple participants were recategorized from normal to mildly-low TBI (TBI 0.30 – 0.70) and 1 patient with mildly-low TBI was recategorized to severely-low TBI (< 0.30) during dialysis.

Conclusion: TBI and toe pressures are impacted significantly (both statistically and clinically) by dialysis but results vary greatly. TBI and toe pressure assessments should be conducted before haemodialysis begins, or between dialysis sessions to avoid variability introduced by haemodialysis.

Acknowledgement: Northern Health Foundation for small research grant.

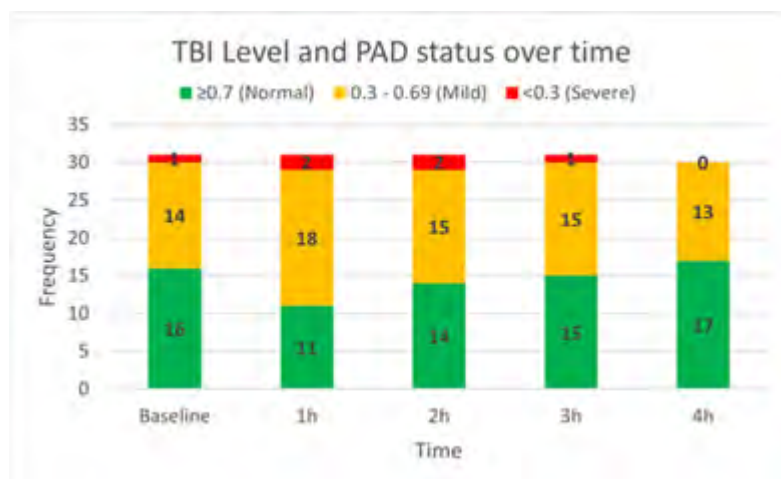


Figure 1 – Toe brachial index (TBI) before and during hemodialysis

P04.3-5

Analysis of chronic clinical efficacy of antibiotic bone cement in the treatment of diabetes

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Objective: Analysis of chronic clinical efficacy of antibiotic bone cement in the treatment of diabetic foot.

Methods: From June 2021 to December 2022, the author's wound restoration section of the author comply with 120 patients with diabetic foot ulcers in accordance with the selected standards will be included in the traditional group according to different treatment methods (35 men and 25 cases, 25 cases, and 25 cases. Age 42 to 82), bone cement group (34 men, 26 women, aged 39 ~ 88). Traditional group patients routine debridement+negative pressure closed drainage, routine debridement+antibiotic bone cement coverage in patients with bone cement group. Looking back at the number of patients with a positive patients in the two groups of patients in the hospital for admission, during the operation, and after surgery, 1D, 7D, and 14D wounded secretions, the number of hospitalization, the number of surgery, the total healing time of the wound, the total cost of hospitalization; 7D, 14D infection indicators WBC, NE, C reactive protein increased number of patients. For data row Fisher's exact probability method inspection and independent sample inspection.

Results: Compared with the traditional group (28 ± 12) d, (3.2 ± 1.8) times, the hospitalization time of the bone cement group (14 ± 8) D was significantly shortened, the number of surgery (2.3 ± 0.8) was significantly reduced, and the postoperative time points The number of positive patients in the wound secretions of bacterial culture is significantly reduced ($T = 6.233, 9.896, P < 0.05$ or $P < 0.01$); the number of patients in the two groups of patients with bacterial culture and the total healing of the number of positive patients, the total cost of hospitalization treatment, the difference, the difference Statistical significance ($T = 4.172, P < 0.05$); when admitting, the differences in number of patients in patients with 1D, 7D, 14D infection indicators WBC, NE, and C infection are statistically significant ($T = 3.426, P < 0.05, P < 0.05$).

Conclusion: Antibiotic bone cement treats diabetes foot ulcers to reduce the number of positive patients and the number of surgicals after surgery, shortening the number of patients in patients, shortening patient hospitalization time, reducing hospitalization costs, and reducing inflammation reactions.

P04.3-6

The association of platelet morphology indices with peripheral neuropathy and nerve conduction among Type 2 diabetes mellitus patients

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Aims: To explore the association between platelet parameters and diabetic peripheral neuropathy (DPN) in patients with type 2 diabetes mellitus (T2DM).

Methods: Medical files were retrospectively collected. The study included 180 patients with T2DM. They were divided into T2DM group without DPN (DM) and DPN group according to the American Diabetes Association recommendation. Parameters were compared between groups. Then multivariate regression, correlation and ROC analysis were performed.

Results: Platelet count (PLT) was lower in the DPN group. Mean platelet volume (MPV), platelet distribution width (PDW) and platelet large cell ratio (PLCR) were higher in the DPN group. There is no significant difference in plateletcrit (PCT) between the two groups. After adjusting the potential related factors, MPV or PLCR was still an independent risk factor for DPN. MPV or PLCR was mainly related to the sensory nerve conduction parameters. Areas under ROC were 0.625 and 0.615 for MPV and PLCR respectively.

Conclusions: The present study showed higher MPV and PLCR were independent risk factors for DPN. They are closely related to nerve conduction parameters. MPV and PLCR might be predictors for DPN in clinical practice.

P04.3-7

Designing an eHealth application for people at risk for diabetic foot ulceration

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Aim: People with a high risk of diabetic foot ulceration (DFU) often struggle to monitor the health of their feet in everyday life. Especially during the COVID-19 pandemic, many people at risk of DFU refrained from visiting the podiatrist for regular checkups. While existing eHealth technologies show promise in supporting self-management of DFU, we identified opportunities to focus on prevention, rather than wound-monitoring, and aim toward easy data sharing with podiatrists.

Methods: In this research, we share how we used a participatory, multistakeholder design approach to uncover the patient journey of persons at risk of DFU and subsequently develop, deploy, and iterate upon a (Dutch) eHealth smartphone application*. The app allows regular monitoring by asking people questions about the health of their feet and taking pictures if needed. The pictures are sent to their podiatrists and stored in their Electronic Health Records. The podiatrists will then contact the patient in case of an identified medical urgency for further investigation.

Results: In the first two years of the app (2020-2022), it has gained hundreds of users who have sent in over 5000 pictures for review by podiatrists. In response to 8.5% of these pictures, the podiatrist called the patient and scheduled a follow-up. In approximately 10% of cases, follow-up treatment was required. The multistakeholder co-design sessions before, during, and after the release of the application supported its iterative development process. We uncovered diverse patient journeys and identified how people's relationship to DFU self-monitoring practices is situated in their habits, cultural norms, material conditions, and physical capabilities.

Conclusions: The application shows that self-monitoring through eHealth technology shows promise for the prevention of DFU. We present the use and user experience of the application by patients and podiatrists. We share our participatory design approach and give guidelines on the design of eHealth applications in the context of DFU. Furthermore, we show that input from stakeholders is critical both before and during app design, and deployment and that application data in isolation is insufficient to steer eHealth development.

* Diabetes Voetencheck

P04.4-1

Evaluation of Diabetic Neuropathy Effects on Functioning and Disability Levels, and its Impact on Quality of Life

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Background: Diabetic polyneuropathy (DNP) directly affects functionality, causing several disabilities. Functionality includes body functions and structures and the execution of tasks in a social context. Disability is related to body structure and function impairments, capacity and activity limitations. Both factors can interfere with global quality of life (QoL). So, the purpose of the study is to investigate the relationship between QoL, functionality and disability in people with DPN.

Methods: Functioning and disability were assessed from the perspective of the International Classification of Functioning, Disability and Health (ICF) in 58 participants with DPN (54.9±9.9 years): (i) body functions and structure and (ii) activities and participation. For (i) assessment, functional balance (Functional Reach Test) [1], foot muscle strength (pressure exerted by the fingers on a pressure platform), signs and symptoms of PND (Michigan Neuropathy Screening Instrument-MNSI), tactile (10g monofilament) and vibratory (128Hz tuning fork) sensitivity were used. For (ii) evaluation the domains "limitations of ADLs" and "disorders in social relationships" of the NeuroQol instrument were used [2]. For the QoL, we used the EQ-5D (5 questions about general health). Three multiple regressions were performed: in the first 2, those collected in assessment (i) were inserted as predictor variables, with the response variables: limitations in ADLs and disorders in social relationships. In the 3rd regression, all project variables were included as predictors and QoL as a response variable.

Results: In regression 1, the final model presented functional balance as a predictor of limitations in ADLs. In regression 2, disorders in social relationships, MNSI and finger strength were the predictor variables. In regression 3, MNSI and ADL limitations were the QoL predictor variables.

Conclusions: Functionality and disability variables in people with DPN should be taken into account to promote care that improves quality of life with rehabilitation strategies aiming at improving DPN signs and symptoms, balance and foot muscle strength.

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P04.4-2

Index Of Multiple Deprivation, A Predictor Of Lower Limb Amputation In Diabetic Foot Disease

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Background: Diabetic foot neuropathy increases the risk of foot ulcers, infection and eventual need for amputation. Indices of multiple deprivation is a measure of relative deprivation.

Objectives: Our aim was to establish the relationship between deprivation and risk of amputation.

Study Design & Methods: We evaluated the diabetic patients, who were admitted to our multidisciplinary unit between 2017 to 2022 and underwent surgery for diabetic ulceration. We analysed the relationship of Index of Multiple Deprivation (IMD) and lower extremity amputation. These patients were followed up until ulcer healing, lower extremity amputation or death.

Results: In our study, 70 patients had surgery for the foot ulceration. The majority of them were males 55(78.6%). The mean age at diagnosis was 45.6(SD 15.8) years and the mean age at first surgery was 61.5(SD=11.4) years. The mean platelets level was 327.71(SD=132.25), while the median leukocytes count was 8.35(IQR: 6.68-10.73). Out of 70 patients 33(47%) had amputation, predominantly the males with M:F (4.5:1). The majority of these amputations were of forefoot 75.6% followed by hindfoot(18.1%) and midfoot(6.06%). None of the patients had below knee amputations. The Index of multiple deprivation for these amputees ranges from 576 to 32098 (Mean 9019.72). Twenty seven patients(81.81.%) had IMD decile 5 or below, and only six patients had 6 or above(18.1%).

Conclusions: Our study shows that in diabetic foot ulceration, index of multiple deprivation has an inverse relation with amputation and residential environment affects the outcome. These results are comparable with the outcome of other diseases such as poor prognosis cancer in low socioeconomic groups. In the treatment of this cohort of patients, many need extra care and support. However, due to the complex nature of the disease, it is difficult to ascertain the role of a single factor as a predictor of amputation. We recommend prospective studies with bigger sample sizes to help to find the definitive answer.

P04.4-3

Predictors of The healing time for diabetic foot ulcers and the direct medical cost during the crisis

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Background: Diabetic foot ulcer (DFU) is one of the slowest healing wounds that hurt the human body. Many studies from developed countries concerned about materials, procedures and equipment that accelerate the healing time. In Sweden; the diabetic foot management costs around 24,965\$/ patient. In this review, we would evaluate the healing time of DFUs during what's considered the worst humanitarian crisis of the 21st century.

Materials and methods: We reviewed the healing time for 1747 neuropathic DFUs (2014 - 2019). We predicted many variables that could prolong the healing time. The cost according to these variables was also reported. The SINBAD Classification was performed to grade the severity of ulcers.

Outcome: The median healing time for DFUs was 8.00 weeks. Almost half of these ulcers healed between 3 to 12 weeks. The time of healing for men was significantly longer than that for women. While the presence of infection doubled the median time of healing, the presence of peripheral artery disease (PAD) doubled the mean of the direct health care cost. The location of the ulcer acted as another independent risk factor. The environment with resource-poor settings should be added to the traditional risk factors that delay the healing of DFUs for months or even years. More studies from disaster areas are needed to evaluate low-cost materials that could be cost effective in applying standard care of the diabetic foot.

Association between categorical variables with healing time of neuropathic DFUs

Table 3: Association between categorical variables with healing time of neuropathic diabetic foot ulcers.							
Variables	frequency	(%)	Healing time (weeks)				p-value (*)
			Median	Mean	Std. Deviation	Mean rank	
SINBAD Classification:							
SINBAD score ≥ 3	768	44.0	14.00	16.34	13.714	1159.35	.000
SINBAD score ≤ 2	979	56.0	4.00	6.31	6.316	650.15	
Presence of infection:							
Yes	553	31.7	12.00	14.78	12.863	1090.06	.000
No	1194	68.3	6.00	8.84	10.104	773.93	
Presence PAD:							
With PAD	251	14.4	14.00	18.40	16.571	1191.03	.000
Without PAD	1496	85.6	6.00	9.43	9.696	820.81	
Location of wound:							
Plantar	581	34	10.00	13.56	13.094	977.39	.000
Non-plantar	1126	66	6.00	9.48	10.229	790.33	
Mann-Whitney U test. PAD: peripheral Artery Disease. (*) Statistically significant, $p < 0.05$							

P04.4-4

Patients compliance to foot care clinic is key to avoid developing diabetic foot and its complication

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Background The diabetic foot is serious complication that may ends in major lower extremity amputation. Foot care and patients compliance is the main factor to avoid such serious outcome. The objective of this study is to report on incidence foot ulcers and amputation on patients compliant to the foot care clinic.

Methods The inclusion criteria were diabetic patients reporting to the Foot Care clinic in Jabir Abu Eliz Diabetic Centre Khartoum every three months for the previous 4 yrs . Patients were examined, their feet were checked for neuropathy using 10gm monofilament nylon, Doppler ultrasound for pedal circulation, and careful foot examination including foot ware. There were e asked about any foot incidence and their reaction to that.

Results A 120 diabetic patients were studied ,66 were females and 54 males with mean age and age range (40 – 60) yrs. 82 (68.3%) had DM more than 5 years.

Frequency of foot care clinic visit was every 3 months in 59(49.2%) and > 3 month in 61(50.8%) patients. Nineteen (31.7%) patients reported a foot incidence as follows, foot ulcer in 7, foot sepsis in 5 callus in 3, sharp object stab in 2, blister and interdigital fungal infection in one each. Their immediate action was report to JADC in 11 patients use of Herbal/traditional medications by 8.

The main problems facing patients reporting to JADC was transport being living in far distance in 36 patients social and financial problems in 14 patients.

The majority of patients 100 (83%) described every 3 months as suitable period for foot care clinic visits. Most patients performed regular daily inspection (n=99; 82.5%), washing feet more than once per day (n=97; 80.8%), drying (n=72; 60%), moistening (n=85; 70.8%), nail clipping (n=11; 94.2%) and never bared their feet (n=98; 81.7%). About one-half of the cases were wearing socks (n=62; 51.7%) and diabetic shoes (N=60; 50%).

Conclusion Patients compliance to foot care clinic is a major factor to avoid diabetic foot and its complication.

P04.4-5

Initial Sharp surgical debridement is limb saving in diabetic septic foot

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Introduction Surgical debridement is a procedure to remove all dead and /or infected tissues foot and assess extent of tissue damage in a diabetic foot. The majority of patients presenting to Jabir Abu Eliz Diabetic Centre in Khartoum have advanced foot sepsis that needs initial major surgical debridement. This study aims to assess the role and outcome of this procedure .

Methods 130 diabetic who presented with major foot sepsis that needed immediate sharp surgical debridement were included. The extent of neuropathy was assessed clinically to determine if there is a need for local anaesthesia as local infiltration or ankle block or neither.

Results 130 patients were studied, 64 were males and 66 females with mean age and SD 56 + 12 yrs. Mean duration of diabetes was 15 yrs SD 9 yrs.. 54% were treated elsewhere and presented to JADC more 4 weeks after the incident. 52% were seen by a medical personnel, 38% had self treatment and 10% ignored the incident. In 27% the cause was sharp prick, in 16% a blister, 10% tight shoes and 9% thermal injury and the rest could not identify the inflicting cause. . 37% of patients reacted immediately and 44% after a week . The size of the wound was more than 5cm in 64% of patients and reaching bone and joints . 63% of patients were Wagner 3. Extension of the wound to the mid foot in the planter surface in 44% and Ray amputation in 42% . The wound was healthy and clean in 62% of patients within 2 weeks and in 27% it was clean in about 30 days. Major lower extremity amputation was done in 10 and minor toe amputation in 5 patients.

Conclusion Major sharp debridement is an essential initial procedure in major septic foot in diabetics in Sudan. The diabetic foot is special entity that needs specialized foot clinics to care for.

P04.5-1

Threshold values of the 10g monofilament test used in diabetic foot screenings for a multi ethnic Asian population

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Background/Aim: There is currently no consensus on the optimal threshold for monofilament testing to determine diabetic peripheral neuropathy (DPN) during diabetic foot screening (DFS). The objective of our investigation is to determine the optimal number of insensate sites required to determine the presence of DPN.

Methods: We retrospectively analysed 10g monofilament test and neurothesiometer vibration perception threshold (VPT) test results of 1451 patients who attended DFS from January 2017 to December 2017. Outcomes measured included differences in proportion of patients assessed to have DPN for well-established monofilament thresholds of ≥ 1 or ≥ 4 undetected sites out of 10 and the specificity, sensitivity and agreement of different monofilament thresholds against VPT.

Results: The mean age of the study population was 63.1 ± 12.3 years. The ethnic distribution was 69.5% Chinese, 13.6% Indian, 10.1% Malay and 6.8% Others. Differences in proportion of patients presenting with DPN for 10g monofilament thresholds of $\geq 1/10$ and $\geq 4/10$ insensate sites was statistically significant ($P < .001$, 95% CI: 26.9-31.8). Further statistical analysis demonstrates that when utilising threshold of $VPT > 25V$ as the reference test to determine DPN, ≥ 3 insensate sites produced the most ideal sensitivity (0.90, 95% CI: 0.88-0.91) and specificity (0.90, 95% CI: 0.80-0.98). Other thresholds of ≥ 1 and ≥ 2 insensate sites were similarly high in sensitivity but had lower specificities (0.64, 95% CI: 0.62-0.80) and (0.76, 95% CI: 0.74-0.80) respectively. Minimal agreement was found for the monofilament thresholds of ≥ 3 ($k=0.30$, $P < .001$) and ≥ 4 ($k=0.35$, $P < .001$) insensate sites and no agreement was found for the monofilament threshold of ≥ 1 ($k=0.08$ $P < .001$) insensate site.

Conclusions: Our results suggest that the optimal threshold for the 10g monofilament test to indicate neurothesiometer determined DPN ($VPT > 25V$) is ≥ 3 insensate sites out of 10 sites for a multi-ethnic population. This threshold should be used during monofilament testing in DFS to improve the accuracy of patient risk stratification, potentially resulting in better allocation of healthcare resources in the face of rising healthcare costs.

P04.5-10

Study of the film loaded mesenchymal stem cells-conditioned medium on diabetic wound healing

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Objective: To evaluate the effect of hydrogel film loaded adipose mesenchymal stem cells-conditioned medium (ADMSCs-CM) on diabetic wound.

Methods: The HUVECs cultured in high glucose was treated with ADMSCs-CM, then detected the cell viability and apoptosis. Loaded the ADMSCs-CM into the hydrogel to prepare the film. Diabetic mice were induced by STZ after 4 weeks high fat diet, then full-thickness skin wounds with diameter about 8 mm on the back of mice were made. We observed the wound healing on the 3, 7 and 10 days after treatment with the film and calculated the healing rate. Observed the pathology of wound tissue at different times by staining H&E. TUNEL staining was used to detect the cells apoptosis in wound tissue.

Results: The cell viability of HUVECs in high glucose group was significantly improved after treated with ADMSCs-CM. Statistical results showed that the wound healing rate of mice in the ADMSCs-film group was increased significantly ($P < 0.05$). The TUNEL showed that the number of apoptosis cells in the DM group were significantly higher than that in the ADMSCs-film group ($P < 0.05$).

Conclusion: The ADMSCs-film could inhibit cell apoptosis at the wound site and promote wound healing.

P04.5-2

Study on predisposing factors and recurrence sites of diabetic foot ulcer in 230 cases

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Aim: Through the study of the inducement and location of diabetes foot ulcer recurrence, it provides a basis for the prevention and control of diabetes foot.

Methods: Data of 230 inpatients with diabetic foot admitted to wound Repair Center of Liyuan Hospital Affiliated to Tongji Medical College of Huazhong University of Science and Technology from January 2019 to September 2021 were retrospectively analyzed. The information collected includes the patient's gender, age, place of residence, underlying diseases, whether other diseases were present at the time of onset, the cause and location of foot ulcers, and risk factors. Data were compared by 2 test and Kruskal-Wallis H test.

Results: 112 cases of foot ulcer caused by daily life and health care behavior, accounting for 48.69% of the total number; Other causes caused ulcer in 69 cases, accounting for 30%; 49 cases (21.30%) were caused by itching, dry chapped skin, edema, corns and other complications. Foot ulcers in patients with more than 178 cases of recurrence, accounted for 77.39%, which caused by inadequate health and daily life behavior of foot ulcer recurrence for 98 cases, accounting for 42.61%, foot ulcer causes lead to the comparison of incipient and relapse, recurrence than incipient, difference was statistically significant. Among the 230 patients with diabetic foot ulcer, 119 cases (51.74%) of the patients with recurrent ulcer were the dorsum of the foot, followed by 40 cases (17.39%) of the plantar, 19 cases (8.26%) of the dorsum and plantar. Incipient and relapse of ulcer area compared, relapse back more than a foot of incipient, difference was statistically significant. 112 cases (48.70%) were caused by inappropriate daily life and health care behavior, and 77 cases (33.48%) occurred in the dorsum of the foot; Compare different ulcer site with incentive, the difference was statistically significant.

Conclusion: The occurrence of diabetes foot ulcer is more recurrent than the initial one. The recurrent part of diabetes foot ulcer is more than the foot bottom, and the recurrent inducement is mostly inappropriate daily life and health care behavior, providing a basis for the prevention of diabetes foot recurrence.

P04.5-3

Increased expression of miR-222-3p in peripheral blood and wound margin tissue of T2DM patients associated with diabetic foot ulcer

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Aim: To investigate the correlations of miR-222-3p expression in the peripheral blood and wound margin tissue of type 2 diabetes mellitus (T2DM) patients with diabetic foot ulcer (DFU) and explore the clinical value of miR-222-3p as a potential biomarker for the diagnosis and treatment outcomes of DFU.

Methods: Seventy newly diagnosed T2DM patients without DFU (T2DM group), 146 T2DM patients with DFU (DFU group), and 70 healthy controls (NC group) were included. MiR-222-3p levels in the peripheral blood and wound margin tissue were determined by quantitative real-time PCR, while clinical features and risk factors of DFU were explored by multivariate logistic regression analysis. The diagnostic effectiveness of miR-222-3p level on DFU was evaluated using ROC curve analysis.

Results: A significant increase in the expression level of miR-222-3p was observed in T2DM group compared with NC group [1.98 (0.98, 3.62) vs 0.92 (0.61, 1.87)] ($P < 0.01$), while a markedly increased miR-222-3p expression level was noted in DFU group compared with T2DM group [5.61 (1.98, 10.24) vs 1.98 (0.98, 3.62)] ($P < 0.01$). Moreover, there was a negative correlation between the expression level of miR-222-3p with healing rate of DFU, both in peripheral blood and wound margin tissue ($P < 0.05$). Kaplan-Meier survival curve analysis showed that the cumulative rate of unhealed DFU in miR-222-3p high expression group is higher than that in miR-222-3p low expression group (log rank, $P = 0.011$, 0.001, respectively). The wound healing time of high expression group is longer than that of low expression group ($P < 0.05$). The multivariate logistic regression analysis confirmed that a high expression of miR-222-3p was an independent risk factor for DFU [OR=3.85, 95% CI 1.18~12.37, $P=0.008$]. The ROC curve analysis indicated that the AUC of miR-222-3p for the diagnosis of DFU was 0.803, with the optimum sensitivity being 96.82% and the optimum specificity of 96.27%.

Conclusions: The increased expression of miR-222-3p in peripheral blood of T2DM patients is closely related to the occurrence of DFU. MiR-222-3p is a potentially valuable biomarker for diagnosis and prognosis of DFU.

P04.5-4

Biofilm and Quorum Sensing genes analysis between carbapenem resistant *Acinetobacter Baumannii* and carbapenem sensitive *Acinetobacter Baumannii* in diabetic foot

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Background: Biofilm is an important virulence factor of antibiotic resistance. Carbapenem resistant *Acinetobacter Baumannii* (CRAB) is more and more in diabetes foot wound, especially in chronic refractory wound. This study attempted to analyze the differences in biofilm and Quorum Sensing genes between CRAB and carbapenem sensitive *Acinetobacter Baumannii* (CSAB), as well as the differences in antibiotic resistance.

Methods: Seven strains were selected from many CRAB strains, and five strains were selected from CSAB strains for sequencing. On the PubMLST website, the whole genome was best matched with the biofilm locus and Quorum Sensing locus. Some materials in the wound that was clinically considered “biofilm” were taken for transmission electron microscopy.

Results: The materials taken from the wound were shown the structure of biofilm by transmission electron microscopy. The genes of CRAB strains were highly identical, among which 6 strains had 14 biofilm genes: bfmR, bfmS, csuA, csuB, csuAB, csuC, csuD, csuE, pgaA, pgaB, pgaC, pgaD, ompA, bap. Only one strain did not contain csuE. Therefore, most of CRAB bacteria can form biofilm. None of the five CSAB strains had 14 biofilm genes. None had bap. One strain had 13 genes. Two strains had 12 genes. One strain lacked ompA and bap, the other strain lacked bap and pgaD. Other two strains, one had 7 biofilm genes, the other had only 4 biofilm genes. It seriously affected the production of biofilm. All CRAB contained Quorum Sensing genes: abal and abaR, which are very important for the initial adhesion of biofilm. Among the CSAB strains, only 2 strains contained abal and abaR, 1 strain had only abal, and the other two had neither abal nor abaR. CRAB strains were resistant to other antibiotics except polymyxin and tigecycline, while CSAB strains were also sensitive or intermediate to other antibiotics except carbapenem, only resistant to cefotetan.

Conclusion: CRAB had perfect biofilm and Quorum Sensing genes, and the formation of biofilm increased antibiotic resistance. While the biofilm and Quorum Sensing genes of CSAB were not perfect, which went against to formation of biofilm and was profit for the killing of antibiotics.

P04.5-5

Outcomes of excimer-laser ablation combined with drug-coated balloon for below-the-knee lesions in patients with diabetic foot

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Aims Diabetic foot is one of the most catastrophic complications in diabetic patients, and most of them are resulting from below-the-knee (BTK) arterial lesions. We conduct this study to evaluate the clinical outcomes of excimer-laser ablation (ELA, approved by FDA) combined with drug-coated balloon (DCB) for BTK lesions in patients with diabetic foot (DF).

Methods Patients with DF accompanying BTK lesions who underwent ELA at two centers from June 2019 to September 2022 were prospectively analyzed. The baseline, lesions characteristics, details of the procedure, and follow-up information were collected and analyzed. The primary endpoint was primary patency, defining as freedom from reintervention and significant restenosis, determined by Doppler ultrasound peak systolic velocity ratio ≤ 2.4 . Secondary endpoints included major amputation-free survival (MAFS) rate, bailout stent, technical success, defining as the residual stenosis was $<30\%$ and no flow-limiting dissection.

Results A total of 22 lesions were enrolled. The mean age was 72.1 ± 10.5 years. The lesions included 3 (13.6%) stenosis and 19 (86.4%) chronic totally occlusion (CTO) lesions. The mean length of these lesion was 25.6 ± 5.7 cm. The technical success rate was 95.5%. Eight (36.4%) patients received contaminant debridement or toe amputation. Flow-limiting dissection was observed in 1 (4.5%) patient. The mean ankle-brachial index (ABI) was significantly improved during the follow-up period. The median follow-up time was 21.5 months. One (4.5%) patient had major amputation due to the unhealing wound and pain. Three (13.7%) patients died during the follow-up due to respiratory failure. 68.2% of ulcer shank or healed at the last follow-up time. The 1-year primary patency was 80.3% (95% confidence interval [CI]: 65.8%-83.5%).

Conclusion ELA combined with DCB was safe and effective in the treatment of atherosclerotic lesions in BTK, and it could improve the patency.

P04.5-6

Risk factors for and prevalence of Charcot foot in subjects with diabetes mellitus: A nationwide cohort study

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Background/Aim: Charcot foot (CF) is a complication of diabetes mellitus (DM) that has potentially disastrous consequences. The epidemiology of CF is still unclear. Here we sought to determine the prevalence and incidence of CF, to propose a prediction model and to identify risk factors for CF in a nationwide cohort study.

Methods: A retrospective register-based cohort for the period 2001–2016 and 2006 - 2016 respectively was assessed using descriptive statistics and logistic regression analyses.

Results: A total of 3,397 subjects with DM and CF were included. The prevalence of CF was estimated to 0.79% in 2016. CF developed later in subjects with T1D than in those with T2D (after 33.1 ± 13.4 years vs. 14.6 ± 9.5 years, respectively), but at a younger age. Female sex was associated with higher risk for developing CF in T1D (odds ratio [OR] 1.29, 95% confidence interval [CI] 1.14–1.45) but with lower risk in T2D (OR 0.60, 95% CI 0.54–0.66). HbA1c, duration of diabetes, micro- and macroalbuminuria, retinopathy and atherosclerosis were identified as risk factors for CF.

Conclusions: In this largest CF study to date, we have estimated prevalence and incidence of CF. In addition, we have proposed a prediction model for the development of CF and identified risk factors.

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P04.5-7

Periosteal distraction: a new milestone in the treatment of diabetic foot

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Background: To explore the characteristics and scope of application of the periosteal distraction technique in the treatment of diabetic foot.

Methods: Clinical data were collected from 2021.06 to 2022.12 from patients admitted to the Department of Trauma Repair at the First Affiliated Hospital of Hainan Medical College for analysis. There were 27 males and 19 females, aged 48-86 years, with a Wagner classification of 2-4. The retraction of the tibial periosteum was increased continuously and evenly between postoperative day 2 and day 21, and the retraction device was surgically removed three weeks later. Patients' preoperative and 1,2,3 weeks postoperative visual pain analogue score (VAS); skin temperature, transcutaneous partial pressure of oxygen, infrared thermography in the traction area and dorsum of the foot; CTA and ultrasound of the lower limb vessels; and wound healing were recorded.

Results: Pre-operative and post-operative comparisons showed a significant reduction in VAS at 1-7 days post-operatively; a significant increase in skin temperature and transcutaneous partial pressure of oxygen in the distraction area and dorsalis pedis post-operatively compared to pre-operatively; an increase in infrared thermography at 1-3 weeks post-operatively compared to pre-operatively; a significant micro-angiogenesis in the distraction area as seen on CTA and ultrasound of the lower limb vessels; and good healing of all wounds.

Conclusions: The periosteal retraction technique promotes microangiogenesis in the lower limbs, improves blood flow, relieves pain and promotes wound healing.

P04.5-8

Early results of a defined surgical treatment protocol including antibiotic loaded resorbable bone graft substitute to treat diabetic foot osteomyelitis

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Background Diabetic foot infections result in high rate of lower extremity amputation and mortality. The optimal management is challenging and needs accurate debridement, antibiotics, and prevention of recurrent ulcers.

Methods Retrospective study comparing debridement alone or debridement with antibiotic loaded resorbable bone graft substitute (Gentamicin or Vancomycin) and a defined treatment protocol.

Patients from January 2017 till December 2018 were not treated via the defined protocol. Patients from January 2019 to September 2020 were treated using the defined treatment protocol. The patients were followed up for 12 months.

Results 140 patients were included with 37 in the pre treatment protocol group and 103 treated via the defined treatment protocol.

In the defined treatment protocol group, there was a lower number of operations per patient (3.4 vs 1.8, $p = 0.0004$) and shorter length of stay (24.1 vs 12.1 days, $p = 0.0077$). The major amputation rate was lower also (4/37 vs 2/103, $p = 0.044$).

At 12 months 92% of patients had a healed ulcer and the mortality rate was 3% in the treatment protocol group.

Conclusion When treating diabetic foot osteomyelitis the early results of a defined treatment protocol including antibiotic loaded bone graft substitute show a reduction in the number of operations, length of stay and reduces the rate of major amputation.

P04.5-9

Ischemia of the lower limb may affect the distribution of pathogens in diabetic foot infection

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Aim: The bacterial profile of diabetic foot infections (DFI) is essential in the prescription of empirical antibiotics before the results of cultures of wound samples are available. This study aimed to explore the correlation between lower limb ischemia and the microbiological profiles of organisms isolated from DFI so as to provide selection rationales for antibiotics.

Methods: In a single diabetic foot center, the results from positive bacterial cultures of patients with DFI from January 2016 to December 2020 were collected and analyzed. According to the level of ABI, patients were divided into the ischemia group (ABI < 0.9) and the non-ischemia group (0.9 ≤ ABI ≤ 1.30). Chi-square test was used to analyze the possible differences in the pathogen features and lower extremities ischemia. The potential risk factors were corrected by Logistic regression.

Results: A total of 210 DFI patients with positive bacterial culture results were included in this study. Polymicrobial infections accounted for 27.6% while monomicrobial infections accounted for 72.4%. Mixed infection was mainly caused by Gram-positive bacteria (G+) and Gram-negative bacteria (G-). Staphylococcus aureus (37.0.%) was the most common G+ isolated, followed by Staphylococcus epidermidis (20.2%) and Streptococcus agalactiae (11.4%). Escherichia coli (21.0%), Enterobacter cloacae (17.9%) and Pseudomonas aeruginosa (14.4%) were the most frequent G- bacteria. In addition, more G+ strains are present in ulcers without ischemia (83.2% vs. 69.9%, p=0.02) while more G- strains are present in ulcers with ischemia (27.0% vs. 47.7%, p=0.007). After adjusting for age, duration of diabetic foot disease, glycosylated hemoglobin level, and history of antibiotic use by Logistic regression, the risk of G- infection in the non-ischemia group was still significantly lower than that in the ischemia group (ORa=0.51, 95%CIa 0.26-0.96, Pa=0.03).

Conclusions: G+ bacteria were the main bacteria isolated from diabetic foot infection patients. And most of them are infected by a single pathogen. Patients with lower limb ischemia have a high risk of G- bacterial infection. Our findings should be fully considered when prescribing empirical antibiotherapy for diabetic foot infections in our setting.

P04.6-1

Prevalence of Diabetic Foot Disease in Patients with Diabetes Mellitus under Hemodialysis Therapy in a third level hospital in Argentina

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Background/Aim It has been studied that in patients with diabetes and on dialysis prevalent foot ulceration was higher in dialysis-treated patients than in predialysis patients. The aim of our study was to assess the prevalence of diabetic foot disease, other risk associated conditions and the follow-up with the orthopedic service in patients with diabetes mellitus on dialysis in a third level hospital in a middle income country.

Methods This was a descriptive , cross sectional study conducted during November 2022 in a third level hospital in Argentina among diabetic patients on dialysis. We performed a podiatric examination searching for ulcers, onychodystrophy, preulcerative lesions, pulses and foot deformities. In addition, using the diabetic foot form of the Ministry of Health of our country, we evaluated the presence of risk factors and diabetic complications. We also registered whether the patients were followed up by the orthopedic service in the last year.

Results During the study period in the hemodialysis service 22 out of 142 had diabetes. It was possible to analyze 20 of them. In the study group the prevalence of diabetic foot disease was 55. %, previous amputations were 25%, prevalence of peripheral neuropathy was 85%, and peripheral arterial disease was 100%. Only 6 patients had follow-up in the last year with the orthopedic service and 9 with the metabolic clinic.

Conclusions We found a high risk (55%) of foot complications in Diabetic patients receiving hemodialysis therapy and only 30 % had foot and ankle clinic following. Having carried out this study helps us to evaluate the dynamics of teamwork and improve care for this group of patients in the future.

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P04.6-2

Survival of people with type 2 diabetes who underwent major diabetic foot amputation from 2010 to 2019 in India

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Background: Diabetic foot complication is common and if untreated or late presentation of the same may lead to foot amputation. The reports on survival rate of people who underwent major diabetic amputation in Indian context is less. Hence, this study aimed to assess the survival status of people who underwent diabetic amputation from 2010 to 2019.

Methods: A retrospective analysis was done in November 2022 and collected data on survival status of the people with type 2 diabetes (T2DM) who had undergone foot amputation from 2010 to 2019 using the medical records. Details such as age, duration of diabetes, presence of co-morbid and diabetic complications were collected. Information of death and its' reason was obtained from medical records of patients or through telephonic follow up of patients or family members. A total of 346 individuals had undergone amputation during 2010 to 2019. Out of 346, data was collected for a total of 211 individuals. Among them 89 were survived and 122 died post amputation during the data collection. The individuals were grouped into group1(survived) and group2(died). The survival time was calculated in months and Kaplan-Meier survival analysis was performed to estimate the cumulative median survival time.

Results: The mean age of the individuals was 62.4±9.2 years. The previous history of foot ulcer and amputation, presence of nephropathy, retinopathy and Peripheral Arterial disease (PAD) were similar between the groups. Presence of hypertension (57.8vs.78.5%;p=0.012) and cardio-vascular disease (CVD) (40.6vs.70.3%;p<0.001) were significantly higher in group2. Median cumulative survival time of the participants was 67 months(95% CI 52.2-81.8). 9% died within 30 days of post-amputation. Survival time did not differ between individuals who had undergone below or above knee amputation. But, survival time differed significantly among those with and without co-existence of PAD and CVD[44 months(95% CI 27.6-60.4)vs. 76 months(95%CI 46.1-106); p=0.02]. The reasons for death were as follows: 30.3% had myocardial infarction, age related or chronic illness(25.4%) and uncontrolled diabetes(20.5%).

Conclusion: The median survival of the people with type 2 diabetes who underwent major foot amputation was 5.6 years. Co-existence of PAD and CVD had a significant impact on the survival period.

P04.6-3

Identifying the gap: existing system analysis of diabetic foot service in Pacific Islands.

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Background There is a high prevalence of diabetes mellitus in Pacific Island Countries and Territories (PICTs) according to the International Diabetes Federation Atlas. Consequently, the prevalence of diabetes-related complications in the Pacific region, including DRFD, is higher than reported for other regions. There is very limited information available with regards to the diabetic foot care model in the region despite the significant burden of disease. The purpose of this study is to survey frontline health services to gain a better understanding of the challenges health services face in diagnosis and treatment of DRFD in selected PICTs namely Fiji, Kiribati, Samoa, Solomon Islands, Vanuatu, and Tonga.

Methods A written survey was designed by the research team to identify the capacity of each hospital, and the number of admissions and procedures relating to DRFD. Questions on the clinical services available in the facility were also included. The survey was sent to 11 hospitals across the 6 selected countries. The survey period was conducted over 6 weeks. Additional records such as grey literature from government and non-government organisations were obtained via handsearching.

Results Responses were received from 7 hospitals across 4 countries. There is no vascular surgeon, endocrinologist, renal or infectious disease physicians servicing the hospitals surveyed. None of the hospitals surveyed has access to inpatient podiatry services and only the Tungaru Central Hospital in Kiribati, has reported having access to orthotist and prosthetist (O&P) services. Plain radiography is easily accessible, but for access to magnetic resonance imaging (MRI) patients will have to travel to Suva or Brisbane, Queensland. There is no vascular ultrasound or digital subtraction angiography service in the region.

Conclusion There are unarguably significant deficiencies in human, technical and clinical resources to provide multi-disciplinary foot care in the Pacific regions. This will likely contribute to the poor outcomes and continue to increase the burden of DRFD in the region. There is an intense need for strong advocacy for support into the region and implement change in a culturally appropriate model of diabetes foot service delivery to improve the outcomes for patients with diabetic foot disease in PICTs.

P05.1-1

Evaluation of the application of TLC-NOSF dressing to surgical wounds in patients with vascular disease following surgery for Charcot Neuropathy

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Aim: Charcot neuroarthropathy leads to deformity and chronic ulceration, reconstructive surgery offers the potential of limb salvage. Wound complications following limb surgery in diabetes can be problematic as rapid predictable healing is required to prevent bacterial colonisation, infection that can lead to failure. A comparative assessment of standard treatment with and without TLC-NOSF dressings as part of a in service quality improvement study in the management of post-surgical wound dehiscence/breakdown following diabetic foot surgery.

Methods All patients with diabetes undergoing staged CN reconstruction with documented PAD, presenting with wound dehiscence or breakdown or reduced healing were included. Patients underwent standard treatment routine office based debridement with standard dressings and total contact casting. From Aug 2021 4pts were also treated with a TLC-NOSF dressing was applied. All patients were prospectively followed up, to primarily assess wound healing, the time to complete healing, and secondarily treatment complications.

Results Fifteen patients were identified from May 2014 - August 2022 in a specialized diabetic foot unit undertaking limb preservation surgery. The overall time to healing was 16.8weeks, and the mean lesion size was 2.3cm², we observed the speed of healing improved with TLC-NOSF dressing from 0.11cm²/week (n=11) to 0.14cm²/week (n=4), leading to a possible reduction in healing time of 2 weeks for every 1cm². No patient required revascularisation during follow-up, but all were treated with bacterial specific antibiotics until wound healing.

Conclusion Early results suggest, wound healing can be improved using TLC-NOSF dressings, allowing timely resolution of wound dehiscence for cost effective care.

P05.1-2

Premature Mortality in Diabetic Charcot arthropathy

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Aims: Charcot arthropathy is a severe joint disease that can result in fracture, permanent deformity, foot ulceration, loss of limb and other morbidities. The mortality associated with Charcot arthropathy is not clear. Two studies have described a very low mortality with, respectively, no deaths in 55 patients followed for a mean 92.6 weeks and two deaths in 115 patients followed for 4 years. In contrast, another study reported a mortality of 44.7% of patients with Charcot's disease after a mean 3.7 years. The aim of this study was to examine the mortality in a cohort of patients presenting to a Multidisciplinary Diabetes Foot Team (MDFT) with Charcot arthropathy.

Methods: This was a retrospective study of 72 patients with diabetes referred to a single centre MDFT for Charcot arthropathy analysed for mortality and morbidities.

Results: Of the 72 patients, there were 28 with Type 1 diabetes and 44 with Type 2 diabetes; 33 were female and 39 male. Mean age at time of referral for Charcot arthropathy was 51 ± 11 with an average follow up time of 13 ± 4 years. On follow-up, 29 (40%) died. Mean age at death was 63 ± 10 years and the mean duration between referral and death was 11 ± 4 years.

Furthermore, 34/72 developed bilateral Charcot arthropathy, 19/29 deaths having bilateral disease; 35/72 developed renal disease, of either CKD Stage 3/4 with 6 patients having end stage renal failure on dialysis and 5 had renal transplants. 13 /73 underwent major operative internal reconstruction, and 8/72 (11%) had minor surgical procedures namely one ankle washout, one exostectomy, five 5th ray amputations and one transmetatarsal amputation. Eleven patients developed peripheral arterial disease needing revascularisation, 5 having balloon angioplasty and 6 open surgical bypass. Ulceration occurred in 60/72 patients and only 6 patients came to major amputation.

Conclusion: This study has indeed demonstrated premature mortality of patients with Charcot arthropathy with a mean age of death of 63 ± 10 years together with considerable morbidity. After presentation to the MDFT, these patients should be followed up for life.

P05.1-3

Investigating the relationship between peripheral arterial disease (PAD) and Charcot neuropathy (CN) to characterise the “neuro-ischaemic Charcot Foot”

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Background: Peripheral arterial disease(PAD) and Charcot neuropathy(CN) are complications seen in diabetic patients. Both increase the risk of infection and amputation, therefore, affecting patients' mobility and quality of life. Previous literatures suggested the potential relationship between PAD and CN. However, no consensus results have been drawn. Thus, the aim of the study was to carry out a systemic search and analyse the potential relationship between PAD and CN in relation to the Eichenholtz classification.

Methods: An electronic systemic search was conducted according to the PRISMA guideline on Medline, Embase and Global Health up to 2022. The following keywords: Charcot, peripheral vascular disease and diabetes were searched. ANOVA test was utilised to determine any significant difference in the rate of suffering from osteomyelitis or diabetic foot ulcer(DFU) between patients with CN and PAD; patients only have CN and patients only have PAD. The statistically significant level was set at $p < 0.05$.

Results: A total of 20 papers with 8341 patients were included. 13 studies included patients with both PAD and CN, the incidence is 33%(603/1826). Only 4 studies described the Eichenholtz classification and PAD($n=352$). 6 patients(1.7%) have stage 0, 85 patients(24.1%) have stage 1, 63 patients(17.9%) have stage 2 and 198 patients(56.3%) have stage 3. Among patients with osteomyelitis(+/-DFU), 67(23.5%) had both CN and PAD. 26(9.1%) and 192(67.4%) patients had CN alone and PAD alone respectively. The most used categorisations for PAD were based on anatomical or clinical exam findings -whether pulses were palpable. In studies that described anatomical distribution, PAD is more common arteries around the ankle(82.8%). Abnormal waveforms were described in 34.3%(42/107) patients, of these 42.7% were monophasic waveforms.

Conclusion: Both CN/PAD co-exist, unsurprisingly it is more likely to be seen in those with chronic stage 3 CN(56.3%). Patients with PAD and CN are more likely to have osteomyelitis, as compared to patients with CN alone. Thus, a combination of different vascular investigations should be performed when planning treatment to build an accurate picture of the extent of PAD and the likelihood of osteomyelitis. Further studies are required to accurately compare the relationship between the severity of CN and PAD.

P05.1-4

Bone marrow edema on dual-energy CT in patients with diabetes mellitus and suspected Charcot neuro-osteoarthropathy

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Aim: This study aims to quantitatively assess the feasibility of bone marrow edema (BME) detection on virtual non-calcium (VNCa) images calculated from dual-energy CT (DECT) in patients with diabetes mellitus and suspected Charcot neuro-osteoarthropathy.

Methods: Patients with diabetes mellitus and suspected Charcot neuro-osteoarthropathy who underwent DECT (80kVp/Sn150kVp) were retrospectively included. Two observers independently measured CT values in Hounsfield Units (HU) on VNCa images using circular regions of interest in five locations in the midfoot (cuneiform bones, cuboid bone and navicular bone) and in the calcaneal bone of the contralateral or (if only one foot was available) the ipsilateral foot. The patients were divided into two clinical groups, Charcot and no-Charcot, based on the final clinical diagnosis. Intraclass correlation coefficients (ICCs) were calculated to test the observer agreement.

Results: A total of 32 patients with suspected Charcot were. Of these patients, 11 had active Charcot. The mean CT value in the midfoot was significantly higher in the Charcot group (-55.6 ± 18.7 HU) compared to the no-Charcot group (-94.4 ± 23.5 HU; $p < 0.001$). In the Charcot group, the difference in CT value between midfoot and the calcaneus was statistically significant ($p = 0.003$); this was not the case in the no-Charcot group ($p = 0.357$). The overall observer agreement was good for the midfoot (ICC = 0.804) and moderate for the calcaneus (ICC = 0.712). With a cutoff value of -87.6 HU, sensitivity was 100.0%, specificity was 71.4%, PPV was 64.7% and NPV was 100.0%.

Conclusions: The detection of BME on VNCa images calculated from DECT has a potential value in patients with diabetes mellitus and suspected Charcot neuro-osteoarthropathy.

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P05.1-5

Sonographic Features of Acute Charcot Neuro-osteoarthropathy of the Diabetic Foot: A Prospective Study

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Background and Aim: Diagnosis of acute Charcot Neuro-osteoarthropathy (CN) is typically made from a combination of clinical and radiological findings. MRI is the more reliable imaging modality to confirm diagnosis, as X-Rays may appear normal during the acute phase. However, MRIs are costly and are not always easily accessible. Ultrasound imaging has been identified as a potential method of identifying signs of acute and chronic CN, and monitoring response to treatment. This study aims to assess the potential role of using ultrasound in diagnosing patients with clinically suspected acute CN.

Methods: A prospective (case-series) study design was employed. Thirty-three patients with clinically suspected acute CN were referred for ultrasound imaging of the symptomatic and contralateral limb. All patients had standard weight bearing plain X-Rays and where possible MRI (5 did not receive MRI).

Results: Following clinical and radiological (X-ray and MRI) assessment, 17 feet belonging to 16 patients had acute CN. Sonographic features (See figure 1) suggestive of acute CN were found in 94% (n=16) of feet. However, as outlined in Figure 1, not every patient had every sonographic feature. In addition, some sonographic features of acute CN were present in those with chronic CN and those who had no CN.

Conclusions: Ultrasound (an inexpensive and easily accessible imaging modality) is a potentially useful tool in identifying acute CN. Combined ultrasound readings with clinical presentation and medical history may facilitate earlier diagnosis and prompt treatment of acute CN reducing risk of subsequent complications and patient morbidity.

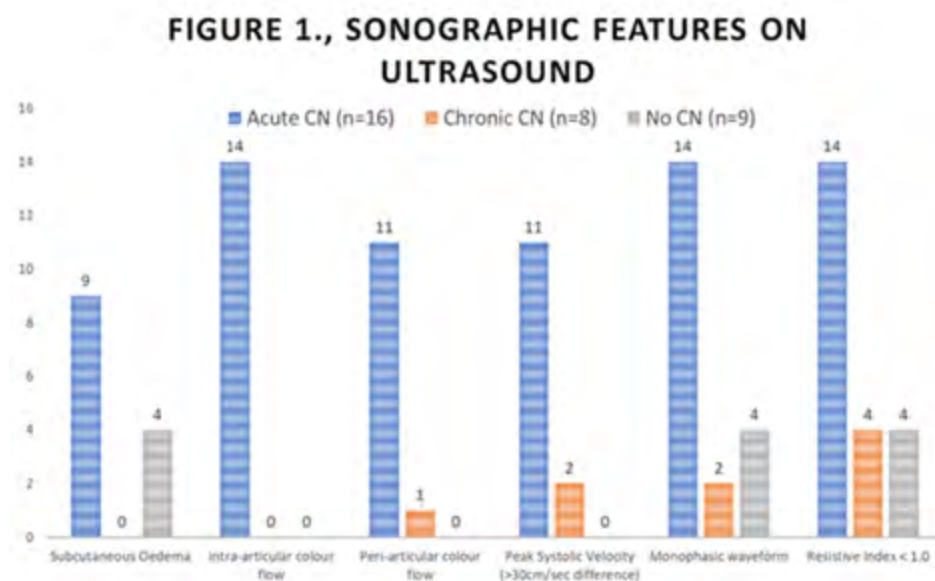


Figure 1. Sonographic features of patients with clinically suspected acute CN

P05.1-6

Using ultrasound to diagnose and monitor the acute Charcot Foot: A case report

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Background and Aim: Charcot neuroarthropathy is characterised by four different disease phases: inflammation, fragmentation, coalescence, and consolidation. During the inflammation phase, those affected experience an exaggerated inflammatory response presenting with oedema, erythema, and warmth of the affected foot without the protective sensation of pain. As the inflammatory phase ends, the disease progresses into the fragmentation, coalescence, and consolidations phases, also referred to as entering remission. Ultrasound, including greyscale and Doppler sonography, has been identified as a potential method of identifying signs of acute CN, and monitoring disease progression. This case report aims to describe the potential use of ultrasound in monitoring progression of acute CN to remission.

Methods: In this case report, we describe the changes in sonographic features of a 66-year-old male with type 2 diabetes, as he was followed prospectively from diagnosis of acute CN towards remission.

Results: The patient was diagnosed with acute CN on 4th February 2020 and reassessed on the 15th May 2020. He was managed conservatively with offloading. Following initial assessment, the asymptomatic foot had no oedema, no colour flow, triphasic waveform and a resistive index of 1.1 indicating no acute CN present. Whereas, as outlined in Table 1, the symptomatic right foot had sonographic features of acute CN which changed as he progressed towards remission.

Conclusion: In this case report we illustrate that sonographic readings return to normal as a patient progresses from the inflammatory phase into remission. Therefore, highlighting the potential use of ultrasound in monitoring patient response to treatment.

Table 1., Case Report		
	4 th February 2020	15 th May 2020
Subcutaneous Oedema	Yes	No
Intra-articular	Yes	No
Peri-articular colour flow	Yes	No
Spectral waveform morphology	Monophasic	Biphasic
Resistive Index	RI: 0.67	RI: 1.0
Peak systolic velocity (>30sec/cm difference)	Yes	No

P05.1-7

Charcot foot offloaded in stage 0 is associated with low risk of needing reconstructive surgery

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Background/Aim: Charcot foot (CF) can lead to foot deformity and ulceration, increasing the risk of needing future reconstructive surgery and amputation. The aim of this study was to investigate whether people with acute CF offloaded in stage 0 differed in future need of surgery compared to those offloaded in stage 1.

Methods: Patients diagnosed with acute CF at our tertiary centre between 2006-2019 were retrospectively studied using electronic medical records. Radiological reports (X-ray, MRI) were reviewed and used for dividing cases into either stage 0 or stage 1 Charcot foot, based on [1]. Only the first acute CF event in either foot was analysed. Future surgery (reconstructive surgery, partial amputation, and above-ankle amputation) was noted. Fisher's exact test was used for testing the null hypothesis. A value of 0.05 was chosen as the significance level for α . Data are given as median (IQR).

Results: 185 persons (aged 61 [52-68] years; 117 persons with type 2 DM; 115 men) and a total of 199 cases of acute CF were reviewed. The median follow-up period was 7.0 (3.9-11) years. 73 cases (37%) were offloaded in stage 0. No person in the stage 0 group had reconstructive surgery, versus 11 persons (8.7%) in the stage 1 group ($p < 0.01$). The frequency of partial (3 vs 4 persons) and above-ankle (5 vs 7 persons) amputation did not differ between the groups.

Conclusions: In this retrospective study, diagnosing and offloading acute CF in stage 0 seemed to prevent the need of future reconstructive surgery, while the risk of future amputation was not affected.

References: 1. Chantelau EA. doi: 10.4414/smw.2014.13948.

P05.2-1

Risk factors for lower extremity amputation and clinical characteristics among inpatients with diabetic foot ulcer

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Background: To explore the risk factors for lower extremity amputation (LEA) of foot ulcers by analyzing clinical characteristics of diabetic patients with foot ulcers (DFU).

Methods: A retrospective analysis was carried out on the clinical data of patients with DFU hospitalized in a multi-discipline-based diabetic center, from January 1, 2012, to December 31, 2020. Demographic, diabetes-related information and ulcer characteristics and final outcome were documented. Patients were evaluated for diabetic complications and co-morbidities while relevant laboratory and imaging tests were performed. The risk factors for LEA were determined using univariate and stepwise logistic regression analysis.

Results: The cohort included 992 patients, 62.7% were male, the mean age being 65.0 years, 71(7.2%) had amputation, 20(2.0%) refused amputation, and 10 (1.0%) died on discharge. Of the 962 patients with or without LEA, the neuro-ischemic foot ulcer was the main type (49.2%), and the first toes (23.7%) and fifth toes (13.4%) were the main sites in inpatients with DFU. Of LEA patients, 23.1% received major LEA and 76.9% received minor LEA, respectively. Those who underwent LEA presented significantly higher levels of white blood cell counts, platelet counts, and C-reactive protein. However, levels of hemoglobin and triglyceride, low-density lipoprotein cholesterol, albumin, uric acid, and ankle-brachial index (ABI) were decreased in patients with LEA. Patients with prior amputation, foot osteomyelitis, and gangrene had much higher rates of amputation. Using the multivariate model, significant risk factors for LEA were prior amputation (odds ratio 6.371, 95% CI 2.050-19.802), foot gangrene (odds ratio 5.585, 95% CI 1.768-17.640), ulcer area (odds ratio 1.013, 95% CI 1.000-1.026) and ABI (odds ratio 0.819, 95% CI 0.691-0.969).

Conclusions: We identified prior amputation, foot gangrene, increased ulcer area, and decreased ABI as significant predictors of LEA in patients hospitalized for DFU. In terms of DFU, the presence of prior amputation and foot gangrene was a determinant for amputation.

P05.2-2

Negative pressure wound therapy with instillation and dwell time with antiseptic solution leads to a shorter treatment term

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Background/Aim: To investigate the effect of negative pressure wound therapy with instillation and dwell time (NPWT-id) using antiinfection solution (AS) versus saline solution (SS) in chronic limb-threatening ischemia (CLTI).

Methods: Forty-eight patients (n=24 SS, n=24 AS) were treated with NPWT-id after endovascular treatment. SS group was median age 68.8 years; 19 males, n=19 hemodialysis, n=23 diabetes mellitus, and AS group was median age 67.4 years; 16 males, n=16 hemodialysis, n=22 diabetes mellitus. Wound bed tissue cultivation was taken in pre and post NPWT-id. The outcomes included bacteria count and length of using NPWT-id. The statistical analysis used t-test and the P value was <0.05.

Results: All patients closed their wounds. There were no adverse events with NPWT-id. There were no differences in outcome among SS and AS groups in the reduction of bacteria count ($p = 0.25$). AS group was shorter using NPWT-id than SS group ($p = 0.02$).

Conclusions: Both groups reduced the number of bacteria. AS group was found to be able to shorten the duration of treatment.

P05.2-3

Adverse and Protective Predictive Markers in An Audit of Foot Ulcer Healing in People with Diabetes: Associations with Glucose-Lowering Agents

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Background/Aim: To identify novel predictors and refine existing associations, this retrospective study explored patient and wound factors associated with diabetes-related foot ulcer (DRFU) healing outcomes. Recently, GLP-1RA usage has retrospectively been associated in some series with reduced amputation in observational diabetes studies[1], but linkages to DRFU healing have not been reported.

Methods: Patients with diabetes-related foot ulceration (DRFU) presenting to the interdisciplinary high-risk foot service at RPA Hospital Diabetes Centre (2017-2021), were assessed. Parameters included: patient and ulcer characteristics, comorbidities, medications prescribed, and key laboratory variables. Associations with DRFU healing rate and overall ulcer healing were determined by univariate studies then multivariable regression analyses.

Results: Patients (n=252) had mean±SD age 64.6±11.8 years, 74.6% were male, 90.8% had type 2 diabetes, with diabetes duration 21±11.8 years, including 17.3% smokers. Overall, 81.9% had a previous DRFU and 9.4% had prior amputation. Of the 563 ulcers in the group, initial ulcer area was 1.96±3.69 cm², 3.0±3.4 mm in depth, and 61.4 % were infected. Mean SINBAD wound score was 3.4±1.1, and 24.2% had leg oedema reported.

Overall, 91% of ulcers healed conservatively: 57% within 12 weeks, and 79% by six months. Median healing rate showed 11.3% weekly reduction in ulcer area. SGLT2i usage predicted 12 week DRFU healing but only by univariate analysis (OR 1.48, P=0.04). Each of: a higher SINBAD score (OR 17.1), leg oedema presence (OR 2.3) or low serum albumin (OR 4.4), and current smoking (OR 2.8), most robustly independently predicted several poor healing outcomes (each P<0.01), whereas GLP-1RA usage (n=10) predicted improved healing (OR 10.0, P<0.01). Model R² values ranged from 0.16 to 0.44, reflecting reasonable clinical utility. Leg oedema as an independent end-point was associated with certain current medicines: insulin treatment (OR 0.43, P<0.001), SGLT2i non-use (OR 1.53, trending at P=0.06), and absence of metformin use (OR 2.1, P<0.001).

Conclusions: Underlying mechanisms for some of these associations with ulcer healing may be mediated through microvascular dysfunction, or oedema. The potential of some newer glucose lowering medications to aid DRFU healing, especially GLP-1RA, requires more intensive and prospective investigation.

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P05.2-4

Continuum of care during all stages of wound healing with Copper Oxide Dressings

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Background Copper induces wound healing through increased angiogenesis, production of extracellular proteins and skin maturation. In our 3.5 years of clinical use of antimicrobial copper-oxide containing wound dressings (COD), we have seen these positive effects through all stages of wound healing, leading us to realize the “continuum of care” by the COD. Our aim was to review selected cases in order to demonstrate the continuum of care concept of COD management.

Methods Retrospective review that included only cases that were followed meticulously medically, with clinical photos and artificial intelligence analysis, from the beginning of COD application until wound closure and skin maturation.

Results We reviewed the cases of 45 patients with diabetes, who recovered from minor foot amputation. Eight patients had mild to moderate ischemia and 8 patients were after improvement of the vascular supply by angiography or bypass surgery. Two patients were on hemodialysis. Two patients, with unsuccessful vascular intervention and severe ischemia, went on to amputation and were not included in the study.

Average wound size was 12.5±4 cm². Average time to healing was 4.5 months. COD conveyed full antimicrobial protection with no events of cellulitis. Nevertheless, 1 patient, who continued to have exposed metatarsal stump, developed osteomyelitis and needed revision surgery and antibiotic therapy. This patient healed eventually with COD.

Significant debridement effect occurred in 17 patients. Granulation and epithelization occurred in all patients. Eventual skin and scar improved appearance was noted compared to what we would expect. None of the patients had significant increased foot pressure.

Conclusions Copper dressings had significant positive effect through all phases of wound healing, including antimicrobial protection, debridement stimulation, granulation tissue formation and epithelization, in patients with diabetic foot even in the presence of mild to moderate ischemia and renal failure. Skin maturation seems to be positively affected by continuous use of copper dressing even after the wound is closed. The “continuum of care” concept and the beneficial effect during all stages of wound healing is in line with the basic science research and is proved highly useful in clinical practice.

P05.2-5

Cell-based therapy in diabetic foot ulcer treatment – promising clinical results of ADSC application

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Background: There is still no effective treatment for diabetic foot ulcer (DFU) to achieve the best prognostic factor - reduced wound healing time. Cell-based therapies are considered as an innovative way of treatment in more and more unresolved clinical situations. There are a continuously growing interest in using mesenchymal stem/stromal cells (MSC) isolated from human donors as an active substance (about 1000 clinical trials currently registered at clinicaltrials.gov). Adipose-derived MSCs (ADSCs) are especially attractive due to the easy access and a rich panel of pro-angiogenic, pro-regenerative and immunomodulatory properties of their secretome. Enhanced healing after the ADSCs application in DFU was reported in 2019, although the applied cells were not the only variable in his trial. We aim to confirm and understand the ADSCs potential in wound healing in DFU by means of clinical outcome and analysis of the wound environment.

Methods: ADSCs suspension in fibrin glue (23 patients) or fibrin glue alone (23 patients) was administered to the wounds in DFU. Wound surface was measured at four consecutive follow-up visits. Short tandem repeat analysis and amplicon deep sequencing was performed to detect traces of donor cells and liquid chromatography with tandem mass spectrometry was used to identify proteome in the selected samples from the wounds one week after treatment.

Results: The wound size reduction at subsequent visits was greater in ADSCs recipients comparing to those who received fibrin glue alone, the 50% reduction was achieved faster (17.6 ± 1.5 days vs 25.5 ± 4.2 days, respectively) and by the end of the study the complete healing was achieved in 7 vs 1 participants. We confirmed presence of delivered cells up to three weeks after application and we found over thirty proteins in the wound of the cell recipients that were not present in the wound of the patients receiving the glue alone.

Conclusions: Application of allogenic ADSCs suspension in fibrin glue to the wound in DFU resulted in reduced healing time in correlation with molecular trace of cell presence and activity – a promising direction for the next steps in clinical investigations.

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P05.3-1

Comparison between Copper Oxide Dressings (COD) and Negative Pressure Wound Therapy (NPWT). Preliminary results of a randomized controlled trial

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Purpose: The purpose of the study was to compare the effect on wound healing efficacy, cost, convenience and complications between treating diabetic foot ulcers (DFU) by Negative Pressure Wound Therapy (NPWT) and Copper Oxide Dressings (COD).

Methods: A randomized controlled trial with 60 diabetic patients is being conducting comparing the reduction of wound size during 3 months of treatment between COD management to NPWT, as the primary end point, by using an artificial intelligence program (Tissue Analytics). The secondary endpoints assessed are percentage of wounds that were closed during the study period ; average time to wound closure; cost of treatment; convenience - patient and caregiver perspective; infectious episodes and other adverse events.

Results: 29 patients finished the study. Average wound area was 21.02 ± 23.36 cm² in the COD arm and 14.84 ± 13.17 cm² in the NPWT arm ($p=0.41$). Reduction of wound size was 61.5% and 41% ($p=0.04$) after 1 month, 80.9% and 69% ($p=0.28$) after 2 months, and 88% and 84% ($p=0.17$) after 3 months, in the COD and NPWT arms, respectively. 7 wounds (46.7%) and 4 wounds (28.6%) were closed in the COD and NPWT arms, respectively. COD therapy was statistically significantly more convenient (Visual Analog Score [VAS] was 8.44 vs. 5.33; $p=0.002$) and less painful (VAS was 1.15 vs. 2.19; $p=0.67$) to the patients in the COD arm than in the NPWT arm. The medical personnel scored COD application as more convenient than the NPWT application (8.29 vs. 6; $p=0.007$). The mean application time was shorter for the COD compared to the NPWT (8.5 vs. 13.25 minutes; $p<0.001$). Cost is estimated to be ~16% in the COD Arm compared to NPWT Arm.

Conclusions: The preliminary results of this RCT study indicate statistically significant non-inferiority of COD dressing therapy than NPWT in terms of wound healing rate of DFU, and superior results in terms of convenience, reduced application time and cost. When considering NPWT for DFU, the use of COD may be the first line of treatment.

P05.3-2

Efficacy of transcutaneous application of CO₂ on improvement of microcirculation and diabetic foot ulcer healing time

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Aim: The difficulty in treating many diabetic foot complications is related to poor perfusion of the wound and surrounding tissues. The aim was to evaluate the effectiveness of improving microcirculation by transcutaneous CO₂ application on the outcome of diabetic foot ulcer (DFU) and neuropathy.

Methods: After surgical debridement and optimal standard surgical care, patients were randomly divided into a study group receiving 20 treatments with transcutaneous application of CO₂ in gaseous form (PVR system) and a control group receiving placebo treatment with air. The following parameters were analyzed before and after treatment with gaseous CO₂ or placebo: Wound surface area and volume, laser Doppler (LD) flux in the cutaneous microcirculation and skin temperature at the first big toe, Semmes Weinstein monofilament test, Rydel Seiffer vibration test. Capillaroscopy and MRI were performed in three randomly selected patients before and after treatment with gaseous CO₂.

Results: DFU in the gaseous CO₂ treatment group showed significantly faster healing: 20 of 30 wounds healed completely within 4 weeks, and on average, median surface area decreased by 96% ($p = 0.001$) and median volume decreased by 99% ($p = 0.003$). In the control group, median surface area decreased by 25% and volume by 27% ($p > 0.1$). LD measurements in the study group showed increased mean relative powers of LD signals in relation to NO-independent endothelial (0.07 ± 0.055 vs. 0.048 ± 0.059 , $p = 0.0058$) and NO-mediated endothelial (0.154 ± 0.101 vs. 0.113 ± 0.108 , $p = 0.015$) activity. Skin temperature measurements, monofilament and vibration tests all showed statistically significant improvement ($p < 0.001$) in the study group, while the control group showed no difference in the assessed parameters before and after treatment. Capillaroscopy showed increased capillary density at the site of the wound and at the nail fold of the skin on the first big toe.

Conclusion: The direct effect of transcutaneous CO₂ application on improving microcirculation has a significant impact on faster healing of DFU and stimulates angiogenesis.

P05.3-3

Multiple dose regenerative therapy using ex vivo expanded autologous peripheral mononuclear cells (MNC-QQ) for nonhealing ischemic foot ulcer -Phase1/2Study-

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Aim; Recently, regenerative therapy using endothelial progenitor cells (EPC) are developing for ischemic foot ulcers including diabetes. However, the function and the numbers of EPC are known to be impaired in diabetic patients. We have previously reported the feasibility and efficacy of MNC-QQ therapy for chronic non-healing ischemic extremity wounds which is a therapy applying peripheral blood mononuclear (PBMNCs) cell cultured by quantity and quality culture system (QQc) 1). QQc is a serum free ex vivo expansion system which generates large number of functional peripheral blood cells from a very small number of blood draw. As a next stage clinical trial, we are now investigating the safety and efficacy of multiple dose application of MNC-QQ therapy for patients with nonhealing ischemic foot ulcers.

Methods; From October 2018 to March 2022, five cases of MNC-QQ cell therapy was performed. 100ml of peripheral blood was collected from four patients (2 males, 2 females, 64.4±7.89 y.o., 2 diabetes), five non-healing ischemic foot ulcers (>3months) with one patient treated on bilateral limb at a different timing. After QQc for 7days, 1×10^7 cells were injected into the muscle and subcutaneous tissue of the foot and posterior leg. The primary endpoint is safety, whereas the secondary endpoint was efficacy including wound healing and improvement of vascular perfusion.

Results; Total of three times injection was conducted on two patients, two time for the two patients, one time for one patient. All patients had no serious adverse events, no deaths, or major amputation for 48 weeks after the 1st cell transplantation. All cases showed complete healing and improvement of the pain and vascular perfusion.

Conclusion; These results indicate that multiple dose MNC-QQ therapy is safe with high efficacy and will be able to transplant highly vasculogenic cells from a small blood sample and will be the first choice adjuvant therapy for the non-healing ischemic diabetic foot ulcer in the near future.

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P05.3-4

Three years' experience in limb salvage using novel biodegradable temporizing matrix – what have we learned?

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Background Healing of complex diabetes-related foot wounds are known to be challenging as these wounds are often subjected to high shear stress or have exposed structures such as tendon, fascia, or bone. Without expedited wound healing, these wounds are at risk of further infection. NovoSorb (R) Bio-degradable Temporising Matrix (BTM) has been utilised at a quaternary hospital since 2019 to address the need for a dermal matrix to assist in wound reconstruction in complex diabetic foot wound. We aim to review our experience in using this novel technology in limb salvage.

Methods All patients with complex diabetes-related foot wounds that were deemed to benefit from BTM application were prospectively observed for 12 months. Indication for BTM, variation from prescribed pilot study protocol, time to complete wound healing, infection rate and incidence of subsequent wound breakdown were analysed.

Results 32 patients with a total of 33 BTM applications were followed up during the study period. 2 patients did not complete BTM treatment as they were palliated for other reasons. One third of the study cohort were classified to be in WIFi clinical stage 4, while only 5 patients were in clinical stage 1 (7 in stage 2, 8 in stage 3). Complete wound healing was achieved in 26 patients (86.7%), and re-occurrence of ulceration within 12 months only occurred in 4 patients (15.4%). 2 patients were reported to have infection of the BTM site (6%), and major amputation rate in this cohort was 6% (2 patients). The length of stay for patients reduced from 5 -10 days following application to 0 day (same day discharge) over the period of the study.

Conclusions BTM has been shown to be safe and effective in management of complex diabetes-related foot wound. We have been able to refine our protocol through experience, efficiently reduced the length of stay and frequency of follow up for our patient's cohort. Additionally, we have also been able to offer this novel technology to our patients in rural and remote area. We aim to further improve on our service to allow BTM application in ambulatory setting.

P05.3-5

Effect of autologous combined leucocyte, platelet and fibrin patch (AP) on hard-to-heal diabetic foot ulcers (DFU)

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Aim: To describe the effect of the AP(I) on hard-to-heal diabetic foot ulcers (DFU) with moderate to high risk of amputation (Wifl) in a mostly inpatient setting.

Method: We conducted a retrospective data analysis from our patients. Treatment involved the application of the AP in addition to best standard of care. To secure the placement of the AP on top of the tendon and above, NPWT (II) was used in 76% of patients. Data collection included patients' demographics, wound grade, wound infection and vascular status (Wifl).

Results: We analysed data from 66 inpatients and 8 outpatients treated between April 2016 to February 2022. Study population: Age 64.7 ± 11.5 years; 90.5% men; BMI = 31 ± 6.3 kg/m²; HbA1c $7.44\% \pm 1.5$; 13% Charcot; 7% ESRD; 51% prior amputation; 77% exposed bone. Risk for amputation based on Wifl was high (59%), moderate (32%), low (5%) and very low (3%). Average number of AP applications was 3.0, average treatment time 15 ± 13.5 weeks. Patient outcomes at week 20 by Wifl risk class: 1 = healed (high risk 44%, medium risk 43%, low risk 60%); 2 = bone tendon over granulated (high risk 10%, medium risk 13%, low risk 20%); 3 = still existing (high risk 26%, medium risk 22%, low risk 20%); 4 = short-term amputation (high risk 18%, medium risk 22%); 5 = amputation > one year (none); 6 = death (high risk 3%). Follow-up data from July 2022 showed 81.1% patients to be alive; 5 died without a wound; 1 died with unknown status; 4 died with a wound; 1 died with amputation, and for 3 patients there is missing data.

Conclusion: AP used in addition to standard wound treatment, seemed to expedite wound healing without any negative side effects among patients with hard-to-heal DFU with high risk of amputation based on Wifl risk

(I): 3CPatch by Reaplix A/S, Europe

(II): NPWT V.A.C. FreedomTM KCI and Suprasorb[®] CNP P3 L&R

Acknowledgment: Reaplix, Bregnerødvej 133A, 3460 Birkerød, Denmark provided the equipment for the treatment. Otherwise, treatment was performed under the budget of the Diabetes Klinik Bad Mergentheim GmbH & Co. KG, Germany.

P05.4-1

Wound Healing Risk Factors - A Phase 3 RCT Post-hoc Analysis of a Novel Macrophage-regulating Drug

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Aim: A phase 3 multinational randomized controlled trial was conducted in the US, China, and Taiwan to investigate the efficacy and safety of ON101, a topical new drug with a M1/M2-macrophage-regulating mechanism, in 236 subjects with Wagner grade 1 or 2 diabetic foot ulcers (DFUs). We analyzed the risk factors affecting wound healing in the Phase 3 RCT post-hoc analysis.

Methods: In this post-hoc analysis, we investigated the impact between risk factors, including baseline HbA1c (7, 9%), ulcer duration (3, 6 months), ulcer location (by pressure severity), ulcer size (3, 10 cm²), amputation history and recurrence, and the complete healing rate (the primary endpoint in the Phase 3 RCT). For the primary efficacy, we used the ROC curve, Chi-square test, and logistic regression model (with intervention as a fixed factor, with the baseline ulcer size and Wagner grade adjusted as covariates). The logistic regression model results are presented as the odds ratio (OR) and 95% C.I., and the Chi-square test results are performed as the P-values.

Results: Based on this post-hoc analysis, HbA1c and ulcer duration are the most important risk factors in poor healing of DFU (p value from area under ROC=0.0014 and 0.0136, respectively). ON101 has been demonstrated with consistent and robust efficacy over the standard care in DFU treatment regardless of these risk factors. Besides, higher proportion of complete healing was reached by early use of ON101 (72.58%).

Conclusions: HbA1c and ulcer duration are key risk factors to impact healing of DFUs, however, regardless of the risk factors, ON101 has demonstrated robust efficacy and safety in DFU treatment. Besides, the early use of ON101 could deliver optimal healing. It is suggested that macrophage rebalance may play a critical role in accelerating DFU healing.

P05.4-2

Freeze-dried human amniotic membrane helps in healing of diabetic foot ulcerations

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Aim: The amniotic membrane contains growth factors, cytokines, and signaling molecules that are important in tissue regeneration and wound healing.

We present results of a multicentre observational study demonstrating the use of a lyophilized amniotic membrane in the treatment of diabetic foot ulcerations, in addition to standard care of the diabetic foot (offloading, revascularization procedures etc) – instead of the choice of wound dressing.

Method: 8 diabetic foot clinics enrolled from 1 to 13 patients with chronic diabetic ulcerations (the mean duration from 3 to 21 months). Totally 57 patients were presenting 67 ulcers (5 patients had multiple ulcers). Amniotic membrane was applied at every ulcer in 1-week intervals. All patients obtained from 2 to 5 applications and we observed the process of wound size change (measured by Electasure software). Last visit was held 2 weeks after last amniotic membrane application.

Results / Discussion: 57 diabetic patients (mean age 63.6 years, 8 women = 14 %, 9 type 1 diabetes = 16 %) with HbA1c mean value 57 mmol/mol, 61 % with normal kidney function. All patients with significant ischemia underwent revascularization procedures before starting the treatment with amniotic membrane. All of them used offloading therapy (crutches, wheelchairs, half-shoes, orthoses etc.). The antimicrobial treatment was used in 50 % of ulcers and finished before first application of the amniotic membrane. Most from 67 defects were localized at plantar part of foot (10 % at plantar surface of toes, 60 % at metatarsal heads, 16 % at heel). The mean wound area before first application was 6.47 sq cm, 2 weeks after last application 1.73 sq cm. 39 % of all ulcers healed completely, 49% reduced their size significantly (mean size reduction 77 % of area, from 53 to 98 %), in 9 % the wound size stayed unchanged and only in 2 (3 %) patients the wound was worse than before.

Conclusion: The application of freeze-dried human amniotic membrane could significantly help in the treatment of chronic diabetic ulceration – could result in complete healing or significant reduction of the wound size during 3-6 weeks of therapy.

P05.4-3

Continuous Diffusion of Oxygen Therapy for Surgically Closed Wounds in Ischemic Diabetic Foot Patients – A Pilot Randomized Controlled Trial

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Background: Ischemic diabetic foot (IDF) encompasses a 31% conversion rate to minor amputations. A high prevalence of necrotic tissue may cause acute complications. Continuous Diffusion of Oxygen (CDO) improves healing in diabetic patients with open wounds, yet its effect in ischemic lesions remains uncertain. We aim to address this gap.

Methods: A randomized controlled trial was performed in IDF patients with surgically closed wounds post minor amputation. Patients were randomized (n = 2:1) to control (CG) or intervention (IG) groups. After primary closure, the CG received a standard of care (SOC) dressing for a 4-week (4W) duration. The IG received SOC + CDO through a cannula connected to a delivery system* for the same period. Outcomes included 1) incidence of wound complications (i.e., dehiscence, or necrosis) and 2) hospital readmission (i.e., revascularization, re-amputation) at 4W.

Results: Seventeen patients were enrolled. However, two were withdrawn before 4W due to lost to follow (n=1) and device uncomfortableness (n=1), leaving a total of 15 (IG, n=4; CG, n=11). Indications for procedures were gangrene (n=11), severe infection (n=2), and non-healing ulceration (n=2) that led to n=14 hallux and n=1 transmetatarsal amputations. Mean age was 64.3±9.4 years (p=0.812), BMI was 28.2±6.5 (p=0.986), HbA1c was 7.8±1.9 mmol (p=0.085), previous 30-day revascularization was 53.3% (p=0.876), heart disease rate was 46.7% (p=0.310), and CKD was 40.0% (p=0.095). At 4W, the incidence of complications (IG=25% vs CG=54.5%, OR=3.67, Effect size g=0.3, p=0.31) as well as hospital readmission (IG=0% vs CG=27.3%, g=0.24, p=0.24) was lower in the IG. However, results did not achieve statistical difference.

Conclusions: A positive non-significant trend in favor of CDO may indicate potential benefit to reduce complications and hospital readmission in patients with IDF undergoing minor amputations. A higher sample size is warranted to confirm this statement.

Acknowledgements *TransCu O2 (EO2 Concepts Inc). This study was partially supported by the device manufacturer.

P05.5-1

Pathological formation of bone tissue after reconstructive surgery of the Charcot foot during treatment with teriparatide

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Background: Charcot foot is a severe complication of DM and is a progressive lesion of bone tissue leading to foot deformity. The results of surgical treatment depend on the ability of the bone tissue to repair. The aim was to investigate the potential of teriparatide as a safe and feasible option in the treatment of Charcot foot after recon-structive surgeon.

Methods: A 34-year-old female with DM presented to clinic with severe deformity of the right foot. Calcaneo-tibial arthrodesis using Ilizarov fixator during 4 months was performed. After dismantling a significant shortening of the lower limb (up to 5 cm) was noted. In connection with the shortening of the limb, a corrective osteotomy of the bones was performed, an Ilizarov external fixation apparatus was installed on 4 modules. Duration of fixator wear was 10 month, lengthening index was 0.75 mm/day. After 4 weeks of off-loading using non-removable TCC, we discovered fracture through the regenerated bone. Treatment include teriparatide 20 mcg per day, a monthly administration of 50,000 IU vitamin D3.

Results: The level of 25 OH Vitamin D at baseline was 18 ng/mg(30-100), PTH - 106.8 pg/ml(15-65). Accord-ing DEXA BMD in the proximal femur, osteopenia up to -2 SD, osteoporosis up to -3.0 SD in the radius was re-vealed. Before surgery, osteocalcin was 20.53 ng/ml (14-42), Cross-linked N-telopeptide of type I collagen - 0.438 ng/ml(0.1-0.85), a month after reconstructive surgery, bone metabolism mark-ers did not change. After cor-rection of vitamin D deficiency, the PTH level returned to normal. After 4 months: osteocalcin level was 133.1ng/ml (11-43), Cross-linked N-telopeptide of type I collagen - 1.69 ng/ml(0.3-0.57). DEXA: + 9.7% in-crease in BMD in the radius, + 5% in the femur. Positive dynamics in relation to the formation of bone regenerate of the bones, the process of formation of cortical plates, increased bone density of the tibial by X-ray.

Conclusions: There was no change in the level of markers of bone metabolism in the blood after sur-gery. Formed hypotrophy of the bone indicates a disturbed osteogenesis. The pharmacological treat-ment of local osteo-porosis is the main determinant of the success of orthopedic surgeries.



A radiograph shows the patient's limbs while wearing the Ilizarov fixator for lengthening of the tibia by 5 cm. (A) - limb shortening, arrow - calcaneo-tibial arthrodesis; (B, C) - unilateral lower-limb lengthenings using the Ilizarov external fixator; (D) - fracture through the regenerated bone; (E) - 6 months of the pharmacological treatment.

P05.5-2

Active Charcot foot – a single centre audit: characteristics, treatment outcomes and complications

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Background/Aim: The diabetic Charcot foot (CF) is a serious complication of diabetes that can often lead to major amputation. The pathogenesis is not fully understood. The diagnosis of active Charcot foot is primarily based on history and clinical findings but should be confirmed by imaging. The treatment is based on offloading, antiresorptive medication and some patients are indicated to surgery. The aim of our study was to review the characteristics, treatment outcomes and complications in patients with diabetes related CF treated at our foot clinic.

Methods: A total of 279 Charcot feet in 231 patients (mean age 60.6 ± 11.9 years, 70% men,) treated in our foot clinic were included in the study between 2014-2021 and retrospectively analysed. Diabetes and foot related characteristics, type of treatment, bilateral CF involvement, treatment results and complications including amputation rates were recorded.

Results: Of 231, 184 CF patients were treated conservatively, 20.3% of patients underwent orthopaedic surgery. Foot ulcers were present in 40.1% of feet, 19% of feet required minor amputations and 15.1% of feet needed other foot surgery. 20.8% of all CF patients had bilateral involvement. Major amputation-free survival was achieved in 98.2% feet after a mean follow-up of 3.7 years.

Conclusions: Conservative and orthopaedic treatment led to increased number of saved limbs in patients with CF in our centre. A common complication of CF treatment is the occurrence of foot ulcers and the associated need for surgery.

P05.5-3

Clinical characteristics, management and outcomes for Australian patients presenting with diabetes and Charcot neuroarthropathy of the foot

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Background Charcot neuroarthropathy (CNA) is an uncommon complication of peripheral neuropathy characterized by inflammation, fractures and deformity of the foot. To our knowledge, there are few Australian data reporting diabetes-related CNA outcomes.

Aims To describe the characteristics, management, and 12-month outcomes for patients with diabetes and CNA.

Methods A retrospective observational study of 83 patients with CNA attending the Fiona Stanley Hospital Multidisciplinary Diabetes Foot Ulcer outpatient clinic between 1st March 2015 and 6th February 2019 was conducted.

Results The mean (\pm SD) age of patients with CNA was 57.1 (\pm 12.2) years and 80.7% of patients had type 2 diabetes. 61.4% were male, 8.4% were Aboriginal and/or Torres Strait Islander people while 25.3% of patients resided in rural/remote areas. Median HbA1c [IQR] was 8.3 [7.2-9.6] %. Fifteen (18.1%) had bilateral CNA- data is reported for the index foot in these patients. 39 (47.0%) patients were treated for acute CNA, with an ulcer present in 15.4% and ulcer with osteomyelitis in 12.8% of acute CNA patients.

Removable knee-high devices (76.9%), irremovable knee-high devices (10.3%) or removable ankle-high devices (7.7%) were the mainstay choices of offloading. The median time to resolution was 184.5 [107.5-307.8] days. 12 months after the onset of acute Charcot foot, 70.6% patients had achieved resolution without a foot ulcer. Of note, 11.8% required major amputation, all of whom had concurrent diabetes-related foot infection (DFI) requiring hospitalisation at the time of initial CNA diagnosis. All patients with acute CNA were alive 12 months after first review compared to 97.7% of patients in the chronic group.

Conclusion The typical patient with CNA was male with type 2 diabetes. Although irremovable knee-high devices were infrequently utilised, resolution time of acute Charcot foot was shorter than comparable published observational data. All major limb amputations occurred in patients with concurrent DFI requiring hospitalisation suggesting that hospitalisation, infection and acute CNA purports a high risk of adverse outcomes.

P05.5-4

Active Charcot foot in the land Down Under and effect of denosumab on inflammation and bone health

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Aim: To clinically characterise people with diabetes mellitus presenting with early stages of active Charcot foot, and ultimately to evaluate whether denosumab improves clinical outcomes.

Methods: A randomised controlled open-label phase 2 study of denosumab in active Charcot foot was conducted across nine specialist foot services. Participants were adults with diabetes mellitus recruited within 3 months of active Charcot foot symptom onset. Based on random 1:1 allocation denosumab was added to standard care, with 60mg administered at baseline and again at 6 months if inflammation persisted. Data collection at baseline and at 1, 6, 12 and 18 months, encompassed bedside assessment, questionnaires, biochemistry, radiographs and calcaneal quantitative ultrasound. Included herein is the ethics-approved interim analysis of amalgamated baseline data with final outcomes available 2023.

Results: Twenty-six participants were recruited (mean age 59±10 years, 85% men), with mean body mass index 33±8 kg/m², predominantly type 2 diabetes (92%) and median diabetes duration 12 (IQR 5-23) years. Time since active Charcot foot onset was a median of 8 (IQR 7-12) weeks, most were Eichenholtz Stage 1 (92%) and 96% involved the midfoot. Comparing the active Charcot foot to the contralateral foot, the maximum temperature gradient was 4.6±1.6 °C. Bone health was poorer in the active Charcot foot with speed of sound 1552±42 versus 1573±39 ($p < 0.001$) and Stiffness Index 90.9±19.9 versus 98.7±18.0 ($p = 0.003$). Significant sagittal deformity had already occurred in the active Charcot foot with cuboid height 2±6 versus 10±10 mm ($p < 0.001$), lateral tarsal-1st metatarsal angle -15±13 versus -5.3±13 degrees ($p = 0.002$), and calcaneal pitch 12±6 versus 17±7 degrees ($p < 0.001$). Quality of life was adversely impacted with limitations in function and role.

Conclusion: Presentation of active Charcot foot to specialised foot services is delayed, with deformity evident at baseline. In comparison to the contralateral foot, bone health is poorer in the active Charcot foot within weeks of disease onset. Effectiveness of denosumab in abating bone loss and potentiating consolidation remains to be determined.

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P05.5-5

Maximising Limb Salvage of the Charcot Foot Deformities Through a Novel Multidisciplinary Team in India.*Dr Srinivas Seshabhaktar¹, Prof Venu Kavarthapu, Dr Raja Sekhar Vuyyuru**¹Apollo Hospitals, Hyderabad, Hyderabad, India*

Evolution of diabetic foot care in India over the past few decades has progressed well but did not include functional limb salvage for limb threatening Charcot foot by a structured and protocol driven multi-disciplinary care. To address this, our existing diabetic foot multi-disciplinary unit (DFMDU) in a major cosmopolitan hospital in south India that did not provide functional limb salvage service for deformities had been complemented with an expansion of the team and structured training and upskilling of the existing team members. The protocols at a well-established DFMDU in England have been implemented in our unit. These included on diabetic foot infection management and advanced wound care, offloading and Charcot foot reconstruction. The aim of this study is to analyze the patient demographics and the early outcomes of limb threatening Charcot foot deformity corrections performed following the implementation in our upgraded unit in India.

Methods All patients presented with limb threatening Charcot foot deformities to our unit since the implementation of these changes have been included in this study. The patient demographic and outcomes have been analyzed.

Results There were 11 patients, 7male and 4 female, with mean age of 65 year, all with type 2 diabetes & peripheral neuropathy. 7 had ulcer at the time of presentation, of which one was actively infected at presentation. The mean number of surgeries performed prior to the index procedure were 3. Two-stage reconstruction was done in 1 and one-stage reconstruction was in 10 feet. Postop management included targeted antibiotic administration and offloading in total contact cast for 3 months. Out of 11 operated patients, 7 patients who had minimum followup of 4 months have been included in the study. The mean follow-up was 8 months. All ulcers healed within 3 months. 7 had full bone healing. None had wound infection or metal work failure. All 7 patients are mobilising full weightbearing in TCC. Limb salvage achieved in all patients.

Conclusions Implementation of well-established protocols and upskilling of the multi-disciplinary team provided satisfactory outcomes of functional limb salvage for diabetic foot deformities at a geographical region that did not have such service previously.

P05.6-1

A multidisciplinary Diabetic foot team reduces mortality and in-hospital complications of patients with diabetic foot ulcer

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Aim: The study aimed is to evaluate the effectiveness of a dedicated multidisciplinary diabetic foot team (MDFT) in the management of hospital patients affected by an acute diabetic foot ulcer (DFU).

Method: The study group was composed of patients who referred to a tertiary diabetic foot service since January 2019 to November 2022 due to a new diabetic foot problem requiring hospitalization. All patients have been managed by a MDFT through a pre-set limb salvage protocol according to International Working Group on the Diabetic Foot guidelines. The MDFT was composed of diabetologist, and among them someone skilled in diabetic foot surgery, interventional radiologists, vascular surgeons, and podiatrists. Diabetes, diabetes complications and concomitant co-morbidities were closely managed. The outcomes measures were hospital mortality, major amputation and in-hospital complications (IHCs).

Results: Three-hundred twenty-two patients were included. The mean age was 68.6 ± 12 years, 75.8% were male, 93.1% had type 2 diabetes with a mean diabetes duration of 20.3 ± 9.8 years, and a mean HbA1c of $8.1 \pm 0.2\%$ (65 ± 1 mmol/mol); 64.5% had ischaemic DFUs, and 84.1% infected DFUs. Overall, in-hospital mortality was 1.5 %, major amputation 4.3%, and IHCs 7.4%. Among IHCs 45.5% of cases were anaemia requiring blood transfusion, 20.8% pneumonia, 8.3% acute heart failure, and 4.1% acute myocardial ischaemia, uncontrolled hypertension, acute kidney failure, bowel ischaemia. IHCs were recovered in 83.3% of cases. Previous history of ischaemic heart disease [OR 3.6 95% CI (1.6-14.2), $p=0.04$] was an independent predictor of IHCs, while IHCs [OR 3.1 95% CI (1.2-7.6), $p=0.03$] was an independent predictor of in-hospital mortality.

Conclusion: The management of patients with DFUs through a dedicated MDFT achieved a low risk of IHCs and in-hospital mortality. Ischaemic heart disease was associated to the risk of IHCs, while IHCs resulted associated to in-hospital mortality.

P05.6-2

Interprofessional Wound Care Team Competency Framework: Results from a Canadian adapted e-Delphi Study

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Background/Aim: An interdisciplinary health care approach is essential to care for individuals with wounds, particularly with diabetic foot ulcers. Currently in Canada, there are no consistent framework to support wound care teamwork. Therefore, we sought expert consensus in Canada on core competencies to prevent and manage all types of wounds in order to develop an interprofessional wound care team competency framework.

Method: A 2-step method involving a patient-centered research approach was conducted: 1) a rapid literature review to draft potential competencies based on seven roles (i.e., wound care expert, scholar, health advocate, leader, professional, collaborator and communicator) using the CanMEDS Framework [1], and 2) an adapted e-Delphi study[2]. Wound care experts were invited to contribute to three rounds of the questionnaires using Qualtrics, an anonymous online survey platform. Suggested competencies were scored on a 9-point Likert scale for agreement. Consensus was defined as at least 80% agreement for each competency. Also, patients and caregivers had the opportunity to provide feedback during a workshop.

Results: A total of 149 experts with at least 2 years of wound care experience were solicited in collaboration with Wounds Canada for the first round. The response rate was 44%. Experts were very diversified in terms of profession, years of practice, setting and place of residence. The central region (Ontario and Quebec) was the most represented, and the northern and Atlantic regions, the least. Four patient partners and 2 caregivers gave retroactions in a 1.5-hour workshop. One hundred fifty-six core competencies have reached consensus by experts after two rounds, and 60% of them achieved 90% or greater agreement. The experts also agreed on the seven roles and wound care team definitions. All feedback towards the open-ended questions was favorable toward the initiative and found the framework relevant and comprehensive.

Conclusion: This initiative has the potential to support education, interdisciplinary team approach and patient-centered care. The next steps are developing indicators to achieve these competencies. We are currently conducting an international validation.

1. Frank and al. The CanMEDS initiative. Medical teacher. 2007;29(7):642-647.
2. McPherson S and al. Methodology update: Delphi studies. Nursing research. 2018;67(5):404-410.

P05.6-3

Risk factors for recurrence in diabetic patients with previous ulcer of the foot

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Background/Aim: Recurrence of lesions in diabetic foot patients is a critical problem. Literature analysis underline a high rate of recurrent ulceration. Aim of our study is to evaluate risk and prognostic factors for recurrence in diabetic patients with previous ulcer.

Methods: We analyzed patients presenting at diabetic foot visit from April 2022 to June 2022. We identify 50 patients with recurrence after previous ulcers and 33 patients with previous lesions but without any recurrence. Study population presented type 2 diabetes (94%), mean age 68±12 years (mean±SD), 82% male, long history of diabetes 19±12years, BMI 30±5 and suboptimal metabolic control (HbA1c 7.8%±1.9). Mean GFR was 74 ml/min; 4 patients were affected by end stage renal disease. Patients with recurrence presented similar age, diabetes duration, metabolic control, BMI and renal function compared to patients without recurrence. Prevalence of neuropathy, vascular disease and ischaemia were not statistically different into the two groups.

Results: recurrence were usually multiple (92%) and localized at toe level (70%). 80% of patients with recurrence presented a low level of foot deformity limited to forefoot with maximum loss of 1 metatarsal head, while 20% presented charcot foot, deformity of rear and middle foot or severe deformity of forefoot. Orthopaedic shoes were prescribed in 66% of cases, but compliance to use was low, with only 17 (34%) patients use orthopaedic shoes more than 6 hours/day. Absence of compliance increased the risk of recurrence despite adequate shoes. Direct causes of recurrence were traumatic event in 20 patients (40%) and conflict with shoes in 27 (54%). Multivariate analysis founded that compliance is a protective factor independent to age, diabetes duration, deformity level and sex.

Conclusions: Ulcer recurrence is a common event in diabetic patients with previous lesions. Data from this study evidence that recurrence is usually multiple and localized at toe level, with adequate compliance as the key element in prevention. More efforts are mandatory to improve the compliance in using orthopaedic shoes at home.

P05.6-4

Internet-based foot-ankle exercises program and its effects on gait biomechanics: a proof-of-concept study

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Background/Aim From the 2000s to the present day, there have been significant advances on foot-ankle exercises programs targeting the main musculoskeletal deficits and gait biomechanics in people with diabetic peripheral neuropathy (DPN) [1]. However, the effects of an internet-based foot-ankle therapeutic exercise program - the Diabetic Foot Guidance System (SOPeD, www.soped.com.br) [2] in people with diabetes and DPN have not yet been evaluated. Thus, the aim of this study was to pursue initial evidence for potential benefits of an internet-based foot-ankle therapeutic exercise program on gait biomechanics in 12 weeks for people with DPN.

Methods We conducted a proof-of-concept study that is part of a full randomized controlled clinical trial—the FOot CAre (FOCA) trial, in which 30 adults with DPN were randomized to either the usual care (control group, CG) or usual care plus an internet-based foot-ankle exercise program through SOPeD (intervention group, IG) 3x/week for 12 weeks, being the first face-to-face session with a physical therapist. We assessed the biomechanical outcomes at baseline to 12 and 24 weeks. Generalized Estimating Equations estimated between-group differences and 95% confidence intervals. The foot-ankle kinematic parameters were recorded using eight infrared cameras following the Oxford Foot Model [3] and the Plug-In Gait setup protocols. Plantar pressure variables were acquired using the emed-q100 pressure platform.

Results After 12 weeks, the pressure-time integral at the medial forefoot increased in the IG compared to CG. After 12 and 24 weeks of followup, ankle plantar flexion angle at push off and hallux to forefoot peak angle were significantly greater in the IG than CG. Hindfoot to tibia peak angle and hallux to forefoot ROM was also greater in the IG than CG after 24 weeks. In addition, at 12 weeks, the maximum and minimum arch height were smaller in the IG compared to the CG.

Conclusions An internet-based exercise program using the SOPeD has the potential to modify foot-ankle motion during gait, that is an important risk factor for ulcers in people with DPN.

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P05.6-5

Perceptions of sensorized offloading boots for diabetic ulcers using the technology acceptance model

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Background: People with diabetic foot ulcers (DFUs) are commonly prescribed offloading boots, but inadequate adherence to prescribed use can be a barrier to ulcer healing.[1-2] We examined user perspectives of irremovable, removable, and sensorized offloading boots to provide insight on ways to help promote adherence. [3]

Methods: Participants were randomized to wear, for 12 weeks or until healed, offloading boots that were: 1) irremovable, 2) removable, or 3) removable and infused with sensors that provided feedback on adherence. Participants reported 12-month fall history and completed a 15-item questionnaire based on the Technology Acceptance Model (TAM) with a 5-point Likert scale, from “strongly agree” to “strongly disagree.” [4] Spearman correlations assessed associations between TAM ratings with participant characteristics. Based on correlation results, Chi-Squared tests compared ethnicities, as well as fall status.

Results: 21 people with DFUs (age 61.5 ± 11.8 years; 85.7% male) participated. Age, dropout, and group assignment were not associated with TAM ratings. Smart boot users reported learning how to use the boot was easy ($p=-.82$, $p \leq 0.001$). People who identified as Hispanic or Latino, compared to those who did not, reported they liked using the boot ($p=0.05$) and would use it in the future ($p=0.04$). Non-fallers, compared to fallers, reported the design of the boot made them want to wear it longer ($p=0.04$) and was easy to take on and off ($p=0.04$).

Conclusion: Sensorized boot users were more inclined to report that learning how to use the boot was easy, suggesting smart technology may ultimately help promote adherence. Perceptions tended to be more favorable, regardless of boot type, in people who identified as Hispanic or Latino or had no self-reported falls in the last 12-month. These observations can help inform patient education and product design to promote adherence.

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Acknowledgements: Thanks to Dr. Jason Hanft, Davide Vigano, and Maurizio Macagno for technical support. This study is supported by National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases (1R01124789-01A1).

P06.1-1

Re-ulceration is common in persons with diabetes and healed foot ulcer after participant-driven education in group: A randomized controlled trial

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Background: Re-ulceration after healing of a diabetic foot ulcer is common. The aim was to compare the number of ulcer-free days during 24 months in persons with diabetes and a healed foot ulcer below the ankle provided with adjusted therapeutic shoes who were given standard information and participated in participant-driven group education compared with standard information alone.

Method: A randomized controlled trial was designed to evaluate the number of ulcer-free days after participant-driven group education in addition to standard information compared to standard information alone. The number needed to treat (N=174) was not met, as only n=138 persons with diabetes and previously healed foot ulcer were recruited (age median 63 years [34–79], 101 male/37 female). The main reason for this was the comorbidities in the group of persons with diabetes and a healed DFU.

Result: 138 persons were recruited, of whom 107 (77.5%) completed the study, 7 (5%) dropped out, and 12 (9%) became deceased. No statistically significant difference was found between the intervention group compared to the control group after 6, 18, or 24 months. After 12 months, more patients in the intervention group had developed ulcers. Seventy-seven participants (56%) developed new foot ulcers, irrespective of side and site. Development of one ulcer appeared in 36 participants, two ulcers in 19, and 22 participants developed three ulcers. Forty-eight participants (35%) remained ulcer-free during the 24-month follow-up. Median ulcer-free days until first ulceration were 368 (4–720); until second ulceration, 404 (206–631); and until third ulceration, 660 (505–701). The participants wore prescribed therapeutic shoes during 88% of the follow-up visits.

Conclusion: One third of the participants remained ulcer free for 24 months. Patient-driven education in groups did not give better results than standard information in this underpowered study. The present study illustrates the challenges to perform comparative preventive studies in this group of patients with extensive comorbidity. Further studies are needed to evaluate interventions on ulceration in persons with diabetes and a healed foot ulcer.

Annersten Gershater M et al *Advances in Wound Care* (New Rochelle). 2022 Mar 22. doi: 10.1089/wound.2021.0007. Epub ahead of print. PMID: 35088617.

P06.1-2

Diabetic foot complications require specialized healthcare skills

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Introduction: Diabetic foot complications require specialized healthcare skills¹.

Background: Structurally disadvantaged Canadians are disproportionately affected by diabetic foot complications, with an increased risk of amputation and death due to inappropriate care and delayed treatment for diabetic foot complications². Leg amputation increases the burden on the Canadian health-care system and also greatly impacts patients' quality of life. Diabetic foot complications are preventable if patients have access to healthcare providers who specialize in foot care, such as chiropodists and podiatrists¹. Due to the current shortage of foot care specialists³, it is necessary to train non-regulated healthcare workers who serve vulnerable populations in providing diabetic foot assessment and education, in hopes of reducing the risk of leg amputation.

Aim: This project will develop co-created, community-driven solutions that meet the needs of vulnerable, under-serviced populations. Employers, educators and healthcare workers will be involved in the co-design of education pathways to equip non-regulated healthcare workers with the skills necessary to deliver high quality foot care education and assessments. The flexible, iterative education pathway process will highlight competency gaps, provide education and healthcare model recommendations, and deliver a comprehensive model sensitive to the needs of at-risk communities.

Methods: The development of the education pathways for this limb preservation project will be first piloted for vulnerable populations. This project will involve multiple stakeholders. To identify competency gaps, key stakeholders will be engaged through surveys, focus groups, and interviews. Their recommendations will be incorporated into the design of the pathways to address their specific needs.

Results: Results related to the stakeholder engagement and the design of the education pathways will be presented.

Conclusions: Upskilling non-regulated health care workers can help meet the demand for evidence-based intervention, prevention and assessment of diabetic foot ulcers leading to referral, early detection, reduction of amputations, and addressing a growing need in the workforce. If scaled nationally, this project has the potential to significantly reduce diabetic foot complications, in vulnerable populations.

Acknowledgements: Future Skills Canada Grant

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P06.1-3

Diabetes, Healthy Feet and You - Train-the-Trainer: A Quality Improvement Inquiry.

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Background/Aim: This quality improvement initiative focused on evaluation of the Diabetes, Healthy Feet and You (DHFY V2.0) program, the Train-the Trainer workshop, and training materials. Wounds Canada (2017) updated, the DHFY program, a self-management educational program designed to empower persons living with diabetes, by adopting self-management behaviours to prevent foot ulcers/amputations through: peer-led workshops and connection to a diabetes community. Our aim was to collect data from DHFY trainers attending training events.

Methods: This initiative utilized Patton's utilization-focused evaluation approach. We explored the effectiveness of the DHFY training program using an open-ended survey methodology. The DHFY program training materials were tested, and feedback was obtained. Thematic analysis generated key themes.

Results: Twenty participants completed the evaluation. Findings included:

- 1) Growing Knowledge in Foot Screening. They discussed growing knowledge
- 2) Engaging in Mock Workshop Training and Receiving Feedback. Participants described the benefits of practicing a mock workshop during which time they received peer and DHFY workshop facilitators feedback.
- 3) Group Facilitation and Communication with Technology, Online and Print Materials. Participants discussed the benefits of reviewing adult education principles and teaching skills in a facilitated, safe learning environment.
- 4) Experiencing Pre- and Post-Workshop Knowledge Questions. Participants described benefiting from completing the DHFY pre/post-workshop foot care questions. This was purposeful, as it gave them the opportunity to answer the same questions they would ask participants in a community-based workshop.

Conclusions: This quality improvement initiative provided constructive information that has been used to improve the DHFY Train-the-Trainer program. Future DHFY training included a greater focus on the role of public speaking, use of technologies, and ways to improve communication with health managers/directors. This study supported the sustainability and scalability of the program for trainers.

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P06.1-4

Update of professional diabetic foot website based on foot clinics real practice requirements

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Background/Aim: Internet is currently a widely used global tool for obtaining up-to-date professional information. However, some professional websites are not updated continuously and on time. The Executive Committee of the Diabetic Foot (DF) Working Group of the Czech Diabetes Society set itself the task of completely reconstructing a very outdated website. We aimed to restore our website based on a survey of real practice requirements among foot clinics.

Methods: In 2021, 35 foot clinics were approached twice to participate in a survey investigating the use of the original DF website and suggesting its modifications. Respondents obtained a 5-minutes online anonymous questionnaire, created professionally in cooperation with a sociologist. The data were statistically evaluated.

Results: A total of 28/87 addressed persons responded to the survey (75% of diabetologists, 18% of nurses, 7% of certified pedicurists) with the predominant age category of 41-60 years (75%). 52% of respondents have been practicing podiatry for >10 years. 43% of respondents followed original website at least once a month, 43% several times a year and 14% have not yet followed it. As for the original website, 84% of persons were used to look for foot clinics contacts, 96% used educational materials free available. Across respondents, the following were requested to be newly added/updated to the website: links to professional healthcare associations related to DF; links to national/international DF guidelines; more educational handouts; actual overview of DF meetings, courses and news; economic data for dealing with the insurance companies; sharing contacts for certified pedicure and orthoprosthesis.

Conclusions: The Executive Committee of the Czech DF Working Group would like to expect better adherence of foot clinics to participate in the survey. Nevertheless, the results obtained were useful and inspiring. On their basis, in 2022 we carried out a complete restoration and update of the DF website. We assume that taking the real requirements of users into account will be motivating for frequent website attendance, and the website will thus be a beneficial tool in the daily practice of people dealing with DF.

P06.1-5

Private practicing podiatrists in Denmark need further education in diabetes

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Background: Competencies on diabetes for private practicing podiatrists are pivotal for early detection and treatment of foot complications in people with diabetes, as it may prevent foot ulcers and reduce the risk of amputations which are costly both socio-economically and for the individual with diabetes. Formal continuing education for podiatrists in diabetes exists on an international level, however, there are no similar offers in Denmark.

Method: Three institutions have jointly developed and tested a 13 days education program in diabetes for private practicing podiatrists. The program is designed to equip podiatrists theoretically and practically to initiate an individual treatment that aims to prevent, detect, and treat diabetic foot ulcers and other foot problems in people with diabetes. Communication skills have been an important part of the program. The program runs over a period of five months and ends with an oral group exam. Teaching is done by teachers with different professional backgrounds. The education program is conducted as a pilot project tested on three classes with 16 students in each class in the period November 2021-May 2023. A qualitative questionnaire is used to evaluate the results.

Results: So far 29 students have finished the education program and 28 students have answered the questionnaire. The preliminary results show that:

- 86% state that they have acquired new skills and greater knowledge in podiatry for people with diabetes.
- 86% state that the continuing education has given them greater professional confidence when treating people with diabetes.
- 86% state that they use their acquired skills when treating people with diabetes.

Furthermore, the students experience becoming better equipped to communicate with people with diabetes. The pilot project also revealed a great demand for the continuing education, as the waiting list consist of more than 180 podiatrists from all over Denmark.

Conclusion: The continuing education gives private practicing podiatrists increased professional confidence when treating people with diabetes and an experience of having acquired new skills and greater knowledge on diabetes. The pilot project will continue until May 2023, and work is underway to ensure permanent nationwide continuing education.

P06.2-1

Predictors Of Poor Surgical Outcome And Repeat Surgery In Diabetic Foot Disease

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Background Diabetic foot disease (DFD) bestows a huge surgical burden on patients and healthcare systems worldwide.

We evaluated for predictive factors, observable at a patient's first presentation for a surgical procedure, which may indicate an increased likelihood of multiple surgeries in future.

Objectives Analysis of the individual and combined effects of different parameters in the prediction of outcome of diabetic foot surgery.

Study Design & Methods Our study included 70 patients with diabetes mellitus who underwent diabetic foot ulcer debridement between 2017 and 2022. These patients were divided into two cohorts. Cohort 1 received single surgery on their diabetic foot and Cohort 2 received multiple surgeries. Statistical analysis was conducted looking at various parameters between the cohorts to assess for any significant differences at the time of first surgery.

Results The majority of the patients were male and had Type 2 Diabetes mellitus (85.7%) compared to type 1 Diabetes mellitus (14.3%). The population mean BMI was 29.87 (Range 19.1 – 43.1). The median leukocyte count was 8.35 (IQR 6.68-10.73) and mean thrombocyte count was 327.71 (Range 77 – 683). The median C-Reactive Protein (CRP) level was 31.5 (IQR 13-111.5). Peripheral artery disease was found in 28.6% patients.

Conclusions Age at diagnosis, age at first surgery, BMI and thrombocyte count was not significantly different between patients requiring single and multiple surgeries ($p > 0.05$). On Mann-Whitney U Test, there is significant difference in CRP level. On Binomial logistic regression model, CRP was found to be a significant predictor for whether a patient will likely undergo one surgery or multiple surgeries (95% CI: 0.978-0.998) with a cut-off ratio of 84. Knowledge of these predictive parameters for poor surgical outcome in diabetic foot disease indicate that there is an increased likelihood that a patient will require further procedures. There is a need for further understanding into this disease and its modifiers.

P06.2-2

Racial Disparities in Lower Extremity Reamputation in Medicare Beneficiaries with Diabetes

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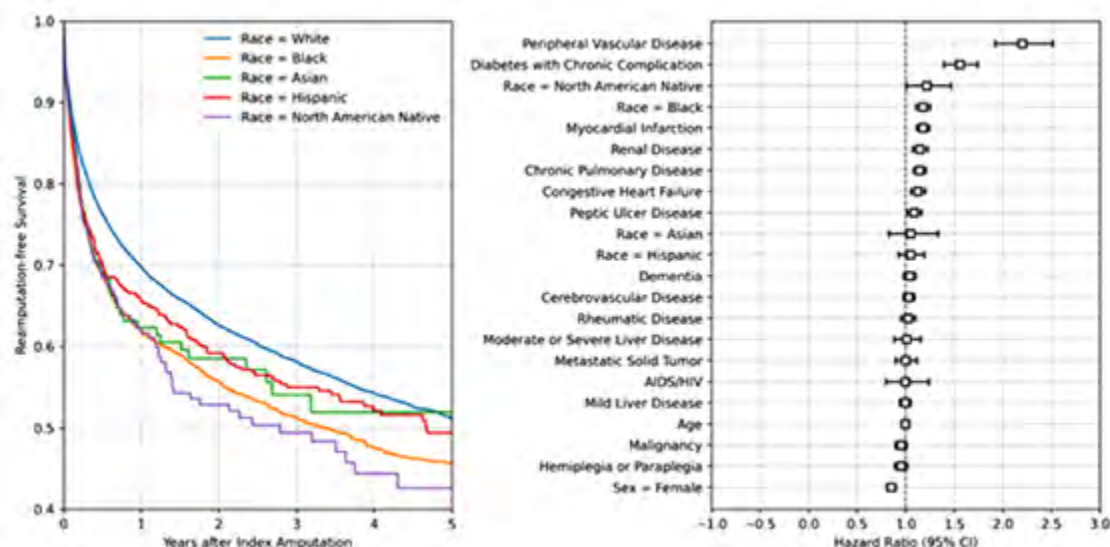
Background/Aim: A recent meta-analysis suggests that the reamputation rate among patients with diabetes is high, with 19% and 37% of patients suffering reamputation within one year and five years, respectively [1]. We aimed to replicate these findings in administrative data and identify health and demographic factors contributing to reamputation.

Methods: We used the Medicare 5% Limited Data Set from 2013 through 2019, which includes data from 3.9m beneficiaries. We excluded subsequent amputation procedures coded as staged or related to the index amputation. We fit a Cox Proportional Hazards model to the reamputation data with covariates including demographic data and Charlson comorbidities. We evaluated significance at $\alpha = 0.05$.

Results: A total of 17,789 beneficiaries with diabetes had at least one amputation from 2013 to 2019 in the LDS sample. At one and five years, the reamputation rate was 32% and 50% among all beneficiaries, respectively. In an unadjusted analysis, beneficiaries identifying as Black or North American Native had an 8% higher absolute risk for reamputation one year after the index amputation. In the adjusted analysis, peripheral vascular disease (HR = 2.2, CI: 1.92 - 2.51), diabetes with chronic complications (HR = 1.5, CI: 1.39 - 1.74), and identifying as Black (HR = 1.18, CI: 1.11 - 1.25) were all significantly associated with increased reamputation hazard, whereas reporting sex as female was significantly associated with decreased reamputation hazard.

Conclusions: Rates of reamputation among Medicare beneficiaries are high and independently associated with race after controlling for health and demographic factors.

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Having peripheral vascular disease, chronic diabetes complications, and identifying as Black or a North American Native increased the hazard for reamputation.

P06.2-3

Correlation between Compensation Level of Diabetes Mellitus Type 2 and Recurrent Surgical Treatment in Patients with Diabetic Foot Syndrome

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Title. Does the surgical treatment volume and length of hospital stay depend on the compensation level of T2DM complicated with DFS?

Methods. The treatment results of 363 patients with a neuro-ischemic form of DFS were processed – 164 (45.2%) men and 199 (54.8%) women. At the time of hospitalization to the surgical department, each patient had decompensated diabetes mellitus type 2 with different nature of surgical signs of DFS. Patients were divided into groups according to the average HbA1c indicator (%): 49 patients with 10.0±1.3; 85 with 12.0±1.1; 30 with 15.0±1.2. Insulin therapy was the only approach for diabetes compensation for the patients. Among 363 patients treated for DFS, 262 (72.2%) patients were diagnosed with T2DM only after the appearance of purulent-necrotic changes on the feet. The most common surgical treatment was the opening of abscesses and phlegmon – operations were performed in 42.2% of cases among women and in 33.5% among men.

Results. The number of repeated surgical interventions in the group of patients with HbA1c 12.0±1.1% was higher than in the group with HbA1c 10.0±1.3% by 21.1% in men and by 19.1% in women. This difference was greater for groups with HbA1c 15.0±1.2% and 12.0±1.1% – for men it was 29.8%, and for women – 31.8%. In patients with an HbA1c level of 15.0±1.2%, the duration of hospital stay increased to 34.66±3.40 days for men and 31.42±3.18 days for women. It was determined that an increase of HbA1c level by 2-3% led to prolongation of the hospital stay by 3.7-14.4 days for men and by 3.8-8.7 days for women and to an increase in the number of surgical interventions by 21.1-29.8% for men and by 19.1-31.8% for women.

Conclusions. The length of hospital stay and number of recurrent surgical interventions for patients with T2DM with a neuro-ischemic form of DFS is determined by the level of diabetic compensation at the time of their hospitalization.

P06.2-4

Decreased expression of 25(OH)VD and vitamin D receptor in type 2 diabetes mellitus patients with diabetic foot ulcers

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Background To elucidate the expression of 25-hydroxyvitamin D (25(OH)VD) in peripheral plasma (P-25(OH)VD) and vitamin D receptor (VDR) in wound margin tissues (T-VDR) of patients with type 2 diabetes mellitus (T2DM) who presented with diabetic foot ulcer (DFU) and diabetic foot osteomyelitis (DFO), and identify its correlation with treatment outcomes of DFU and DFO.

Methods 156 patients with T2DM with DFU (DFU group), 100 newly diagnosed patients with T2DM without DFU (T2DM group), and 100 healthy controls (NC group). DFU group were further categorized into DFO (n = 80) and NDFO subgroups (n = 76). Expression levels of P-25(OH)VD were measured via chemiluminescence, and T-VDR was measured through quantitative real-time PCR.

Results DFU group showed significantly lower P-25(OH)VD expression and had a higher proportion of vitamin D deficiency and insufficiency than those in the T2DM group ($P < 0.05$). DFO group showed significantly lower P-25(OH)VD and T-VDR expression than those in the NDFO group ($P < 0.05$). Furthermore, P-25(OH)VD and T-VDR expression of DFU group were negatively correlated with ulcer course, Wagner grade, wound infection severity, the detection rate of drug-resistant bacteria, recurrence rate, and amputation rate of foot ulcer ($P < 0.05$). However, P-25(OH)VD and T-VDR expression were positively correlated with ulcer healing rate after 8 weeks ($P < 0.05$). Multivariate logistic regression analysis demonstrated that low expression of P-25(OH)VD were an independent risk factor for DFU and DFO (ORDFU = 2.42, ORDFO = 3.05, $P < 0.05$), and low expression of T-VDR was an independent risk factor for DFO (OR = 2.83, $P < 0.05$). The ROC curve analysis revealed that the AUC of 25(OH)VD related to the diagnosis of DFU and DFO was 0.821 (95% CI: 0.754–0.886, $P < 0.001$) and 0.786 (95% CI: 0.643–0.867, $P < 0.001$), When establishing a diagnosis of DFO, the AUC of T-VDR was 0.703 (95% CI: 0.618–0.853, $P < 0.001$).

Conclusion Decreased expression of P-25(OH)VD and T-VDR of patients with T2DM are closely related to the occurrence, development, and prognosis of DFU and DFO. These results can consequently be applied as potential biomarkers and be used to predict DFU and DFO.

P06.2-5

Lower limb amputations in Slovenia between 2015 and 2021

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Aim: Lower limb amputations are a quality marker of diabetes care in general and diabetic foot care in particular. Worldwide, the outbreak of COVID-19 epidemic had a significant impact on health care delivery. In Slovenia, the access to diabetic footcare services has remained unlimited during the lock-down period [1]. We analyzed the data on hospital admissions for lower limb amputations in Slovenia in the period 2015 – 2021.

Methods: The data from the national study on hospital admissions between January 1st, 2015 and December 31st, 2021 were analyzed. The overall diabetes prevalence in the country was estimated from the number of recipients of antidiabetic drugs (national data base).

Results: Between 2015 and 2021, the total population of Slovenia increased by 2,13% (from 2.064.632 to 2.108.708) and the absolute number of recipients of antidiabetic medications by 16% (from 106.318 to 123.420). In the observed period, there was a steady increase in the number of major and minor amputations in the people with diabetes mellitus (DM) but not in those without DM. During the COVID-19 period, the number of all amputations in the people without DM decreased, while in those with DM there was only a transient decrease in major amputations in 2020 (Table 1).

Conclusions: Amputation registry in Slovenia does not exist. Our study was the first systematic data collection on amputations in the country and provides a good basis for future planning of health services. The increase of amputations in the patients with diabetes is an emergency call to strengthen the network of diabetic foot clinics in the country.

Reference: 1. Urbančič-Rovan V. Diabetes Care. 2021 Feb;44(2): e27-e28.

Table 1. Hospital admissions for major and minor amputations in Slovenia between 2015 and 2021

	2015	2016	2017	2018	2019	2020	2021
Minor amputations - DM	455	409	444	489	573	616	648
Minor amputations - no DM	327	356	329	330	343	295	254
Minor amputations - all	782	765	773	819	916	911	902
Major amputations - DM	123	124	137	137	149	131	173
Major amputations - no DM	97	118	93	128	126	99	94
Major amputations - all	220	242	230	265	275	230	267

P06.3-1

Clinical characteristics of patients referring to a specialized diabetic foot service for an acute diabetic foot problem

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Background/Aim: The study aimed to evaluate the clinical characteristics and severity of patients referring to a specialized diabetic foot service (DFS) due to a new diabetic foot problem.

Methods: The current study is a retrospective observational study including consecutive patients referring to a DFS from February 2022 to November 2022 due to a new diabetic foot problem. At the assessment, demographic and clinical data such as the characteristics of foot problems were recorded. The rate of hospitalization and the main causes of hospitalization were reported. In addition, the rate of in-hospital major amputation and its relation with the clinical pattern at the first assessment was reported.

Results: Two-hundred four patients were included. The mean age was 73.5±21.6 years, 91.1% were affected by type 2 diabetes with a mean duration of 16±8 years; 38.2% had ischaemic heart disease while 15.7% were on dialysis. Overall, 68.9% of patients had an ischaemic/neuro-ischaemic wound, 82.1% had an infected wound and 6.7% reported severe infection. Hospitalization was required in 76% of cases. The main causes of referral were respectively the presence of gangrene (30.6%), osteomyelitis (18.6%), abscess/phlegmon (7.5%). The main reasons requiring hospitalization were respectively infected gangrene in 93.1% of cases, osteomyelitis in 88.9% of cases and abscess in 86.7% of cases. Among 204 patients included, 4 (1.9%) had in-hospital major amputation. All of them referred for the presence of an infected gangrene, 3 patients received major amputation due to the extensive tissue loss not allowing a functional surgical foot salvage, while 1 patient was amputee in relation to the unsuccessful peripheral revascularization and progression of both ischaemia and infection.

Conclusions: The current study reported as the main reasons of referral to a specialized DFS for a new diabetic foot problem was the presence of infection, specifically gangrene and osteomyelitis. In the majority of cases, patients required hospitalization for managing their clinical condition. Extensive foot gangrene not treatable surgically was the main cause of in-hospital major amputation.

P06.3-2

Diabetes-related foot interventions to improve outcomes for Indigenous Peoples in high-income countries: a scoping review

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Background/Aim: Indigenous Peoples from high income countries experience higher rates of diabetes and diabetes foot disease, in comparison to relevant resident populations. Building an understanding of Indigenous Peoples perspectives on foot health, decolonising healthcare research, and well-organised diabetes foot interventions may improve outcomes. This scoping review describes the range of publications detailing diabetes foot interventions that incorporated a focus on equity for Indigenous Peoples. Studies were evaluated against the CONSoLidated critERia for strengthening reporting of health research involving Indigenous Peoples (CONSIDER) statement which encompasses relationships, participation, governance, prioritisation, methodology, analysis, interpretation, and dissemination.

Methods: The PRISMA-Scoping Review guide was followed. MEDLINE, Informit indigenous collection, CINAHL, PsychINFO, SCOPUS, and Embase were searched to June 2021. Search terms included diabetes, foot, interventions, and Indigenous Peoples. Eligible publications described diabetes foot interventions that included Indigenous Peoples from high-income countries. Two reviewers independently screened titles, abstracts, and full-text publications, and contributed to data charting. Key study characteristics included country, Indigenous population, intervention description, foot-related outcomes, and alignment with the CONSIDER statement guidance.

Results: We screened 730 publications and 30 met the eligibility criteria. Interventions focused on Indigenous Peoples from Australia (n=12), Canada (n=6), USA (n=6), New Zealand (n=2), Greenland (n=2) and Nauru (n=2). Primary prevention interventions were predominant (n=20) with a focus on increasing foot screening rates (n=16). Other interventions included health promotion and education (n=4), comprehensive foot interventions (n=4), a diabetic foot ulcer management protocol, and a service brokerage model. Indigenous knowledge or cultural approaches to foot interventions were overlooked. Only 1 study of the 27 evaluated met all the CONSIDER statement reporting guide requirements; 55% (n=15) met fewer than 9 items; few (n=3) met both items in the participation domain.

Conclusion: Few publications described diabetes-related foot interventions that demonstrated improved outcomes for Indigenous Peoples. Attention to Indigenous Peoples perspectives on foot health was neglected and alignment with the CONSIDER statement domains was lacking. These findings reflect areas of focus for future development of diabetes foot programmes.

P06.3-3

Clinical Outcomes in Diabetic Foot Patients With and Without Cancer Admitted for Interventional Procedures.

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Background - Diabetic Foot Syndrome (DFS) is associated with a high risk of cardiovascular morbidity and major amputation (MA). Likewise, cancer is a well-established risk for cardiovascular disease.

Aim of the study - To assess if DFS patients with cancer have a worse cardiovascular profile and surgical outcomes compared to DFS patients without cancer.

Patients, Materials and Methods - We retrospectively analyzed the charts data of 223 consecutive DFS patients [M:166/F:57, age: 69.6±10.4, T2DM 94.66%/T1DM 5.4%] admitted between January 2019 and December 2021 in our Department for interventional procedures (Revascularization and/or foot surgery). Prevalence of cancer, cardiovascular pathologies, MA and re-intervention were derived.

Results - Cancer was observed in 47 (21.1%) DFS patients. Patients with cancer were older (71.5 vs 68 yrs, $p<0.01$) and with a longer history of diabetes (24.5 vs 19 yrs, $p<0.05$). Major cardiovascular events, atrial fibrillation and renal failure prevalence didn't differ between patients with and without cancer. After a median time of 5 months, reoperation was performed in 35.4% of patients, without any difference between cancer+ and cancer- DFS. Globally, MA prevalence was 9.6%. Although, MA prevalence did not differ between patients with and without cancer, patients with blood cancer ($n=9$) showed a higher prevalence of MA than those with solid tumors (33.3% vs 5.1%, $p<0.05$) and those without cancer (9.7%, $p<0.05$).

Conclusion - Cardiovascular profile, surgical outcome and reoperation rate didn't differ between DFS patients with and without cancer. More studies are needed to confirm that DFS patients with blood tumors could present higher risk of MA.

P06.3-4

Diabetes Foot Disease Risk, Ulceration and Social Deprivation

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Aim: Diabetes foot disease is known to be associated with social deprivation. The aim of this study is was to evaluate the significance of the association in the St. James's hospital population.

Methods: This prospective observation study of risk factors for diabetic foot disease utilised the Scottish risk assessment tool. A post hoc analysis of this database was performed using the pobal online map for deprivation indices based on address. This breaks down addresses into eight different categories of social deprivation from extremely disadvantaged to extremely advantaged. There were a total of 210 participants were included in this study. In the group who developed DFU during the follow up period this was also compared by deprivation index.

Results: When separating the individuals by diabetes foot disease risk the results are as follows, the low risk group included 96 participants, intermediate risk 67 participants and high risk 47 participants. The total number of participants with an affluent index are 108, vs 102 with a disadvantaged index. When comparing the two groups using linear regression, the results are $t\ 3.37$, $p\ 0.001$ (with a 95% confidence interval of .1527008 - .5904202). In the group who developed DFU ($n=9$), 55% ($n=5$) were from disadvantaged areas. Of the remaining participants ($n=4$), 3 of these were in the average category. Of those developing DFU, only a single participant resided in an affluent area.

	Affluent (n=108)	Disadvantaged (n=102)
Low	50.9% (n=55)	38.67% (n=41)
Moderate	28.7% (n=31)	33.9% (n=36)
High	20.4% (n=22)	23.6% (n=25)

Conclusion: In conclusion this analysis supports the theory of deprivation index being an independent risk factor for diabetes foot disease in this population. This is more noticeable in the group developing DFU with 88% not residing in an affluent area.

P06.4-1

Interactive Exercise Program (Tele-Exergame) to Improve Balance and Cognition in Older Adults with Mild Cognitive Impairment or Dementia

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Background/Aim: Physical and cognitive exercise programs improve the healing of diabetic foot ulcers by better blood circulation and slow cognitive decline in individuals with diabetes. Although physical and cognitive exercise programs for individuals with diabetes are critical, conventional exercise programs are not tailored to individuals with diabetes, and exercise adherence is often poor due to unsupervised settings. This study explored the acceptability and feasibility of a sensor-based in-home interactive exercise system, called tele-Exergame in older adults with mild cognitive impairment (MCI) or dementia.

Methods: Our tele-Exergame is designed to improve balance and cognition while a telemedicine interface remotely supervises the exercise. Fourteen older adults with MCI or dementia (Age: 68.1 ± 5.4 years, 12 females) participated. All participants were asked to wear a motion sensor (i.e., LEGSystTM) at the top of their foot for foot flexion exercises and the middle of their upper leg for leg raising exercises and performed tele-Exergame (i.e., leg raising or foot flexion exercises) with explicit augmented visual feedback twice weekly for six weeks at their homes. Before and after 6 weeks, participants' acceptance was assessed by Technology Acceptance Model (TAM) questionnaire, and participants' cognition and anxiety level were evaluated by the Montreal Cognitive Assessment (MoCA) and Beck Anxiety Inventory (BAI), respectively.

Results: After completing 6 weeks of in-home exergaming exercises, TAM results supported acceptability regarding user-friendliness and ease of use, perceived benefits, and positive attitudes toward the use of the system by showing significantly improved questionnaire scores (all $p < 0.040$). In addition, participants significantly improved their cognition level (9.7%, $p = 0.017$) and lowered their anxiety level (-27.6%, $p = 0.019$) compared to before 6 weeks.

Conclusions: The findings of this study demonstrate the feasibility, acceptability, and potential benefit of home-based and self-administered tele-Exergame as well as improved cognitive function and reduced anxiety levels among older adults with MCI and dementia. Future study warrants exploring the validity of tele-Exergame to improve motor performance (gait and balance), mobility, cognition, and anxiety in Individuals diagnosed with diabetes.

P06.4-2

Patients, carers and healthcare providers' perspectives on a patient-owned surveillance system for diabetic foot ulcer care: A Qualitative Study

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Background/Aim: Digital health has recently gained a foothold in monitoring and improving diabetes care. We aim to explore the views of patients, carers and healthcare practitioners (HCP) regarding the use of a novel patient- owned wound surveillance application as part of outpatient management of diabetic foot ulcer (DFU).

Methods: Semi-structured online interviews were conducted with patients, carers and HCPs in wound care for diabetic foot ulcers. Participants were recruited from a primary care polyclinic network and two tertiary hospitals in Singapore within the same healthcare cluster. Purposive maximum variation sampling was used to select participants with differing attributes to ensure heterogeneity. Common themes relating to the wound imaging app were captured.

Results: 20 patients, 5 carers and 20 HCPs participated in the qualitative study. None of the participants have used a wound imaging app before. Regarding a patient-owned wound surveillance app, all were open and receptive to the system and workflow for use in DFU care. Three major themes emerged from patients and carers: (1) Accessibility, (2) User interface and experience, (3) Feasibility of using the wound imaging app. Four major themes were identified from HCPs: (1) Attitudes towards wound imaging app, (2) preferences regarding functionality, (3) perceived challenges for patients/carers, (4) perceived barriers for HCPs.

Conclusions: Our study highlighted several barriers and facilitators from patients, carers and HCPs regarding the use of a patient-owned wound surveillance app. These findings demonstrate the potential of digital health and areas to improve and tailor a DFU wound app suitable for implementation in the local population.

P06.4-3

Patients with diabetic foot ulcers experiences with telemedicine solution. A scoping review

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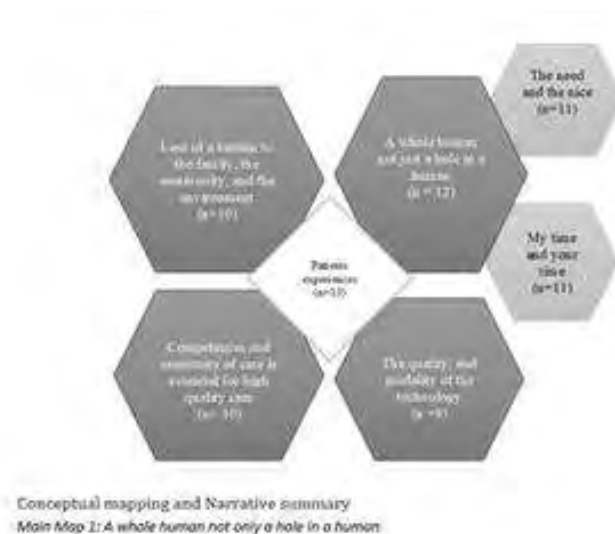
Background Diabetic foot ulcer (DFU) is a common, complex, and severe complication of diabetes and are associated with severely decreased health-related quality of life. Treatment of DFU calls for multi-sectorial performances incorporate interdisciplinary care pathways. Telemedicine (TM) may be used as a communication tool between caregivers across health care sectors to obligate the needs for close follow-up including early intervention on preventing the recurrence of DFU.

Aim The objective of this review was to identify, examine, and conceptual map the available literature on patients' experiences and views regarding the use of TM solutions among patients with DFU.

Methods We identified the Population, Concept, and Context to pinpoint the focus of this review, to construct the research question, the title, and to facilitate the strategy for the literature search. The literature examined stem from 13 sources. We had no limit on the included studies methodological approach neither on the form.

Results During the review process four themes emerged: "A person-centered holistic approach", "Optimizing time use", "Assisting being less a burden", and "A digital solution". Conceptual mapping and narrative summary are showed in figure 1.

Conclusion Further investigation from both patient and the multi-sectorial caregivers' perspective are needed focusing on whatever modifications of the TM intervention may fit the FDU care pathway better taking the patients' experience into account.



Conceptual mapping and Narrative summary
Main Map 1: A whole human not only a hole in a human

P06.4-4

Improving care for Aboriginal people in Australia with diabetes-related foot complications.

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Aim: Enhance delivery of high-risk foot services (HRFS) to Aboriginal people with diabetes-related foot complications (DRFCs) through improved access to specialist services, upskilling clinicians, and incorporating a dedicated Aboriginal Health Practitioner (AHP).

Background: Aboriginal people have elevated incidence of diabetes (3 fold), foot complications (10 fold) amputation (30 fold) compared to the rest of the Australian population. People living in rural and remote communities are also at higher risk of DRFCs due to difficulties and delays in accessing expert assessment and care.

Methods: Access to the HRFS was expanded through Telehealth, including rapid access (same day) appointments. A new dedicated high-risk foot coordinator role was established to facilitate improved care coordination. A dedicated AHP ensured cultural safety within the service and was essential in building relationships with both clinicians and patients. All Aboriginal people admitted to the acute Vascular ward were linked with an AHP. Clinicians in the community were upskilled in assessment and stratification of foot complications to expediate referral or active treatment through a virtual reality education package and site visits. Visits were provided to 3 key sites in South Australia to engage and improve relationships, and to provide education and equipment.

Results: Telehealth participants had high attendance rate of 90%. Interim results following 28 Aboriginal people who consented to study as part of telehealth showed 53 % had healed foot ulcers at three months, demonstrating that earlier access led to concomitant healing in vulnerable patients. At interview, 30 % of this cohort collectively reported that video telehealth improved communication and built an environment of trust and cultural safety. There were 3 cases of rapid access Telehealth consultation with direct admission to acute hospital within 48 hrs for DRFC. On discharge these patients were reviewed by Telehealth, a service that was not previously available, reducing delays to return home.

Conclusion: Providing culturally safe care through a dedicated AHP and utilising telehealth increases the access to high-risk foot services and may provide better outcomes in relation to amputation rates and ulceration in this patient population.

P06.4-5

Improving telemedicine delivery for Aboriginal and Torres Strait Islander people with diabetes-related foot complications using virtual reality technology

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Aim: To implement and test a virtual reality (VR) education module to meet the needs of Aboriginal people in Australia with diabetes-related foot complications (DRFCs) by supporting and upskilling community health providers.

Background: Diabetes affects Aboriginal and Torres Strait Islander people in Australia three-times more often than non-Aboriginal Australians, with rates of diabetes-related foot complications ten times the non-Aboriginal population. There is a substantial training gap for community health workers in regional Australia to assess and triage DRFCs in Aboriginal people, lengthening delays for timely escalation to specialist care that is not readily available at community health centres.

Methods: Our “VR DRFC clinic” was developed in consultation with multi-disciplinary stakeholders to improve service delivery and reduce amputations in Aboriginal people. The training includes five case patients (using Aboriginal models) in escalating stages of risk and active foot disease, with prompted training in assessing and triaging each case. Target sites for implementing and testing of VR training were three rural Aboriginal community-controlled health partners. Clinical team visits to the 3 key sites provided equipment (Meta Quest 2 [Reality Labs, USA] virtual reality headsets with embedded education package, SysToe toe pressure index equipment, 10g monofilaments) to facilitate best-practice care. Questionnaires pre- and post-training were solicited of participants evaluating confidence in performing DRFC assessment; post-training feedback on the VR training was sought using System Usability Scale and Training Evaluation Inventory validated questionnaires.

Results: Evaluation from an initial 15 participants demonstrates that the VR training is well-received; feedback (e.g., “I would recommend this training to my colleagues”) was strongly positive in 66%. Confidence scores across 10 categories of DRFC assessment increased by an average of 12-29 percentage points, demonstrating increase in self-efficacy from one hour of virtual training.

Consulsion: Preliminary reviews for VR training in DRFC assessment and triage are positive; VR represents an opportunity to scale DRFC assessment training to underserved health professionals at rural health centres.

P06.4-6

The citizens WoundApp

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Background/Aim: The aim of the HealthD360 project was to create better health and wellbeing for the citizens having diabetic foot ulcers by focusing on patient reported- and 24/7 data. More specifically the project aimed for improving the empowerment of the citizen in the progress of having a diabetic foot ulcer and ultimately minimize the delays between contact with healthcare professionals at clinics or at home.

Method: The Wound App (SårApp in Danish) has been developed as a part of the Danish HealthD360 project (www.healthd360.dk). The Wound App is for the citizen, co-designed and tested by citizens in collaboration with healthcare professionals, relatives, companies and researchers. The citizen can register a wound and report the wound size, pain, infection/inflammation and wound fluid on a daily or weekly basis. Pictures of the ulcer are taken by the patient or healthcare professionals. The progress of the wound healing is visualized together with self-registered and collected data within the app. A data plugin collects numbers of steps, activity and other data from Apple Health and Google Fit. Data from municipalities and national registers are included as well in the data analysis of the project.

Results: The WoundApp helped patients to regularly register their diabetic foot ulcer and its development, and the progress was visualized for the patients. More active patients have wounds with less depth and length. The level of pain, moistness and inflammation were positive correlated with the wound area, and the patients were generally more physical active in middle of the day and during the summer months and less active during weekends. Patients were interviewed after the pilot test and the following was e.g., stated: “useful”, “gave insight”, and “I use data on a daily basis”.

Conclusion: The benefits of using the WoundApp need to be clear for patients, and engagement and involvement of health care personnel is critical to ensuring continued patient use of the app. The study indicated that the WoundApp increase compliance, empowerment, and knowledge among citizens. Challenges and barriers were identified, and an optimized WoundApp version will be tested in a decentralized clinical trial as a next step.

P06.4-7

Contemporaneous blood pressure, lipids and glucose control using remote management vs. standard care in people with diabetes: A Meta-analysis

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Background/Aim: The aim of this meta-analysis was to pool evidence from randomized controlled trials (RCTs) testing remote management interventions to simultaneously control blood pressure, blood glucose and lipids compared to standard care in people with type 1 or type 2 diabetes.

Method: PubMed/Medline, EMBASE, CINAHL and the Cochrane library were systematically searched for randomized controlled trials (RCTs) until 20th June 2021. RCTs that reported participant data on blood pressure, blood glucose, and lipid outcomes in response to a remotely delivered intervention compared to standard care was included. Primary outcomes were glycated hemoglobin (HbA1c), total cholesterol (TC), low-density lipoprotein cholesterol (LDL-c), systolic and diastolic blood pressure (SBP & DBP). Risk of bias was assessed using the Cochrane collaboration RoB-2 tool. Meta-analyses were reported as standardized mean difference (SMD) with 95% confidence intervals (95%CI).

Results: Twenty-seven RCTs reporting on 4581 participants randomized to remote management and 4519 to standard care were included. Components of the remote management interventions tested were identified as patient education, risk factor monitoring, coaching on monitoring, consultations, and pharmacological management. Comparator groups were typically face-to-face usual patient care. Remote management significantly reduced HbA1c (SMD -0.25, 95%CI -0.33 to -0.17, $p < 0.001$), TC (SMD -0.17, 95%CI -0.29 to -0.04, $p < 0.0001$), LDL-c (SMD -0.11, 95%CI -0.19 to -0.03, $p = 0.006$), SBP (SMD -0.11, 95%CI -0.18 to -0.04, $p = 0.001$) and DBP (SMD -0.09, 95%CI -0.16 to -0.02, $p = 0.02$), with low to moderate heterogeneity ($I^2 = 0$ to 75). Sub-group analysis identified differences in the efficacy of intervention components for each risk factor and limited effectiveness of remote management in people at high risk of diabetes complications. Twelve trials had high risk of bias, 12 had some risk and three were at low risk of bias.

Conclusions: Remote management significantly improves control of modifiable risk factors. Heterogeneity and potential publication bias may limit applicability of findings. Further research is needed to assess the cost-benefit and translatability of findings in populations at high risk of cardiovascular complications.

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P06.5-1

Characteristics and outcomes of patients hospitalized with a diabetic foot ulcer – results of a nationwide survey

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Background: Among the OECD countries, Israel has the highest rate of major amputations in patients with diabetes. The Ministry of Health conducted a national quality survey in all hospitals assessing the quality of care of patients admitted with a diabetic foot ulcer (DFU).

Methods: As part of the national survey, all hospitals were requested to submit data of all patients admitted due to a DFU during January-June 2021. Hospitals identified these patients based upon relevant diagnosis or procedure codes, or according to the admitting department (in hospitals having dedicated DFU units). Data regarding demographic characteristics, procedures and length of stay were collected. Disparities by hospital size and location were calculated.

Results: During study period, a total of 2,332 admissions of 1,943 patients in 25 hospitals were reported (table). Patients admitted to tertiary centers were younger, had a shorter length of stay, and were more likely to undergo any surgical procedure (including amputation), peripheral vascular intervention (PVI), have PICC-line insertion or undergo minor amputation. PVI was uncommonly performed in small or peripheral hospitals, yet, patients still underwent major or minor amputations in these hospitals.

Conclusions: While the data collected may be incomplete due to under-reporting, they provide an estimate of the magnitude of in-patient DFU, resources required, procedures and outcomes. Prospective collection of data, including comorbidities and ulcer severity at baseline, as well as adherence to a uniform codes for DFU may lead to better understanding of treatment disparities.

Characteristics of patients hospitalized due to a diabetic foot ulcer

	Size of hospital			Location of hospital		Overall
	Tertiary center	Medium to large	Small	Central	Peripheral	
N	740	1367	225	1942	390	2332
Age	66.4±12.6**	69.0±12.8	71.0±14.1	68.6±12.8*	67.0±13.4	68.3±12.6
Males (%)	72.0%	68.8%	69.8%	70.9%*	64.9%	69.9%
Duration of stay (median [IOR])	8 [2.9-18]**	9 [4-17]	8 [4-15.9]	8 [3.5-17.9]**	9.0 [4.1-16.2]	8.0 [4-17]
Patients undergoing any surgical procedure (%)	54.3%**	45.2%	36.0%	47.6%	45.1%	47.2%
Patients undergoing PVI (%)	11.6%**	10.8%	1.3%	11.5%**	3.1%	11.1%
Patients inserting PICC-line for long term IV antibiotics (%)	10.3%**	1.8%	3.1%	3.2%**	11.5%	4.6%
Patients undergoing major amputation (%)*	13.5%*	16.5%	10.7%	15.3%	13.1%	15.0%
Patients undergoing minor amputation (%)**	17.7%**	13.9%	12.0%	15.0%	14.6%	14.9%

*p<0.05; **p<0.01; *Calculated as major amputation vs. no major amputation; **Calculated for major vs. minor vs. no amputation.

P06.5-2

Epidemiological investigation and analysis of inpatients with chronic refractory wounds in a wound repair center in China

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Aim: The epidemiological characteristics of inpatients with chronic refractory wounds in a wound repair center were analyzed by reviewing data to provide reference for the formulation of prevention and treatment strategies.

Methods: The case data were collected including the patient's gender, living area, occupation, underlying disease, smoking history, wound type, age, hospital stay, hospitalization cost, treatment method and wound surface detection of pathogenic bacteria. The information data were compared by chi-square test and Kruskal-Wallis H test.

Results: A total of 2402 inpatients with chronic refractory wounds were included in this study, including 66.3% males and 33.7% females, and 60.7% urban population, 39.3% rural population. Among them patients engaged in retirement(52.1%) and manual labor(28.8%) was relatively large, 74.4% patients had diabetes, 57.5%hypertension and 31.8% heart disease. 52.7% of patients had a history of smoking. diabetic wounds were accounting for 62.3%, followed by pressure wounds (13.9%), arterial wounds(6.2%); venous wounds(5.1%), and wounds caused by other reasons(12.5%). The gender and age distribution were compared, the age group with the highest prevalence rate was 61-80 years old(54.7%), followed by 41-60 years old(29.4%) and over 80 years old(11.8%). Among the 2402 inpatients, pressure wounds had the longest average hospitalization time, arterial wounds was the highest average hospitalization cost, followed by diabetic wounds. Among the patients treated by surgery, pressure wounds had the longest hospitalization time, arterial wounds had the highest hospitalization costs. Among the 2402 patients, 22.0% were cured, 76.3% were markedly effective, 1.7% were not cured, and 0.5% of them died. Among the 2402 patients, 38.6% were examined for pathogenic bacteria on the wound surface, of which 73.5% were positive for pathogenic wounds. Gram-negative bacteria accounted for 50.8%, Gram-positive bacteria accounted for 42.4%, fungi(6.8%).

Conclusions: The inpatients with chronic refractory wounds are mainly middle-aged and elderly people, and there are more males than females. Diabetic wounds, pressure wounds and vascular wounds are the main causes. The main treatment method is surgery. The center adopts a multidisciplinary diagnosis and treatment mode for wound treatment, and the healing rate is high. Gram-negative bacteria are the most common pathogens on the wound surface.

P06.5-3

A cross-sectional study on the origin and initial location of diabetic foot wounds in China

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Aim: To explore the origin and initial location of diabetic foot wounds and multiple risk factors related to diabetic foot in China, and provide clinical guidance for future prevention and treatment of diabetic foot.

Methods: A multicenter cross-sectional survey was conducted in diabetic foot ulcer in China, and the data of 3117 patients with diabetic foot ulcer was collected through the diabetic foot data platform (<https://bs.jnqdt.com/admin.php?s=/Public/login.html>).

Results: In this study, there were 56 initial locations of foot wounds. The incidence of ulcer of the first toe was 21.0%, and the tip of the first toe was the most common site of the foot wound, followed by the dorsum of the first toe, the inferior nail margin of the first toe, the dorsum of the foot, and the dorsum of the second toe. Meanwhile, this study included 6 types of external wound causes, and the most common cause was wearing inappropriate shoes (34.6%), followed by trauma such as collision, puncture, and scald (26.6%), improper foot care behavior (11.4%) and foot related diseases (6.7%). And many patients could not determine external wound causes (3.5%). In addition, peripheral neuropathy and lower limb vascular disease had different effects on the origin and initial location of diabetic foot wounds. The wounds of patients with no neuropathy, vascular disease and only peripheral neuropathy mainly started at the dorsum of the foot, and the main cause of wound was trauma. In patients with lower extremity arterial disease, the initial location of the wound was the toe tip of the first toe. Relatively speaking, the probability of wound on the toe tip and back of the first toe of the left foot was higher than that of the first toe of the right foot, which may be related to that the right side is dominant for most people, while the left foot is a supporting foot, and usually bears more pressure.

Conclusions: This study revealed some internal correlations between the origin and initial location of diabetic foot wounds and the risk factors of diabetic foot, which will help guide the clinical prevention of diabetic foot.

P06.5-4

A Review of Diabetic Foot Ulceration in Latin America and Caribbean Region

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Background/Aim: Data on diabetic foot ulcer (DFU) within the Latin American and Caribbean (LAC) region is limited. This study seeks to summarize current epidemiological data and risk factors of DFU in this geographical region

Methods: PUBMED, EMBASE (OVID), DART, CARPHAS electronic databases were searched for studies describing the prevalence and risk factors for diabetic foot in LAC (Search strategy: “diabetic foot” OR “diabetic foot ulcer” AND “incidence” OR “prevalence” OR “risk factors” OR “Caribbean” OR “Latin America”). Studies were retrieved from 2012-2022. All studies involving risk factors, incidence, prevalence, or commentary on diabetic foot ulcer within the geographic location of the Caribbean and Latin America were included. There were no limits to study types. Reference list from retrieved articles were hand searched. One researcher screened the articles by title and abstract. Two researchers reviewed full text for references meeting the eligibility criteria-abstracting, study author, year, type, main findings, conclusion using the CASP tool for systematic reviews.

Results: Twenty-four studies were selected for the analysis and included three Caribbean countries and seven Central/ South American countries. The population sizes were non-homogenous.

Incidence and Prevalence of DFU: Data on incidence and prevalence was very limited. A Peruvian study found inpatient diabetic foot prevalence to be 2.8% (CI 95%;3.4-3.1), with higher prevalence in coastal and jungle hospitals [1]. In Caribbean studies, data was collected on foot ulceration incidence within Jamaican (4.3% prevalence) [2] and Barbadian samples (14.7%; 1 year period prevalence) [3].

Risk factors for DFU: From this study, myocardial infarction, or stroke history, and “region of origin” showed association with increased DFU in Latin American populations with cardiovascular disease history increasing risk for Caribbean populations [3].

Conclusions: There is a lack of data on diabetic foot ulcer in the LAC region; however, previous cardiovascular disease was a probable risk factor, which is already demonstrated in the literature. Given the high incidence of hypertension and cardiovascular disease in the region, more research is needed to understand risk factors.

References:

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P06.5-5

Outcomes of costs and care for Diabetic Foot Ulcers collected from an electronic health record in the Netherlands

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Background/Aim: In the Netherlands about 1,2 million people are suffering from diabetes and the estimated incidence is increasing to 1,5 million in 2040 [1]. Diabetic foot ulcers (DFUs) are known to be a big burden for patients and are associated with several comorbidities and high mortality. In addition, DFUs often need medical supplies and wound care at home, these costs combined haven't been published before in the Netherlands.

Method: The retrospective data is collected between January 2017 and December 2022 by tissue viability nurses or nurse practitioners working at a specialized wound care homecare company [2]. Data is selected in an electronic health record (EHR) on patient level, but also relating to unique wounds [3]. Even the number of home visits were recorded to the minute and what amounts has been reimbursed by health insurance, as well as the amounts and costs of supplies used during treatment.

Results: In total 10.684 patients with a total of 23.554 wounds. Of which one third of the patients older than 60 years suffer from diabetes. The first comorbidities are seen in patients older than 30 years. Of the total group of patients, 1.188 patients (11%) with 2.352 wounds were defined as DFUs. From these patients 668 received care and supplies, in this group costs of care are €1.385.885, costs of supplies €524.856, with a total of €1.910.742. These patients were 41.963 times treated at home with an average of 32 per patient.

Conclusion: Costs of de DFUs are a big burden on the healthcare costs, even more then presented due to additional costs in secondary care. For the DFUs the costs of care take up the largest share of the total costs. This data set can contribute to learn more about patients with DFUs. And can be helpful to select the patients that are most at risk to have a hard to heal wound.

1 Ligthart. The Lancet Diabetes & Endocrinology, 4(1), 44–51. [https://doi.org/https://doi.org/10.1016/S2213-8587\(15\)00362-9](https://doi.org/https://doi.org/10.1016/S2213-8587(15)00362-9)

2 PatDoc

3 QualityZorg

P06.5-6

Risk factors for diabetic foot ulcer: data from a prospective cohort

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Background/Aim The occurrence of a foot ulcer in a diabetic patient remains frequent and has a poor prognosis. The international diabetic foot risk classification identifies only part of the risk. The aim of this study is to assess prospectively risk factors for diabetic foot ulcer.

Method A total of 200 patients with type 2 diabetes were included. They underwent a neurological assessment (monofilament and thermal sensitivity, vibration perception threshold, neuropathy symptom score, neuropathy disability score, sudomotor function), a vascular assessment (palpable pulses, TcPO₂, systolic pressure index), a clinical foot exam (foot deformities, joint stiffness), a measurement of plantar pressure and skin microcirculatory reactivity to acetylcholine, heating and pressure. The primary endpoint was the occurrence of a foot ulcer. Statistical analysis were performed to compare these different parameters between the "Foot ulcer" group and the "No foot ulcer" group.

Results A foot ulcer occurred in 29 patients (14.5%) over a mean (min-max) follow-up of 2 (0.5-1) years. They were mainly men (76%), aged 67.1±11.2 (mean±SD) with a previous wound (83%). There was no significant difference in univariate analysis between the two groups regarding the age, the duration of diabetes, NSS, vascular parameters, joint stiffness, skin microcirculatory reactivity to acetylcholine and pressure. In multivariate analysis, patient in the group "Foot ulcer" had greater impairment of plantar sudomotor function ($p=0.015$, OR=4.38) and skin microcirculatory reactivity to heating ($p=0.021$, OR=0.99), more deformities ($p=0.040$, OR=4.75) and higher plantar pressures ($p=0.047$, OR=1.31) than those in the group "No foot ulcer".

Conclusion This study shows that, next to IWGDF risk classification, additional factors are associated with the occurrence of ulcer. Considering them to better assess the risk and to optimize prevention appears important.

P06.6-1

Anemia at admission is not associated with a worse short-term prognosis in diabetic foot inpatients

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Aim - Anemia is a marker of severity in patients with diabetes mellitus, associated with higher mortality. Aim of this study was to test its impact on diabetic foot (DF) inpatients.

Methods - we retrospectively searched patients admitted for DF in our Department between July and December 2021 (Group A) and compared them with patients admitted in the same period in Diabetology Department for diabetes-related diagnosis different from DF (Group B). We compared demographic and clinical characteristics focusing on blood crasis: mean (HB) or maximum (HHB) haemoglobin concentration, mean corpuscular volume (MCV), mean corpuscular hemoglobin content (MCH), mean corpuscular hemoglobin content (MCHC), red blood cell count (RBC) and hematocrit (HCT) were extracted from charts at admission. Length of admission and in-hospital mortality were compared.

Results - We studied 211 patients: 106 in Group A and 105 in Group B. No differences in age while patients of Group A had a longer disease duration (19.4 ± 11.3 yrs vs 7.96 ± 10.4 yrs, $p < 0.05$). Anemia was more prevalent in Group A (72.6%) than B (52.3%): $p < 0.01$. HB (10.34 ± 2.0 g/dl vs 11.1 ± 2.2 g/dl, $p < 0.05$) was significantly lower in Group A with no difference in HHB, MCV, MCH and MCHC. HCT was significantly lower in Group A ($32.3 \pm 5.7\%$ vs $36.5 \pm 7.3\%$, $p < 0.05$) as well as RBC ($3.7 \pm 0.7 \times 10^6/\text{microl}$ vs $4.2 \pm 0.8 \times 10^6/\text{microl}$, $p < 0.05$). Group B showed longer duration of admission (13.8 ± 9.6 days vs 7.6 ± 4.9 days, $p < 0.001$) and higher mortality rate during admission (8.58% vs 0.94%, $p < 0.01$).

Conclusions - Despite its high prevalence in DF inpatients, anemia is not associated with a worse short-term prognosis.

P06.6-2

Diabetic Foot Syndrome (DFS) and Cancer: Metaphore or Reality?

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Background - Diabetes Mellitus(DM) is associated with an higher incidence of many forms of cancer, while DFS is characterized by high cardiovascular mortality and morbidity, but its propensity to cancer has not be ascertained so far.

Aim of the study - to measure the prevalence of cancer in DFS and check for possible associations between the two conditions.

Patients, Matherials and Methods - we retrospectively searched the databases of our Department for all the consecutive patients admitted in the Medical department of our hospital between January of 2019 and december of 2021 with a admission diagnosis of DM with (DFS+) or without(DFS-) DFS.We compared the prevalence of cancer between the groups and we checked for possible correlations between the two conditions not influenced by other known possible predictors (familiarity, age, sex, smoking, rena insufficiency, anaemia).

Results - Comprehensively 222 DFS+ and 223 DFS - controls were studied.

Overall cancer prevalence was 15.3% and in DFS+ was significantly higher than both DM (11.7% $p=0.008$) and controls (13.3%, $p=0.031$).Univariate regression showed a significant association between cancer and DF($p = 0.007$), age at admission($p = < 0.001$), years of diabetes($p = 0.017$) and hemoglobin($p = 0.03$). At multivariate regression only DF($p=0.021$), and age at admission ($p < 0.001$) persisted as independent predictors.

Conclusion - DFS is characterized by a higher prevalence of cancer compared to both DM patients and non diabetic controls and can be considered as an independent risk factor for neoplasms.

P06.6-3

Clinical presentation of diabetic peripheral neuropathy in an urban diabetes clinic in India; an observational study

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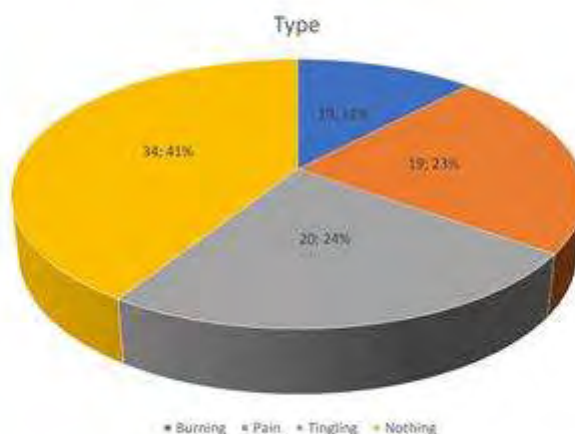
Aim - To study the various presentation of diabetic neuropathy in an urban diabetes clinic in India

Methods - Randomly selected diabetic patients consenting to the study were enrolled between August 2022 and October 2022 in the clinic. Detailed history taken. Foot assessment was done and documented. At the end of the duration of the study, statistical analysis was done.

Results - 7% patients had both signs and symptoms suggestive of diabetic neuropathy. Another 7% had symptoms of neuropathy but there were no signs on examination. Around 50% patients did not complain of any symptoms but had signs of diabetic neuropathy on examination.

Conclusion - Nearly half of the diabetics do not complain of any neuropathy symptoms or symptoms related to feet. Only a thorough and regular foot assessment can detect the abnormalities. This is important for prevention of the diabetic foot problems and is likely to help reduce the rates of loss of limb.

Sensory symptoms



P06.6-4

An epidemiological profile of people at risk for diabetic foot ulceration

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Aim: The aim of this study was to prospectively identify risk factors for the development of diabetic foot disease in patients attending specialist diabetes clinics in a large urban teaching hospital in Ireland.

Methods: This observational non-interventional study opportunistically recruited 216 individuals attending for specialist diabetes review during 2021 in order to record the presence of risk factors for foot disease utilising the recommended screening protocol of the international working group on the diabetic foot. Following foot assessment patients were stratified using the Scottish risk stratification tool. Observed risk status were compared statistically using a combination of t-test, chi-squared, ANOVA and fishers exact test. Significance was considered when the p-value ≤ 0.05 .

Results: Of the 216 participants the following risk factors were associated with statistically significant increase in risk status and DFU development are shown in the tables below.

Variable (n=102) (n=67) (n=47) (n=216) Gender, n(%)	Low risk Moderate High risk Total p-value				
Male	67 (66%)	41 (61%)	39 (83%)	147 (68%)	0.038*
Age, years					
Mean (SD)					
Median (IQR)					
56.0 (13.9)					
57.5 (19.75)					
60.5 (11.59)					
61 (11.5)					
62.6 (11.36)					
62 (14.5)					
58.8 (12.94)					
60 (16)					
0.006**					
LOPS	2 (2%)	14(21%)	33 (70%)	49 (23%)	<0.001*
Hx	0 (0%)	0 (0%)	29 (62%)	29 (13%)	<0.001*
PAD	0 (100%)	1 (1%)	4 (8%)	5 (2%)	0.005*
Renal disease					
Yes					
No					
2% (n=2)					
98% (n=100)					
6% (n=4)					
94% (n=63)					
32% (n=15)					
68% (n=32)					
10% (n=21)					
90% (n=195)	<0.001				
SD = standard deviation					
*Chi-squared test					
**ANOVA					

Variable (n=9) (n=207) (n=216)	DFU No DFU Total p-value				
LOPS	9 (100%)	40 (19%)	49 (23%)	<0.001*	
PAD	1 (11%)	4 (2%)	5 (2%)	0.193*	
History	9 (100%)	20 (10%)	29 (13%)	<0.001*	

*proportions test/ fisher's exact test

Conclusion: This is the first reported epidemiological risk profile in Ireland of those attending for diabetes management in specialist centres. Those at high risk are greater than in other published studies. The results support the significance of LOPS, PAD and history of disease being predictors of DFU. The findings of this study may help to inform resource allocation and preventative care.

P06.6-5

Exploring the relationship between post-contrast acute kidney injury and different baseline creatinine standards: a retrospective cohort study

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Objective: According to previous studies, the incidence of post-contrast acute kidney injury(PC-AKI) in diabetic is far higher than that in the general population. Therefore, we explored the relationship between the incidence of PC-AKI and different baseline serum creatinine (SCr) levels, and determined the relationship between PC-AKI and different types of contrast media (CMs), different doses of CM, and different examination methods in this specific population.

Materials and Methods: Patients with diabetes in whom CM was used between 2010 and 2020 at our institution were included. Participants were identified according to the following three schemes: Scheme 1 (n=5911), SCr was detected before and within 72 h after using CM; Scheme 2 (n=2385), SCr was detected within 24 h before and within 24–72 h after using CM; and Scheme 3 (n=81), SCr was detected within 24 h before and within 0–24, 24–48, and 48–72 h after using CM. The incidence of PC-AKI with different types of CM, incidence of PC-AKI on digital subtraction angiography (DSA) and enhanced computed tomography (CT), proportion of PC-AKI with different doses of CM, and baseline SCr at different stages of PC-AKI were compared. Multivariate logistic regression analysis was used to explore risk factors for PC-AKI.

Results: A total of 29,081 patients were included in this study. The incidence of PC-AKI in Scheme 3 (22.22%) was higher than those in Schemes 1 (6.19%) and 2 (7.71%). The incidence of PC-AKI on DSA was higher than that on enhanced CT (8.30% vs. 5.80%; $P<0.05$). The incidence of PC-AKI in the increased-dose CM group was higher than that in the non-increased-dose CM group (7.9% vs. 5.7%; $P<0.01$). Moreover, there were differences in baseline SCr values at different stages of PC-AKI ($P<0.01$). Multivariate logistic regression analysis showed that hypertension, chronic kidney disease, heart failure, peripheral vascular disease, metformin, diuretics, and CM dose were risk factors for PC-AKI.

Conclusion: The incidence of PC-AKI increased significantly with increasing time requirement and frequency of SCr detection. Moreover, before using CM, we should control the blood pressure and heart failure, stop using metformin and diuretics, and use CMs at the minimum dose to avoid PC-AKI.

P07.1-1

Effectiveness of Dressing Retention Sheet for Prevention of Ingrown Toenails in the Diabetic Patients

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Background: Diabetes mellitus leads to several complications including diabetic neuropathy and peripheral arterial disease. Therefore, proper foot and nail care should be implemented to prevent foot ulcer which is associated with amputation and mortality. One of the most common foot problems in diabetic patients is an ingrown toenail, as a result of inappropriate nail care. Ingrown toenails can lead to foot infection. Hence, we developed the technique using the dressing retention sheet for prevention of ingrown toenails.

Methods: The diabetic patients previously diagnosed with ingrown toenails at the foot clinic of our tertiary hospital were selected to undergo these steps to prevent ingrown toenails (figure). First, we cut the toenail straight across (step 1). The dressing retention sheet, width 1 cm and length 3 cm, was inserted at the distal end of the lateral nail fold using the nail file (step 2). Then, we applied pressure to prevent the sheet from slipping out and attached the other side of the sheet to the ventral side of the toe. We repeated step 2 at the other side of the lateral nail fold (step 3). These processes were replicated daily to prevent formation of ingrown toenail (step 4).

Results: All the diabetic patients who underwent these procedures (120 patients) successfully prevented the formation of the ingrown toenail.

Conclusions: To the best of our knowledge, this is the novel technique using a dressing retention sheet to effectively prevent the formation of ingrown toenails in diabetic patients.

Dressing retention sheet refers to Fixomull® Stretch.



Procedures using dressing retention sheet to prevent ingrown toenail

P07.1-2

Registered nurses' experiences and opinions regarding self-care to protect the feet in persons with diabetes

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Background and Aim Diabetes mellitus can cause peripheral neuropathy, which may result in dry skin, cracks, calluses and increase the risk of development of diabetic foot-ulcers. The prevalence of diabetes foot ulcer is 4 to 10 % and the lifelong risk to develop an ulcer is estimated to 25%. Diabetes foot-ulcer is a devastating complication of diabetes mellitus and cause burden for the patients and the health care system. Therefore, patients with diabetes are given the recommendation to daily inspect their feet and to use emollients. However, how these recommendations are communicated and followed up by the health-care professionals are unknown and therefore the aim of this study was to explore the clinical decision-making process and how nurses in diabetes inform and educate the persons with diabetes in preventive foot-care.

Methods Digitally focus group interviews with nurses in diabetes in primary and community healthcare, were used to describe experiences and opinions regarding self-care and education to protect the feet and development of foot ulcers in persons with diabetes. The data was analyzed with thematic content analysis inspired by Braun & Clarke. In relation to the aim of the study relevant features were identified and labelled with codes. Codes were clustered together to create themes.

Preliminary results The description of the preliminary result is based on four focus group interviews with totally 11 nurses in diabetes, both from the primary healthcare and from community healthcare. The nurses used person-center information and self-care recommendations to their patients. Regardless of care guidelines most of the information and recommendations were based on the nurses' clinical experiences. Frustrations towards the chain of care were described. It was in general a lack of collaboration between the primary care and the community healthcare. Furthermore, a desire of more specialists in foot-care for diabetic patients to whom they could refer their patients to.

Conclusion This study increases the understanding of how nurses in diabetes experience the self-care and the education to protect feet from developing foot ulcers. Furthermore, it identifies gaps which indicates that better collaboration between healthcare-services can improve the care of the persons with diabetes.

P07.1-3

Reducing the impact of diabetic foot ulcers (REDUCE): Results of a multi-centre, parallel group, randomised, controlled pilot trial

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Background: There is currently a lack of evidence-based treatments to prevent ulceration of the foot in people with diabetes, either education alone or interventions targeting psychological/behavioural factors. We have therefore developed the “REDUCE” programme, a complex intervention targeting psychological/behavioural factors associated with ulcer recurrence and healing. It comprises eight virtual 1:1 sessions with trained health care professionals and access to a digital maintenance programme for longer term support. Here we report the results of our pilot trial, which aimed to investigate: feasibility of recruitment, adherence to and attrition from REDUCE intervention, and feasibility of obtaining outcome data from medical records

Methods: A multi-centre, parallel group, randomised, controlled pilot trial undertaken in two UK NHS centres. Main participant inclusion: Diabetes, aged >18 years, two lower limbs, a recently healed diabetic foot ulcer (all fully healed if >1 ulcer, minimum 2 weeks), cognitive capacity to provide informed consent and engage with study intervention. Primary clinical outcome: ulcer free days extracted from clinical healthcare records at 4 months by research staff blinded to allocation.

Results: 103 patients assessed for eligibility (29 ineligible, 54 declined). Twenty participants (70% male, mean age 68 (range 47-88) years, 80% Type 2 diabetes) randomised 2:1 to REDUCE intervention (n=13) or usual care (n=7) June-September 2021. Two participants withdrew from intervention, but allowed outcome collection. Mean [median] number of 1:1 sessions completed 6.5 [8]. Primary outcome of ulcer free days within 4 months collected in all participants. REDUCE Intervention; mean (SD) ulcer-free days 110.0 (27.8), usual care; 91.9 (35.6); [median(IQR) 122 (113, 122), 115 (53, 122) days respectively]. No adverse events related to the intervention were reported.

Conclusion: This pilot trial confirms that the REDUCE intervention is acceptable to patients, and that recruitment to a definitive trial and collection of the primary outcome is feasible. Descriptive summaries provided some evidence that the primary outcome of ulcer free days was higher in the intervention arm and indicated the promise of the intervention. A definitive trial is now underway.

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P07.1-4

Predictors of adherence to prescribed footwear among people at high risk of developing diabetes-related foot ulcers

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Background/Aim Adherence to wearing prescribed footwear is essential to prevent diabetes-related foot ulcers, but is often low. The study aimed to investigate predictors of adherence to prescribed footwear.

Methods We followed 53 participants (10 women, mean age 65.3 years [SD 9.4]) at high risk of foot ulcers for seven consecutive days. Adherence was defined as the proportion of weight-bearing activity time prescribed footwear was worn. Wearing time and weight-bearing activity were assessed with a temperature sensor in the footwear and a body-worn tri-axial accelerometer, respectively. The raw data were processed using the Groningen algorithm, version 2, to calculate adherence. Clinical assessments and two questionnaires were used to collect data on potential predictors of adherence. Linear regression analyses were performed.

Results Participants used their prescribed footwear on average 62.2% (SD 23.4%) of weight-bearing activity time. In univariate regression analysis, standardized coefficients β were -0.19–0.18 ($p=0.20$ –0.96) for demographic and medical variables, -0.08–0.28 ($p=0.06$ –0.94) for footwear usability and -0.20–0.10 ($p=0.17$ –0.90) for quality of life (Table 1). No multiple regression analysis was performed as only one variable had a p -value <0.10 in univariate analysis (Fit of footwear, $p=0.06$).

Conclusions This study did not find any predictor of adherence to prescribed footwear among demographic and medical variables, quality of life, or opinions on footwear usability and associated health care services. We suggest that future research focus on other factors, such as, contextual and behavioral factors.

Acknowledgements Funded by Amsterdam Movement Sciences and ZGT Wetenschapsfonds.

Table 1. Predictors of adherence to prescribed footwear

Variables		Mean adherence (SD)	Univariate analysis	
			β	p-value
Demographic and medical variables				
Sex	Female	57.5 (29.1)	-0.10	0.49
	Male (ref)	63.3 (22.1)		
Age		---	-0.01	0.96
Education level	Low (ref)	56.1 (30.6)		
	Medium	65.8 (19.4)	0.18	0.29
	High	63.7 (20.9)	0.16	0.34
Work situation	Employed	60.3 (19.5)	-0.07	0.60
	Not employed (ref)	63.7 (26.1)		
Living alone	Yes	62.8 (22.2)	0.02	0.88
	No (ref)	61.8 (24.6)		
Mobility device	Yes	66.1 (25.3)	0.09	0.54
	No (ref)	61.2 (23.0)		
Body mass index		---	-0.09	0.51
Diabetes type	Type 1 (ref)	63.0 (27.1)		
	Type 2	62.0 (22.7)	-0.02	0.90
Diabetes duration		---	-0.01	0.96
HbA1c		---	-0.19	0.20
Time since DFU healing		---	-0.03	0.85
Current smoker	Yes	61.5 (25.6)	-0.01	0.94
	No (ref)	62.3 (23.4)		
Alcohol use	Yes	62.4 (22.0)	0.01	0.93
	No (ref)	61.8 (26.4)		
Charcot foot deformity	Yes	64.8 (28.2)	0.03	0.82
	No (ref)	62.0 (23.3)		
Amputation	Yes	60.2 (24.9)	-0.07	0.63
	No (ref)	63.5 (22.6)		
Footwear type	Conventional shoes, custom-made insoles (ref)	63.9 (15.4)		
	Prefabricated shoes, custom-made insoles	68.1 (23.2)	0.08	0.71
	Fully custom-made footwear	59.4 (24.6)	-0.09	0.67
Owns prescribed indoor footwear	Yes	58.7 (27.4)	-0.08	0.56
	No (ref)	63.2 (22.3)		
Footwear usability (Monitor Orthopedisch Schoeisel questionnaire)				
Walk distance		---	0.05	0.74
Pain in skin of feet		---	-0.08	0.61
Pain in muscles and joints of feet		---	-0.08	0.59
Esthetics of footwear according to self		---	0.16	0.28
Esthetics of footwear according to others		---	0.01	0.94
Fit of footwear		---	0.28	0.06
Walking ability with footwear		---	0.19	0.22
Ease of donning/doffing footwear		---	0.19	0.21
Satisfied with wearing time of footwear		---	0.01	0.92
Physician listened		---	0.17	0.27
Shoe technician listened		---	0.02	0.90
Prioritizes footwear solves foot problems over esthetics		---	0.13	0.39
Advantages of footwear outweigh disadvantages		---	0.07	0.64
Quality of life (SF-36)				
Physical functioning		---	-0.20	0.17
Role—Physical		---	0.03	0.87
Bodily pain		---	0.10	0.48
General health		---	-0.09	0.55
Vitality		---	-0.02	0.90
Social functioning		---	-0.02	0.88
Role—Emotional		---	-0.11	0.45

P07.1-5

Research priorities to prevent and treat diabetic foot ulcers – A digital James Lind Alliance Priority Setting Partnership

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Background/Aim: Diabetic foot ulcer (DFU) is a common and often devastating complication of diabetes mellitus, resulting in a global burden for patients and the healthcare system. Therefore, preventing and treating DFUs is extremely important. Thus, the aim was to establish a priority setting partnership between participants with diabetes mellitus and clinicians to identify the top 10 research priorities for preventing and treating diabetic foot ulcers.

Methods: Due to the COVID-19 pandemic, the James Lind Alliance Priority Setting Partnership process was adapted into a digital format which involved a pilot survey to identify uncertainties with high relevance for participants tested by calculating the content validity index; a main survey answered by 53 participants with diabetes and 49 clinicians; and a final digital workshop to process the final top 10 research priorities.

Results: The content validity index was satisfactory for 20 out of 25 uncertainties followed by minor changes and one additional uncertainty. Next the uncertainties from the main survey and seven current guidelines were processed, resulting in a list of 28 uncertainties for discussion in the digital workshop. After the first ranking of the research uncertainties in small groups and discussions in the whole group (8 persons with diabetes, 5 clinicians, 3 researchers), a consensus on the top 10 research priorities was reached. (Table 1)

Table 1. Final top 10 research uncertainties for preventing and treating DFU

Rankings Uncertainties

- 1 Organisation of diabetes care
- 2 Screening to detect diabetes
- 3 Screening to detect impaired blood circulation in the foot
- 4 Screening to detect neuropathy in the foot
- 5 Screening/grading skin's properties at risk for developing and healing a DFU
- 6 Vascular surgical treatment of DFU
- 7 Self-care to prevent DFU
- 8 The importance of significant others in preventing DFU
- 9 Preventing DFU with the help of relief (shoes, insoles, or similar).
- 10 Treating infection in DFU

Conclusion: The top 10 research priorities for preventing and treating DFUs represent consensus areas from persons living with diabetes and clinicians to guide future research. These research priorities can justify and inform strategic allocation of research funding.

P07.2-1

The association between toe pressures, tobacco smoking and severity of foot ulceration in patients attending a high risk foot service

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Smoking underpins many pathophysiological mechanisms that increase the risk of diabetic foot disease. It does so by impairing glycaemic control and promoting the formation of advanced glycated end-products (AGE's) and worsening peripheral neuropathy. Additionally, smoking can delay wound healing by accelerating atherosclerotic plaques. Surgical wounds are known to heal slower in current smokers.

We hypothesised that current smoking would be associated with lower toe pressures.

We aimed to determine the prevalence of tobacco smoking and whether absolute toe pressures differed in smokers among patients with a diabetic foot ulcer (DFU) attending Blacktown Mount Druitt Hospital (BMDH) High Risk Foot Service (HRFS).

Methods: This study used our prospectively collected clinic database. Eligible participants were adults attending BMDH HRFS between June 2020 and April 2022. Participants were included if they had at least one absolute toe pressure reading completed at their initial visit. A total of 60 participants were included, comprising of 20 smokers, 20 ex-smokers, and 20 controls who had never smoked. Smoking status was by self-report.

Data was analysed using SPSS (SPSS Inc., Chicago, Ill., USA).

Results: Current smokers had a significantly lower absolute toe pressure of their left foot ($p = 0.004$) and a trend to lower toe pressure on the right ($p = 0.052$). Results were similar comparing current smokers only to ex-smokers ($p = 0.014$ and $p = 0.057$).

There were more past amputations of right digits which may have reduced statistical power for right foot. Current smokers were also significantly younger at initial presentation to BMDH HRFS ($p = 0.002$). Lastly, socioeconomic status (SES) was lower in the smoking group ($p = 0.015$, Fisher's exact test).

In conclusion, toe pressure is lower in current smokers presenting with a DFU to the HRFS. Further studies should be undertaken to determine the difference in absolute toe pressures between smokers and non-smokers. This could include correlation between ulcer size and current smoking status. If this translates to impaired healing, this data may assist patient education for smoking cessation.

P07.2-2

The effectiveness of Autologous Peripheral Blood Mono-Nuclear Cells implant in subjects with diabetes with no-option chronic limb-threatening ischemia

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Background: Autologous Peripheral Blood Mono-Nuclear Cells (PBMNCs) have been shown to have a strong angiogenesis capacity together with the ability to immuno-modulate chronic wound tissue through polarization of macrophages from the M1 inflammatory to the M2 regenerative phenotype (1-2).

Aim: The main objective of this study is to evaluate PBMNCs role in diabetic patients with no-option Chronic Limb-Threatening Ischemia (CLTI).

Methods: We performed a retrospective, observational study recruiting consecutive subjects treated from October 2018 to October 2021 with PBMNCs at our Diabetes Center because of diabetes complicated by no-option CLTI. Patients were considered no option if deemed not revascularizable by conventional angioplasty or distal bypass after at least one endovascular intervention attempt performed by a senior experienced operator thus defining a condition of very high major amputation risk. PBMNCs were produced in the operating room by selective filtration point of care system and immediately implanted, after appropriate surgical debridement of the wound bed, by multiple perilesional and intramuscular injections for a maximum of three times for each patient at intervals of 30-45 days from each other. The occurrence of major amputations and the number of healed patients were the primary study outcomes.

Results: Overall, 59 patients (mean age 71.9 ± 10.7 years, disease duration 26.5 ± 13.4 years, mean HbA1c levels 63.1 ± 15.3 mmol/mol, 81.4% males) were studied. After excluding losses to follow-up ($n=11$, 18%), healing and major amputations were recorded in 54.1% ($n=26$) and 25 % ($n=12$) of the cases, respectively. No procedure-related adverse effects were recorded.

Conclusions: The use of PBMNCs appears to be an effective and safe therapeutic option to prevent major amputation and promote healing in no-option CLTI patients.

Key words: Peripheral blood Mono-Nuclear Cells, diabetic foot, major amputation

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P07.2-3

Long-term follow-up in diabetic patients with no-CLI treated with autologous peripheral blood mononuclear cells (A-PBMNC)

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Aim: Not revascularized critical limb ischaemia (no-CLI) is affected by high amputation rate (30% at 1 year) and high mortality rate (50% at 1 year). Treatment with autologous peripheral blood mononuclear cells (A-PBMNC) showed to be promising in limb salvage and survival rate. To describe the effectiveness and the management in the long term, this study evaluates prospectively not only healing rate but also ulcer-free survival and recurrences in diabetic patients with no-CLI treated with A-PBMNC.

Method: We evaluate 102 diabetic no-CLI patients with similar baseline characteristics and indications underwent 288 A-PBMNC implants from January 2017 to September 2022. Minimum follow-up period was 12-months.

Results / Discussion: Sixty-nine patients completed at least a 1 year follow-up alive and without recurrences, 5 patients completed a 5 years follow-up, 17 patients a 4 years follow-up, 6 patients a 3 years follow-up, 5 patients a 2 years follow-up and 26 patients a 1 year follow-up. The healing rate at 12-months follow-up was 68% (69/102) and the recurrences rate was 7,2% (5/69). In patients in remission mean ulcer-free survival days was 946,4+/-521,26, median ulcer-free survival days was 594,55. Overall mortality rate was 32,3% (33/102). Overall amputation rate was 10.7% (11/102).

Conclusion: A-PBMNC therapy showed to be effectiveness to improve limb salvage and survival rate but also long term management and remission parameters in diabetic no-CLI patients.

P07.2-4

The role of frailty on presentation and outcomes in chronic limb-threatening ischaemia and diabetes-related foot ulcers: A systematic review

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Background/Aims: Frailty represents a state of multisystem impairment that may adversely impact people presenting with chronic limb-threatening ischemia (CLTI) and diabetes-related foot ulcers (DFUs). The aim of this systematic review was to explore the association between frailty and clinical presentation and outcomes in people with CLTI and DFUs.

Methods: We performed a systematic literature search of electronic databases to find studies using a validated measure of frailty in individuals with CLTI and/or DFU. The primary outcomes were the impact of frailty on the severity of initial clinical presentation; and unfavorable follow-up outcomes including re-admissions, amputation, mortality, cardiovascular events, re-vascularization, and wound healing.

Results: Ten cohort studies were included. Two studies had a low risk of bias, one was unable to be assessed, five had moderate risk of bias and two high-risk of bias. The prevalence of frailty in people presenting with CLTI ranged from 27% to 88% and was 71% in people with DFUs. In general, CLTI patients in the non-frail group were more likely to initially undergo open or hybrid surgical procedures compared to those without frailty. The presence of frailty in both people with CLTI and DFUs was associated with substantially increased severity at presentation (severity of ischaemia and tissue loss) and poorer outcomes at follow-up including risk of re-admission (15.1% in frail CLTI group vs. 7.7% in non-frail group and 90.3% in the frail DFU group vs. 54.0% in the non-frail group), major limb amputation (34% amputation free survival in frail CLTI group vs. 72.9% in non-frail) and higher all-cause mortality.

Conclusions: The presence of frailty in both people with CLTI and DFUs is likely associated with substantially higher complexity at presentation followed by a greater risk for readmission, amputation, and death during follow-up. Heterogeneity in the tools used to screen for frailty, poor definition of frailty and unclear evaluation of exposure and outcomes limit further interpretation of findings. Further research is needed to evaluate how frailty can best be identified and addressed in these two populations.

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P07.2-5

Analysis of proteomic differences in artery plaque above or below the knee in patients with diabetic foot and PAD

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Aim: Patients with diabetic foot and peripheral vascular disease have multi-stage extensive plaques, which are more common below the knee, which is difficult to treat and the effect is not satisfactory. This study was performed for proteomic analysis of plaques below or above the knee.

Methods: 3 diabetic foot patients with the plaques below the knee as D1 group, 3 diabetic foot patients with the plaques above the knee as D2 group and 3 non-diabetic patients as C group. During intervention of the arteries of the lower extremities, plaques were collected. The plaques were analyzed by mass spectrometry followed by between-group differences using bioinformatics.

Results: 1. A total of 5292 proteins were obtained, of which the quantifiable proteins were 4464. 2. Quantitative difference analysis showed there were upregulated 1504 proteins and downregulated 1350 proteins between D1 and D2 groups. The number of up-regulated and down-regulated proteins was greater than that of D1 and C, and D2 and C. Cluster analysis showed that the similarity of the three samples was high within each group, and the similarity was very low between groups. 3. The functional difference showed between D1 and D2, the GO enrichment top3 were nucleic acid binding, primary metabolic process and membrane-enclosed lumen and KEGG pathway enrichment top 3 showed diabetic cardiomyopathy, prion disease and Alzheimer disease. Among them, diabetic myocardial pathway is the most different. The protein interaction results showed that 5 clusters could be formed between the two groups, but the protein interaction between the differential proteins between D1 and D2 was more complex. 4. The cell localization and domain of D1 and D2 differential proteins are also different from those of the control group.

Conclusions: Plaque proteomics below the knee of patients with diabetic foot and peripheral artery disease differs from that of above the knee. From the perspective of the number and function of differential proteins, it has a greater impact on the cardiovascular and cerebrovascular, and the top proteins and pathways are useful for in-depth research.

P07.3-1

Does the skin heat up before it breaks down in diabetic foot ulceration?

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Background/Aim: Most diabetic foot ulcers are caused by tissue stress from being ambulatory in people without protective sensation. These ulcers are suggested to be preceded by local skin temperature increase due to inflammation of underlying tissue, a so-called hotspot. Evidence to support this mechanism of ulcer development is meagre at best. Our aim is to investigate whether non-traumatic diabetic foot ulceration is preceded by increased skin temperature.

Methods: We included 151 participants with diabetes, peripheral sensory neuropathy, and a healed foot ulcer in the last 48 months or Charcot neuro-osteoarthropathy, being the intervention arm of our multicentre randomised controlled trial on effectiveness of at-home foot temperature monitoring to prevent ulcer recurrence. Participants received usual care plus instructions to measure each day at home their skin temperatures at 6-8 predefined plantar locations (hallux, second and third toe, first, third and fifth metatarsal heads and maximum two additional high-risk locations) on each foot using a handheld infrared thermometer. A hotspot was a temperature difference $>2.2^{\circ}\text{C}$ between corresponding locations on both feet for two consecutive days. Participants with non-traumatic ulcers were classified by having in the two months prior to ulceration: 1) a true hotspot, at or adjacent to the ulcer; 2) a false hotspot, at another location; 3) no hotspot.

Results: Of 151 participants, 29 developed a non-traumatic ulcer while being adherent to measuring foot temperatures. Eight participants (28%) had a true hotspot. The first and last hotspot appeared on average 37 and 9 days prior to ulceration respectively; a hotspot was present 26% of days between first hotspot and ulceration. Seven participants (24%) had a false hotspot and 14 (48%) had no hotspot. No significant group differences were found for demographic, disease- and ulcer-related characteristics.

Conclusions: The skin of the majority of non-traumatic diabetic foot ulcers did not heat up before it broke down, or when it did, not directly before breakdown. This questions the mechanism of foot temperature increase before ulceration and with that the potential of at-home foot temperature monitoring in preventing ulcers in the majority of high-risk patients.

P07.3-2

The Feasibility of a Home-based Training Protocol while Offloading a Diabetic Foot Ulcer

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Aim: We designed a 6-weeks aerobic and strength intervention program for Type 2 diabetes mellitus patients with Diabetic Foot Ulcers (DFU), to be applied during the offloading phase. Is this program feasible and what are the physical health benefits?

Design: Feasibility study with a longitudinal prospective design. Participants: Five (4 male) patients with a diabetic foot ulcer. Intervention: Six weeks of home-based moderate aerobic and resistance exercise training using elastic resistance bands and an arm crank ergometer. Outcome measures: Primary outcome: patient experience and self-reported adherence to the instructed frequency, intensity and duration of the aerobic and resistance training. Secondary outcomes: RAND SF-36 questionnaire, wound healing, grip strength (left/right) measurement, heart rate recovery, arm crank incremental exercise test.

Results: Protocol adherence ranged from 58.3% to 83.3% for the aerobic training and 44.4 to 100% for the resistance training. Reported average physical activity per week during the training intervention ranged from 21 to 128 minutes. The monitored actual performance of aerobic training intensity approached the intended amount. No substantial change in quality of life was observed. Individual improvements were seen in peak heart rate (4.7% - 8.3%) and incremental test duration (4.0% - 10.0%).

Conclusion: This feasibility study shows that the included participants were able to perform and adhere to a home-based resistance and aerobic training program for 6 weeks during DFU wound treatment.

P07.3-3

Variations in wearing time of prescribed footwear in people at high risk of diabetes-related foot ulcers: a one-year follow-up study

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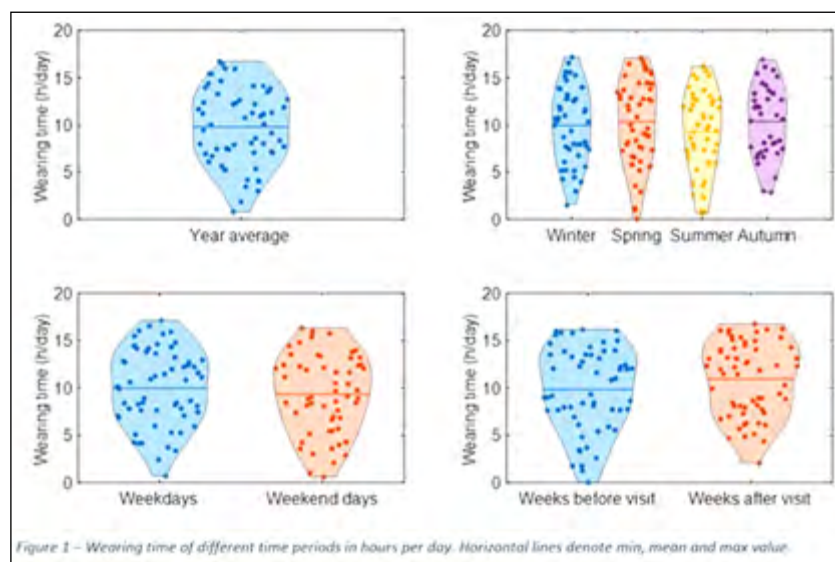
Background/Aim: Wearing prescribed footwear is essential for people with diabetes to help prevent foot ulcers. However, most studies measure prescribed footwear adherence or wearing time during one week only, without considering variations over time. Our aim was to investigate the variation in wearing time during one year.

Methods: In an observational prospective cohort design, we longitudinally followed 60 participants with diabetes and neuropathy (all IWGDF risk 3) for 12 months. A validated temperature sensor measuring every 15 minutes was secured in participants' prescribed footwear. We determined wearing time per day on average during one year, the four seasons, weekdays and weekend days. To investigate the effect of study visits on wearing time, we determined wearing time of the weeks before and after a study visit. We used Student's t-test and one-way ANOVA for statistical analyses.

Results: The average wearing time during one year was 9.8 (SD:4.0) h/day (Fig. 1). Wearing time differed across seasons, although not statistically significant (range: 9.2-10.4 h/day, F3,186=0.75, p=0.52). Wearing time was higher during weekdays than weekend days ($\Delta=1.1$ h/day, p=0.41), and higher during the weeks after a study visit than the weeks before a study visit ($\Delta=0.6$ h/day, p=0.15), although both not statistically significant.

Conclusions: We found small and non-significant differences in wearing time per day across seasons, between week and weekend days, and the week before and after a study visit at a group level. Future research should investigate individual variations over time.

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Wearing time of different time periods

P07.3-4

Promoting Foot Self-Assessment and Self-Management with a Commercially Available Infrared Thermometer: Findings of a Mixed Methods Study

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Background/Aim: Daily foot assessment, with appropriate action, is recommended for patients with diabetes to prevent diabetic foot ulcers (DFUs). Affordable self-management tools and education are needed to support foot assessment and direct action. Self-monitoring of foot temperature using a medical-grade infrared thermometer has been associated with a reduction in DFUs. This study evaluated the impact on assessment and the patient perspective of using a low-cost, commercially available infrared thermometer (CAIT).

Methods: This sequential exploratory mixed methods research design had three phases. Phase 1: self-management was explored using qualitative methods and what was learned informed the education + CAIT intervention. Phase 2: a 6-month pilot RCT was conducted to test the intervention's effectiveness. Participants were randomized to the intervention group (n = 34) and control group (n= 26). Phase 3: interviews were conducted with participants regarding their experiences with the intervention.

Results: There was no difference between the two groups for DFU. However, the intervention group had more days where an assessment was completed (150.98 vs 119.84, p =.02). In the Phase 2 exit interview, 96.8% of participants indicated they would continue to use the CAIT. Benefits identified in the phase 2 and phase 3 interviews included prompting foot assessment, monitoring for hot spots, and providing direction for appropriate action to protect their feet. The thermometer engaged participants and provided reassurance regarding foot health. Issues were identified related to the need for clarity regarding the purpose of the thermometer; the logistics of using the CAIT; and the challenges of interpreting the results and taking action.

Conclusion: A CAIT is an available affordable tool that could support foot self-assessment and self-management for people with diabetes. Specifically, using a CAIT may offer several benefits, such as promoting and providing structure for a foot assessment and direction for action. Understanding possible challenges with using the thermometer can help clinicians strengthen patient education and reinforce foot self-assessment as part of regular follow-up.

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P07.3-5

The design of an integrated personalized assistive devices approach to reduce foot ulcer recurrence in diabetes

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Background/Aim: Healthcare is shifting from stratified care to personalized medicine, accelerated through developments in wearables and assistive devices. However, for research into diabetic foot ulcer prevention it is still common to assess single interventions provided to all participants in the same way. Therefore, we aimed to design a treatment approach in which multiple preventative assistive devices interventions are integrated into a personalized approach to reduce foot ulcer recurrence in diabetes.

Method: We used existing clinical guidelines and systematically searched the literature for proven interventions to prevent diabetic foot ulceration. For custom-made footwear, at-home foot temperature monitoring and patient education, we found twelve, seven and ten studies, respectively. Three studies were identified that assessed a form of integrated care, but none combined all the above-mentioned single interventions.





Combining these outcomes with our clinical experience, we designed a state-of-the-art integrated approach. This design was discussed with a multidisciplinary group of 22 experts (i.e. rehabilitation and internal medicine specialists, shoe technicians, podiatrists, scientists, patient representatives, and an implementation specialist), before finalizing the design.

Results: We combined four modalities into an integrated approach, that was personalized by individual biomechanical and behavioral profiles based on objective measurements and questionnaires (Table 1).

Conclusion: This new design for an integrated personalized assistive devices treatment approach represents a shift from stratified healthcare towards personalized medicine to prevent foot ulcer recurrence in diabetes. The approach is currently studied in a multicenter randomized controlled trial to assess its efficacy from a clinical, health-economic and patient-related perspective.

Acknowledgements:
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Table 1: Modalities included in the personalized intervention

	Intervention	Personalization
	Pressure-optimized custom-made footwear, according to a state-of-the-art design protocol 1,2,3	The design is based on the patient's foot type and personal preferences, and individually tested and optimized for pressure distribution with in-shoe plantar pressure measurements.
	Pressure-optimized custom-made indoor footwear, according to a state-of-the-art design protocol 2,4,5	The design is based on the patient's foot type and personal preferences, and individually tested and optimized for pressure distribution with in-shoe plantar pressure measurements.
	At-home daily foot temperature monitoring at high-risk locations 6,7,8	Personalized for a maximum 3 locations that are at high risk, based on previous foot ulcer locations, high in-shoe pressure areas and/or signs of pre-ulceration. Usability and temperature profiles evaluated every 3 months to determine need to continue.
	Patient education, including motivational interviewing and personalized feedback 3,9,10,11,12,13	Based on a structured model focusing on risk factors and prevention strategies, with multiple teach-back moments. Personalized feedback is given on footwear use, plantar pressures, temperature monitoring and self-care. Motivational interviewing is provided after randomization, 3, 6 and 9 months, to increase or maintain treatment adherence.

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P07.3-6

Patients' and clinicians' experiences of using a digital tool, D-Foot, in the screening of risk factors for diabetic foot ulcers

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Background: Regular screening of risk factors for developing diabetic foot ulcers (DFUs) is an important part of the efforts to prevent foot ulcers. Digital tools could aid such screening.

Aim: To evaluate patients' and clinicians' experiences of using a digital tool, the D-Foot, in the screening of risk factors for developing DFUs. Secondary aims were to investigate whether patients had had their feet examined by a nurse or doctor during the past year, had been referred to podiatry and received information about self-care.

Methods: 90 patients with diabetes visiting a Department of Prosthetics and Orthotics (DPO) were included in the study. Two Certified Prosthetists and Orthotists (CPOs) assessed foot status and the risk of developing DFUs with the D-Foot prior to prescribing footwear. The patients answered the Orthotics and Prosthetics Users' Survey (OPUS) to assess quality of services at the DPO. The CPOs answered the System Usability Scale (SUS) before and after the study to assess the usability of the D-Foot.

Results: No patient had risk grade 1 (healthy foot), one (1%) had risk grade 2 (neuropathy or angiopathy), 78 (87%) had risk grade 3 (previous DFU, amputation, foot deformity or skin pathology) and 11 (12%) had risk grade 4 (active DFU, osteopathy or pain syndrome). Patients reported high levels of satisfaction on eight of ten OPUS items. The two items with lower scores were not related to use of the D-Foot. The two CPOs reported usability levels above the mean both before (77.5 and 90) and after (70 and 97.5) using the D-Foot. 78 (87%) patients had undergone foot examination by a nurse or doctor during the last year, 59 (66%) had got podiatry, and 59 (66%) had got information about foot self-care.

Conclusions: Patients expressed high levels of satisfaction with the services when their feet were examined with the D-Foot. The CPOs found that the D-Foot was usable. A number of comments were provided by patients and CPOs and will support the future development of the D-Foot. There is a need to increase foot examinations, preventive podiatry and improve information on self-care for patients at risk of DFUs.

P07.3-7

Use of Thermovisual Monitoring for prevention of reoccurrence of DFU: Case Reports

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Aim: Diabetic Foot Ulcers (DFU) are associated with high morbidity and mortality. A DFU is a pivotal event in the life of a person with DM and a marker of serious disease. Once healed, the incidence of ulcer recurrence is high. Approximately 40% will reoccur in 12 months. The lack of research focus on DFU prevention is well recognised and deemed a priority area for future research. Remote temperature (RTM) monitoring has been proposed to reduce the high rates of recurrence. The addition of remote visual monitoring (RVM) may also offer advantages in identifying issues not identified by RTM alone. The aim of this study is to present individual case reports of our experiences of RTM and RVM.

Methods: BlueDrop Medical have developed the Delta Foot Scanner (DFS), which allows for combined thermal data and visual images of the feet to be taken in an easy to use device. The device is designed to look and behave like a standard home weight scale and takes 30 seconds to use per day. In the ongoing study, participants use the device in their homes daily and collected data is remotely reviewed for signs of skin damage. If an issue is identified the patient is contacted for remote care or to schedule an in-person appointment. 30 patients, with a history of DFU will be recruited in total, with a 3 month follow-up period.

Results: We present case reports of our experiences of RTM and RVM in patients with previous DFU including a patient who developed a skin fissure without evidence of concomitant temperature elevation and the prospective monitoring of the lesion to closure.

Conclusion: Daily monitoring of the lesion ensured no exacerbation was occurring without scheduling an unnecessary clinical visit demonstrating the value of RTM and RVM as a cost-effective, preventative strategy for prevention of re-ulceration in this high risk population.

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P07.4-1

Patients with diabetic foot syndrome and compression therapy: A lot is possible!

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Background/Aim Indications for compression therapy are acute venous or chronic venous insufficiency, lymphedema or Lipoedema. Compression therapy is basic of conservative treatment of varices and peripheral oedema. The aims are reduction of venous hypertension at rest and under activity, reduction of pathological stasis, increase of reabsorption of the oedema, attenuation of the inflammatory response in the tissues, prophylaxis of the progression of tissue damage and no obstruction of arterial inflow. Should compression therapy be performed also to reduce oedema at patients with diabetic foot syndrome (DFS): What are the challenges and opportunities?

Methods Recent research of literature and (German) guideline recommendations regarding compression therapy to reduce oedema at patients with PAD and diabetes.

Results According to IWGDF oedema therapy is recommended.¹ There is an interrelation between PAD and Diabetes.² Compression therapy improves arterial circulation already at low level by reducing the venous pools within the leading veins.³ Patients with PAD and DFS (>50%) can be treated with compression if perfusion is assured (no critical ischaemia), effective antibiotics and local wound therapy in infected lesions, pressure padding for extensive soft tissue lesions, in-situ bypass devices. The efficacy of compression therapy is much better, the more a patient is moving/walking!⁴ Some contra-indications are chronic critical limb ischaemia with ABI < 0.5, or absolute ankle pressure < 60 mm Hg or toe pressure < 30 mm Hg, acute limb ischaemia, acute soft tissue phlegmon/sepsis and extra-anatomical bypass.

Conclusion Compression therapy for patients with DFU is useful at chronic venous insufficiency, ABI > 0.6, TcPO₂ > 40 mm Hg and when there is no clinical relevant infection. Best practice recommendations: Usage of multi-layer compression bandages or multi-component systems, combined with manual lymph drainage, if necessary, in the decongestion phase.⁵ After initial decongestion, change to two-layer ulcer compression stocking systems.⁵ If the leg circumference changes, application of a medical adaptive compression system.⁵ Selection according to disease, patient preference and patient complaints.

P07.4-2

Intussusceptive capillary remodeling mediates post-ischemic muscle regeneration in aged but otherwise healthy mice

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Background: The contribution of arterial collaterals in post-ischemic blood flow recovery is well recognized. Tissue microvasculature is also known to undergo remodeling in response to ischemia. However, how this remodeling is exactly related to the recovery process is still not completely understood. The aim of this study was to establish how the microvasculature co-ordinates post-ischemic tissue outcome.

Methods: Using state-of-the-art high-resolution contrast ultrasound¹ and photoacoustic imaging² combined with thorough immunohistological analyses³, muscle-level microvascular blood flow alterations, hemoglobin oxygenation, and post-ischemic capillary and myofiber responses were studied and chronologically aligned in aged C57Bl/6J mice after acute hindlimb ischemia.

Results: 1 to 4 days after the ischemic insult, capillary enlargement coincided with a phase of ischemic damage during which microvascular blood flow was not yet completely recovered but hemoglobin oxygenation controversially was. Between 4 to 11 days the muscle was under regeneration, capillary size returned to normal and capillary density increased coinciding with completely recovered blood flow and decreased hemoglobin oxygenation.

Conclusions: These results display the dynamic adaptation of the microvasculature in response to acute ischemia leading to complete muscle regeneration. The microvascular alterations, preceding changes in functional parameters, can even be seen to co-ordinate both the process of post-ischemic blood flow recovery as well as tissue outcome. Especially the role of initial, transient capillary enlargement seems essential for the recovery process. Understanding the dynamic nature of the microvascular changes under ischemia should be taken into consideration when designing novel treatments targeting the microvasculature in ischemic tissues.

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2) Needles A, Trans Ultrason Ferroelectr Freq Control. 2013; 60(5): 888-97

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P07.4-3

Popliteal/saphenous block in autologous peripheral blood mononuclear cells therapy in diabetic no-CLI patients

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Aim: autologous peripheral blood mononuclear cells (A-PBMNC) implants are performed with a 21 G needle, extremely painful also for neuropathic patients. The choice of the best anesthesia regimen remains an open question. This study compared hemodynamic variations, VAS scale, surgeon comfort, post-operative pain and side effects in 2 groups of diabetic not revascularized (no-CLI) patients with deep sedation (DS) or popliteal/saphenous block (PSB) under ultrasound guidance.

Method: 102 diabetic no-CLI patients with similar baseline characteristics and indications underwent 288 A-PBMNC implants: 42 patients with DS (122 implants) and 60 with PSB (166 implants). Blood pressure, heart rate, oxygen saturation and post-operative NRS scale were evaluated. Surgeon comfort and side effects are reported. In all the patients we implanted 12 mL of A-PBMNC, collected by selective filtration from 120mL of peripheral blood. The A-PBMNC treatment was repeated for a maximum of three times. If necessary, foot surgery was performed at the same time of the last implant.

Results / Discussion: SD determined a higher variation in blood pressure (± 20 mmHg), heart rate (± 20 bpm) and oxygen saturation (± 5 mmHg) than PSB, respectively 35 vs 26 patients ($p=0,007$); 97 vs 33 patients ($p=0,000$); 10 vs 7 patients ($p=0,14$). In 160 PSB procedures sufficient anaesthesia and akinesia was achieved and in 6 cases SD was associated. Only in 32 SD procedures akinesia was achieved. Mean surgical time was 35.7 minutes. VAS pain scale in PSB patients was $2.4 \pm 0,8$ during the procedure and $2.2 \pm 0,3$ after. No side effects were registered.

Conclusion: the use of PSB showed to be more effective and as safe as SD.

P07.4-4

Toe-brachial index and toe systolic blood pressure for the diagnosis of peripheral arterial disease

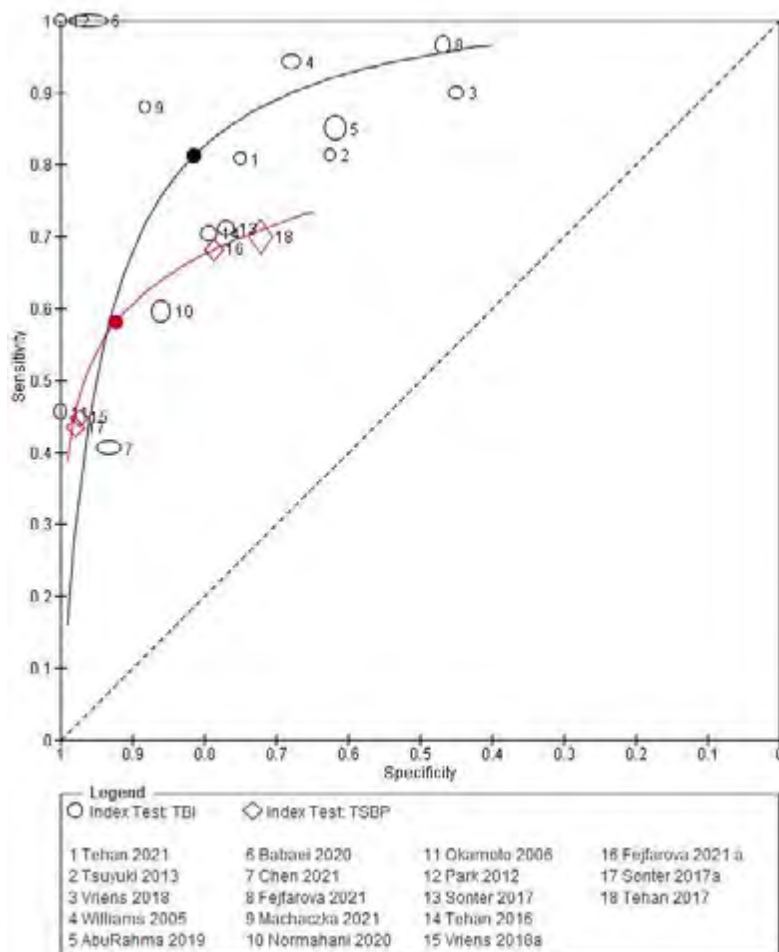
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Background The aims of this systematic review and meta-analysis were to (1) estimate the accuracy of toe systolic blood pressures (TSBP) and toe-brachial index (TBI) for the diagnosis of peripheral arterial disease (PAD) in the lower extremities at different cut-off values for test positivity in populations at risk of PAD, and (2) compare the accuracy of TBI and TSBP for the diagnosis of PAD in the lower extremities.

Methods MEDLINE, Embase, CINAHL, Web of Science, LILACS, Zetoc and DARE databases and World Health Organization International Clinical Trials Registry Platform and ClinicalTrials.gov trials registers were searched up to 1 August 2022. We included all diagnostic case-control, cross-sectional, prospective and retrospective studies in which all adult participants had either a TSBP or TBI measurement plus a validated method of vascular diagnostic imaging for PAD. Quality assessment was undertaken using QUADAS-2 and GRADE certainty of evidence was appraised.

Results TBI was investigated in 14 studies that included 1585 participants and 2124 limbs. TSBP was investigated in five studies that included 719 participants of which 701 limbs has TSBP measured. The Figure included displays the summary points for both TSBP and TBI. Sensitivity analyses provide some evidence that diagnostic accuracy may be higher in diabetes populations, and automated conduct. Furthermore, using a threshold of 0.60 or below for TBI may have a greater diagnostic odds ratio for PAD, compared to a threshold of 0.70 and above.

Conclusions This meta-analysis demonstrates that TSBP and TBI can discriminate PAD in a mixed population at risk of PAD, that TBI is particularly useful in populations with diabetes.



Summary receiver characteristic curve of pooled studies TBI and TSBP

P07.5-1

Reulceration rates and microcirculation improvement after healing in patients with neuroischemic diabetic foot ulcers treated with sucrose octasulfate dressings

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Aim: To evaluate recurrence after a 1-year follow-up period of healed diabetic foot ulcers after treatment with sucrose octasulfate impregnated dressing.

Method: Forty-four patients with neuroischaemic DFU after the healed with sucrose octasulfate impregnated dressing were prospectively follow-up during 1-year. Patients were assessed monthly in the specialized out-patient clinics following the International Working Group Guidelines. Reulceration, minor, major amputation and death were recorded during this period. Additionally, TcpO₂ value was measured using TCM400 device (Radiometer, Copenhagen) after 1 year of healing.

Results: During the follow-up period 14 patients (28%) suffered from a reulceration event, of whom 7 (14%) required a minor amputation, and 4 (8%) required major amputation. Additionally, 7 (14%) patients died. Patients with impaired microcirculation at inclusion (<30mmHg) showed an increase of tcpO₂ values from day 0, 20.20 ± 5.38 mmHg to healing, 31.28 ± 13.74 mmHg, ($p=0.023$) and these tcpO₂ increasing remained constant after 1 year of ulcer healing, 33.66 ± 13.83 mmHg ($p=0.011$). Those patients who suffer a reulceration in the follow-up had tcpO₂ values lower 27.90 ± 17.35 mmHg compared to non-reulceration patients 41.63 ± 12.81 mmHg, ($p=0.048$).

After adjusting the analyses, we observed that neuroischemic patients that had impaired microcirculation after the 1-year follow-up period resulted in more reulceration events, 8 (57.1%) compared with neuroischemic patients with normal microcirculation status, 6 (42.9 %), ($p=0.013$).

Conclusion: This study suggests that the application of a sucrose octasulfate impregnated dressing may improve clinical characteristics of the foot in patients with impaired microcirculation status and thus, it could prevent further reulceration events.

P07.5-2

Plantar sudomotor dysfunction: a risk factor for diabetic foot ulcer recurrence

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Background/Aim More than a half of patients with a healed diabetic foot ulcer will have a recurrence within 3 years. Risk factors found in the literature are very heterogeneous. The aim of our retrospective study is to assess the impact of different factors on the risk of recurrence.

Method A total of 71 patients with type 2 diabetes and a history of foot ulcer were included. They underwent a neurological assessment (thermal sensitivity, vibration perception threshold, neuropathy symptom score, neuropathy disability score, sudomotor function), a vascular assessment (palpable pulses, TcPO₂, systolic pressure index), a clinical foot exam (foot deformities, joint stiffness), a measurement of plantar pressure and skin microcirculatory reactivity to acetylcholine, heating and pressure. Statistical analysis were performed to compare the group "No recurrence" including patients with a history of only one ulcer, and the group "Recurrence" including patients with a history of at least two foot ulcers.

Results A history of multiple foot ulcers was found in 34 patients (48%). There was no significant difference in univariate analysis between the two groups in term of age, diabetes duration, vascular parameters, vibration perception threshold, NDS, NSS, joint stiffness, plantar pressures and skin microcirculatory reactivity. In multivariate analysis, patients in the Recurrence group were more frequently male (91 vs 62%, $p=0.042$, OR=5.985), with a history of retinopathy (82 vs 57%, $p=0.016$, OR=6.492), cardiovascular complications (50 vs 16%, $p=0.035$, OR=6.547) and a more frequent impairment of plantar sudomotor function (74 vs 54%, $p=0.039$, OR=5.523) than those in the group "No recurrence".

Conclusion This study suggests that taking into account demographics data (gender and diabetic complications) and an assessment of plantar sudomotor function could be useful to optimize secondary prevention in a group at very high risk of recurrence.

P07.5-3

Podological Procedure is Able to Restore Skin Elasticity in Diabetic Foot Patients (DFP) at High Risk for Ulceration

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Aim – To test if mechanical keratolysis (MK) is able to restore skin elasticity in high-risk DF patients.

Patients and methods – A cohort of consecutive DFP attending the preventative outpatient clinic of the diabetic foot (DF) section of our hospital was prospectively evaluated for the presence of localised hyperkeratosis (HK), deformities (D) and skin temperature (ST), and underwent keratolysis mechanically removing keratosis with a #10 scalpel in the hand of expert podologists (LAN, EL, NR). Skin hardness was blindly measured before and after the procedures by means of a durometer by another podologist (LA) at I and V metatarsal-phalangeal Joints (I-MTP, V-MTP) and at the heel.

Results – 102 DFP [age 74.1±10.5 yrs; DM duration 19.4±8.7 yrs; HbA1c 7.8±1.9%: 52% males; 61 with (Group1) and 41 without (Group2) HK] were studied. Group1 showed a higher prevalence of D (95.1% vs 78.6%, p=0.014) and higher ST (33.4±1.9°C vs 32.6±1.8°C, p=0.03) compared to Group2. SH at I-MPJ (39.2±20.4 UI vs 27.2±15.9 UI p=0.002) V-MPJ (37.2±19.3 UI vs 28.8±17.5 UI p=0.027), were significantly greater in Group1 compared to Group2, while no differences were found at heel. MK reduced significantly SH both at I-MPJ (ΔSH 5.0±7.0 UI, p=0.0024), V-MPJ (ΔSH 3.4±5.6 UI, p=0.0008) and at heel (ΔSH 1.3±3.2UI, p=0.03), annulling the differences in SH with Group2.

Conclusions – HK is a frequent feature in high-risk DFP and is associated with D and increased ST; MK performed by expert podologists is able to restore skin elasticity in DFP at high ulcerative risk.

P07.6-1

Mean HbA1c and glycaemic variability are associated with adverse outcomes following infra-inguinal bypass for PAD. A retrospective cohort study

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Introduction: Glycaemic variability (GV) measured by visit-to-visit changes in HbA1c is associated with increased risk of several adverse outcomes in people with diabetes (DM). However, the impact of GV on graft patency following infra-inguinal bypass (IIB) for peripheral arterial disease (PAD) is unknown.

Methods: A 3-year single centre retrospective case notes analysis of all people undergoing IIB between 2017-2019. HbA1c values for 5 years pre-procedure (with a minimum of 3 measurements) were used to calculate a mean (\pm SD) HbA1c (MH) and GV. Time to re-intervention, ipsilateral amputation or death were recorded to determine primary (PP) and secondary patency (SP).

Results: 193 IIB outcomes were analysed: mean (\pm SD) age 68.9 (9.2) years; 135 (69.9%) male. 157 (81.4%) had pre-operative HbA1c for analysis and 88 (45.6%) had DM; 87 (45.1%) were current smokers; 107 (55.4%) underwent emergency procedures. Those without diabetes were more likely to smoke ($P=0.011$), but those with DM had higher Rutherford stage ($p=0.0006$), underwent more distal bypasses ($p=0.004$) and more emergency procedures ($p=0.04$).

Those with DM had longer median [IQR] hospital stays 9 [5-21] vs. 7 [4-15] days ($p=0.017$), lower PP 335 [184-542] vs. 883 [436-1437] days ($p=0.04$) and lower SP 751 [387-1108] vs. 1079 [895-1593] days ($p=0.037$).

Both MH and GV were associated with amputation free survival time ($r=-0.232$, $p=0.004$ and $r=-0.243$, $p=0.011$ respectively). A $GV>9.1\%$ was associated with significantly lower PP than $GV<9.1\%$, 198 [105-377] vs. 713 [313-1287] days ($p=0.02$).

Conclusions: We have shown a significant relationship between mean HbA1c and glycaemic variability and risk of adverse outcomes in people undergoing infra-inguinal bypass. Lowering glycaemic variability should be an additional therapeutic target together with mean HbA1c.

P07.6-2

Superficial venous arterialisation of the lower limb as last resort in patient with chronic limb ischemia

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Critical limb ischemia (CLI) is characterized by ischemic resting pain or tissue loss related to peripheral artery disease. Due to the lack of revascularisation options end stage CLI has a high amputation rate. There is also a higher mortality rate associated with CLI, with a mortality rate of 20% after 1 year, and 60% after 5 years (Aulivola, 2004; Ploeg et al., 2005). In patients with CLI and no revascularisation options, a venous arterialisation may be considered (Schreve et al., 2017). In this case series we present a new technique for venous arterialisation that is an extension on the In Situ Reverse Arterialization technique used by D. Chayen (Chayen et al., 2019).

With this technique the superficial venous bed is used to supply arterial blood to the distal limb. The valves of the great saphenous vein are destroyed up to the foot using a valvulotome. The great saphenous vein is anastomosed to the proximal superficial femoral artery. Only proximal saphenous tributaries are ligated in order to prevent high systemic pressure in the venous low-pressure system of the foot. This technique allows all incision sites to be located above the knee to prevent further wound complications.

With this procedure the primary outcome is limb salvage, thereby preserving the limb as much as possible and preventing a major amputation. The secondary outcome is accelerated wound healing and decrease of CLI symptoms including resting pain and claudication.

In this case series 10 patients who were scheduled for major limb amputation were followed over a period ranging between 4 months and 2 years. All patients underwent a superficial proximal venous arterialisation of the great saphenous vein. In 5 out of 10 patients limb salvage was achieved with a minimum follow up of 4 months. In these patients there was an increase in TcPO₂ value to 54mmHg and above.

In this case series we had a limb salvage rate of 50%, compared to the 100% predicted major amputation rate/risk. This technique can therefore be a last resort for patients that would normally receive an amputation.

P07.6-3

Integrated complementary care of surgical and endovascular revascularisation in chronic limb threatening ischaemia; angioplasty need not always come first

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Aims: Controversy remains regarding the roles of vascular bypass and angioplasty in treating chronic limb threatening ischaemia (CLTI) and whether angioplasty should be always carried out first. Also, it is not known how often these procedures need repeating and how often the contralateral leg to the index limb needs intervention. The aim was to analyse treatment of CLTI by the Multidisciplinary Diabetes Foot Team (MDFT) to inform these controversies.

Methods: This was a retrospective study of 252 consecutive patients with diabetes attending a single centre MDFT for CLTI and tissue loss who underwent revascularisation over a three year period, analysing their treatment and outcomes.

Results: Of the 252 patients, 157 (62%) underwent a single revascularisation procedure to the index limb; 133 had angioplasty as a single procedure involving multiple segments, 45% requiring crural or ultra-distal (below ankle) revascularisation. and 24 had single bypass with the highest proportions, femoral to popliteal (29%) and popliteal to ultra-distal (29%).

However, 95/252 (38%) patients required multiple revascularisation to the index limb; 26 underwent repeated angioplasties involving multiple segments (10% iliac, 38% femoral, 19% popliteal, 29% crural, 4% ultra-distal) and 50/252 patients had angioplasty followed by bypass, including 4 hybrid procedures. A higher proportion of femoral (34%) and crural (30%) segments were angioplastied with the majority of eventual ensuing bypasses, popliteal-ultra-distal (30%) or popliteal-crural (26%).

19/252 underwent bypass followed by angioplasty with 7 (21%) hybrid procedures. There were 32% femoral-popliteal and 26% femoral-crural bypasses with ensuing angioplasties at predominantly femoral (24%) and ultra-distal (21%) segments.

The contralateral limb needed intervention in 46/252 patients; 25 had angioplasty and 5 had bypass as a single procedure; 16 patients required multiple revascularisation, 4 having repeated angioplasties and 12 angioplasty and bypass.

Only eight of 252 persons had major amputation.

Conclusions: This study indicates angioplasty does not always need to be first; 56/252 persons (22%) had bypass as the initial intervention. Furthermore, 38% needed multiple revascularisation to index limb. All cohorts highlighted the complex multisegmental disease pattern of CLTI in patients with diabetes, indicating both limbs need close surveillance with an integrated complementary revascularisation approach by MDFT.

P07.6-4

Guillotine transmetatarsal amputation with adjuvant endovascular therapy and staged closure in chronic limb threatening ischemia patients

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Background: Advanced chronic limb threatening ischemia (CLTI) patients often present with gangrene, severe infection, lack of tissue, and/or poor perfusion to the plantar flap that increases the risk of major amputation. Guillotine transmetatarsal amputation (gTMA) with adjuvant endovascular therapy and staged closure may be an alternative treatment for limb salvage in this population. We report the long-term outcomes of such technique.

Methods: A single-center-retrospective cohort study of CLTI patients undergoing gTMA between 2016 and 2022 was performed. Wound healed, freedom from major adverse limb events (MALE-free), and amputation free survival (AFS) were quantified using Kaplan-Meier median estimate (standard error, SE) analysis. Binary logistic regression was used to identify outcome predictors.

Results: Seventy-two gTMA procedures were reviewed. Median follow-up was 340 (Interquartile range [IQR], 203 – 499.7) days. Mean age was 65.5 ± 10.7 years, 55 (76%) patients had diabetes mellitus, 31 (43%) had end stage renal disease, 59 (81.9%) had infra-popliteal disease, and 59 (81.9%) had previous endovascular therapy (n=54/59, 91.5%) and/or deep vein arterialization (n=17/59, 28.8%). After gTMA, 80.6% (n=54/67) were able to ambulate after a median interval of 3 (IQR, 1-4.2) days. Eventual coverage was achieved in a personalized and staged approach by using a combination of skin substitutes (86.1%, n=62/72) and/or split thickness skin grafts (STSG, 50%, n=36/72). KM median estimate for wound healed was 52.7% at 206 (SE=10.7) days, AFS was 65.2% at 385 (SE=45.2) days, and MALE-free was 73.6% (no median estimate). Wound healed was significantly associated with ambulation (p=0.039, OR=11.73, 95% CI 1.13 – 121.3) and STSG application (p<0.001, OR=12.47, 95% CI 2.83 – 54.9). AFS (p=0.007, OR=4.5, 95%CI 1.5 – 13.5) and MALE-free (p=0.013, OR=0.2, 95%CI 0.05 – 0.72) were also significantly associated with STSG application.

Conclusion: gTMA resulted in acceptable wound healed, AFS, and MALE-free rates during long-term follow-up in CLTI patients. Early ambulation and adjunctive STSG placement may enhance wound healing. Surgeons may consider gTMA as an alternative to increase limb salvage in advanced CLTI patients at high risk of major amputation.

P08.1-1

VITAFooter- a pilot, double-blind, randomised controlled trial of vitamin supplementation in people with non-healing diabetes-related foot ulcers

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Background: Diabetes-related foot ulcers (DFUs) are common and burdensome, and despite optimal care many fail to heal. There are few interventions supported by high quality well-designed clinical studies to improve DFU healing outcomes. Micronutrients such as Vitamin C (VitC), Vitamin A (VitA) and zinc have essential actions in wound healing by stimulating epithelialisation and cellular proliferation. Deficiencies of these micronutrients are common amongst people with DFU but data regarding the effect of supplementation on DFU healing is limited.

Aims: To determine if administration of a 28 day course of a combination vitamin supplement containing VitC, VitA and zinc is associated with improved DFU healing compared to placebo.

Methods: 76 participants (of a planned 100) with a DFU present for greater than 4 weeks, have been recruited from a hospital based multidisciplinary diabetes foot ulcer service, including both inpatient and outpatient care. The design of this pilot study is a randomised placebo-controlled double-blinded clinical trial, in which participants receive either 28 days of a combination vitamin supplement containing VitC 1000mg, VitA 750mcg/2500IU and Zinc picolinate 25mg daily or placebo. The primary outcome is reduction in wound area from baseline to 12 weeks. Secondary outcomes are i) percentage of completely healed wounds ii) minor or major lower limb amputation or death and iii) wound healing trajectory at 12 weeks.

Results: The median age [IQR] of participants was 64 [54-71] years; 62 (81.6%) were male and 67 (88.2%) had type 2 diabetes. Median HbA1c was 8.0 [6.8-9.9]% (64 [51-84] mmol/mol). Median DFU wound area at baseline was 0.95 [0.33-2.9] cm². Of the 76 patients recruited thus far 34 (44.7%) participants had VitC deficiency at baseline, 1 (1.3%) had VitA deficiency and 8 (10.5%) were deficient in Zinc. Currently the investigators remain blinded to the allocation, but an interim analysis will be performed in April 2023 for all participants with an evaluable outcome.

Conclusions: Vitamin C deficiency is common amongst people with DFU. A combined vitamin supplement may prove to be an inexpensive, well tolerated and readily available intervention to improve DFU healing.

P08.1-2

Utilizing an immunocompetent 3D skin ulcer model to characterize macrophages in the diabetic foot

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Background: Current treatments for diabetic foot ulcers (DFU) do not guarantee a permanent solution, highlighting the necessity for more effective interventions. Immune cells involved in the healing process have been previously considered an attractive target. However, the complexity of the DFU, the difficulties in obtaining human material and the lack of animal models, have prevented a clear understanding of the molecular mechanism leading to dysfunctional monocytes/macrophages. Here we have developed a human skin organoid to study DFUs' pathophysiology and dissect the molecular pathway directly involved in the impaired immune response.

Methods: Based on a previously published method [1], we have established a 3D immunocompetent skin ulcer model, consisting of fibroblasts, monocytes, and keratinocytes layered step-by-step on transwell inserts in six-well plates. This way, the skin models can be air exposed from the apical side leading to keratinization of the upper layer, imitating real skin. To study the DFU, we perform an incision on the keratinocytes layer, through which acute stimuli (such as LPS or fluids collected from patients) can diffuse into the model.

Results: Primary human monocytes are cultured in the 3D skin model and successfully differentiate into macrophages, migrating to the location of the artificial wound. Using glucan-encapsulated siRNA particles (GeRPs) [2,3] a patented technology which is specifically targeting macrophages, we can track their movement and manipulate their gene expression.

Conclusions: Functional studies in human organoids using gene manipulation in macrophages will provide a novel tool to understand and validate the molecular target aiming to treat patients with non-healing ulcers and significantly decrease the amputation rate.

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P08.1-3

Peripheral blood mononuclear cells therapy: a new frontier for patients with diabetic foot ulcers and no-option critical limb ischaemia

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Background/Aim: Up to 30% of patients with diabetic foot ulcers (DFUs) and no-option critical limb ischaemia (NO-CLI) had major amputation. The current study aimed to evaluate the effectiveness of peripheral blood mononuclear cell (PB-MNCs) therapy as adjuvant treatment for patients with DFUs and NO-CLI who had unsuccessful lower limb revascularization.

Methods: This study is a prospective non-controlled observational study including patients with neuro-ischaemic DFUs and NO-CLI who had unsuccessful revascularization below-the-ankle (BTA) and persistence of foot ischaemia defined by TcPO₂ values less than 30 mmHg. After unsuccessful revascularization, all patients received PB-MNCs therapy. PB-MNCs were administered through a "below-the-ankle approach" in the affected foot along the wound related artery according to the angiosome theory. The treatment was repeated for three times 21-42 days apart. The primary outcomes measures were healing, major amputation, and survival after 1-year of follow-up. The secondary outcomes measures were the evaluation of tissue perfusion by TcPO₂ and foot pain defined by the Numerical Rating Scale (NRS).

Results: Thirty-six patients with unsuccessful BTA revascularization were considered for the study. Among those, 2 were excluded due to the extensive tissue loss non allowing surgical foot reconstruction and salvage. Thirty-three patients were definitely included. The mean age was 75±7yrs, 27 (81.8%) were male, all of them were affected by type 2 diabetes with a mean duration of 22±7yrs. At 1-year of follow-up after PB-MNCs therapy, 28 (84.8%) patients healed and survived, 2 (6.1%) deceased with wound healing, 2 (6.1%) reported non-healing ulcer, 1 (3%) had major amputation. Mean TcPo₂ valued increased significantly from baseline and after PB-MNCs therapy (14±9 vs 42±10 mmHg, $p < .0001$) and pain was significantly reduced from baseline and after PB-MNCs therapy (NRS 7/10 ± 2/10 vs 2/10 ± 1/10, $p < 0.002$)

Conclusions: The current study highlights the potential benefit of PB-MNCs in patients with NO-CLI neuro-ischaemic DFUs and unsuccessful BTA revascularization by promoting wound healing and reducing major amputation.

P08.1-4

A wound environment control system to avoid major amputation in diabetic foot ulcer

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Introduction: Diabetic foot ulcers remain a major cause of amputation. Factors related to direct wound environment are important to accelerate healing and decrease the risk of amputation.

Vistacare® (DTAMedical SAS, Loulle, France) is a device including a generator and a closed chamber where the foot with the ulcer is placed (Figure 1). Moisture, temperature and oxygen levels are controlled and modulated at each stage of healing. No dressing is required for the duration of the treatment, which is applied 16 hours per day for 14 days.

Case report: We report the case of a 58-year-old patient with diabetes and necrosis of the first toe leading to first ray amputation associated with endovascular revascularisation. Due to unfavourable evolution, a transmetatarsal and then a Lisfranc amputation were performed.

She was admitted to our unit with a risk of transtibial amputation despite offloading, negative pressure therapy and an appropriate antibiotic treatment. At admission, the ulcer of 63 x 42 x 36 mm was painful, covered with fibrin and necrosis.

Treatment was initiated with a set to improve debridement (high levels of moisture). At day 3, the necrosis was removed without any pain by mechanical debridement. At day 7, the set was changed to pursue debridement and stimulate granulation. At day 14, the ulcer showed healthy granulation tissue and a skin graft was then performed with complete healing.

Conclusion: Vistacare® is a new and innovative device that can be useful in some in patient with severe diabetic foot ulcer to prevent amputation.



Vistacare® device. A. The generator and the chamber where the leg with the wound is placed; B. Monitor with a tactile screen displaying pre-determined set (A for debridement, B for granulation, and C for epithelialisation).

P08.1-5

Microcirculation improvement in diabetic foot patients after the treatment with sucrose octasulfate impregnated dressings.

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Aim: Sucrose octasulfate impregnated (TLC-NOSF) dressing showed an increase in local Transcutaneous Oxygen Pressure (TcPO₂) in patients with neuro-ischaemic Diabetic Foot Ulcers (DFUs). The aim of this study was to demonstrate the patient's microcirculation improvement after the treatment with this dressing.

Methods: 50 patients with neuro-ischaemic DFUs were included in a prospective study between July 2019 and February 2022. TcPO₂ values were measured using TCM400 device on the dorsalis pedis or tibial posterior arteries angiosome according with ulcer location (forefoot or rearfoot). TcPO₂ values were assessed at day 0 and every 4 weeks during 20 weeks of follow-up or until wound healing. TcPO₂ values were analyzed in the total sample and in patients according microcirculation impairment and ulcer location.

Results: TcPO₂ values with TLC-NOSF dressing showed an increase between day 0 and the end of the study, 33.04 ± 12.27 mmHg and 40.89 ± 13.06 mmHg respectively, ($p < 0.001$). Patients with impaired microcirculation showed an increase of TcPO₂ values from 20.20 ± 5.38 mmHg to 31.28 ± 13.74 mmHg, ($p = 0.02$). Patients with normal microcirculation also shown an increase from 41.60 ± 6.80 mmHg to 46.73 ± 8.53 mmHg ($p = 0.007$). Furthermore, a significant increasing in TcPO₂ values was observed in forefoot DFU from 32.85 ± 12.76 mmHg to 41.34 ± 12.02 mmHg ($p = 0.001$) and in rearfoot DFU from 33.80 mmHg ± 10.66 mmHg to 39.25 ± 17.21 ($p = 0.203$).

Conclusion: Local treatment with Sucrose octasulfate impregnated dressing improved microcirculation in patients with DFU regardless vascular status at baseline and in forefoot location.

P08.1-6

Effectiveness of Sucrose Octasulfate dressing in the treatment of Neuro-Ischaemic Diabetic Foot Heel Ulcers: A Retrospective Single arm Study

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Aim: In the respect of the benefits of TLC-NOSF in forefoot and midfoot neuro-ischaemic DFUs¹, this current study aimed to evaluate the effectiveness of TLC-NOSF in the management of neuro-ischaemic heel DFUs.

Methods: This study is a retrospective single arm non-comparative study including consecutive patients with a non-infected neuro-ischaemic heel DFU (Grade IC or IIC of Texas University Classification, TUC). All patients were managed according to IWGDF Guidance². After the revascularization of affected limb and the surgical removal of non-viable tissues, the local treatment with TLC-NOSF was regularly performed. After 24 weeks of follow-up, the following outcomes were evaluated: wound healing, healing time (days), wound area regression (>50%), re-ulceration, and safety.

Results: Thirty patients were included. The mean age was 67±11 years, 17 (56.7%) were male, 30 (100%) were affected by type 2 diabetes with a mean duration of 18±7 years. Twenty patients (66.7%) had deep ulcers (TUC grade 2), the mean TcPO₂ value after revascularization procedure was 42 ±7 mmHg.

Twenty-two patients (73.3%) healed in a mean time of 84±32 days. Twenty-eight patients (93.3%) had wound regression, 2 (6.7%) had ulcer relapse after healing, 2 (6.7%) had mild infection, and 1 (3.3%) reported major amputation due to severe infection. No serious adverse events related to TLC-NOSF or local reactions were reported during the course of the study.

Conclusions: The current study highlighted the potential benefit of TLC-NOSF also in the management of neuro-ischemic heel DFUs as a part of the integrated standard of care.

P08.2-1

Relationship between neutrophil to lymphocyte ratio and healing of neuropathic diabetic foot ulcer

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Background/Aim: Emerging evidence suggests that the neutrophil-to-lymphocyte ratio (NLR) is a novel potential marker of inflammatory responses. Few studies have investigated the predicting value of blood NLR for wound healing in diabetic foot ulcers (DFU). To our knowledge, wound NLR was not previously investigated in this issue. The study aims to assess the possible relationship between NLR both in blood and wound and the healing of DFU.

Methods: This prospective study included 63 diabetic patients with neuropathic DFU. Ischemic and infected ulcers were excluded. NLR in blood and direct aspiration from wound were calculated in the first visit. All patients received standard wound care with subsequent assessment of ulcer surface area 4 weeks later. Carotid intima media thickness (CIMT) was assessed by a single experienced radiologist.

Results: Mean age of studied patients was 55.10 ± 5.39 years, 52.4% (33) were males, 85.7% (54) were Type 2 diabetes mellitus (DM), median DM duration was 15 (3-35) years, mean body mass index was 29.16 ± 4.59 kg/m². On first visit, median ulcer duration was 8 (1-104) weeks and median ulcer surface area was 0.70 (0.5-3.75) cm². After 4 weeks, median reduction of ulcer surface area was 65 (28.6-93.3) %. 14.2% (9) of ulcers did not show size reduction, 17.5% (11) were completely healed, 25.5 % (16) and 42.8 % (27) of ulcers showed < 50% and $\geq 50\%$ size reduction, respectively. Percent of ulcer surface area reduction was negatively related to ulcer duration, $p=0.007$. Comparing those with <50% versus $\geq 50\%$ ulcer surface area reduction, no significant difference found regarding ulcer surface area on first visit ($p=0.056$), NLR in blood ($p=0.83$), NLR in wound ($p=0.446$) and right or left CIMT ($p=0.558$ and $p=0.573$). Neither blood nor wound NLR was correlated with percentage of ulcer healing ($r=-0.18$, $p=0.157$, $r=0.045$, $p=0.724$, respectively). No correlation found between CIMT and blood or wound NLR.

Conclusions: NLR in blood or wound is not a reliable predictive biomarker for short term healing of non infected non ischemic neuropathic DFU.

P08.2-2

Making 100% individually therapeutically shoes for severe foot ulcers at Augusta Victoria Hospital, Palestine

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Background: Diabetic foot-ulcers is an increasing problem in many countries. It decrease the quality of life for the patient and family. Costly for patient and the public health system. It leads to amputation and dead. The shoe is for use in the period of healing of the ulcers or until the patients have new permanent shoes.

Aims: The aims is to make individual, better, quicker and cheaper mobilization for patients with severe foot-ulcers. To make 100% individually therapeutically shoes for a price 80% lower than manufactory made shoes within 2 hours.

Methods: Making total examination of the foot and ulcers. Joint movements, blood supply, skeleton disorders, Charcot-foot?, loads on the foot, need for rocker sole? Do measuring and surveying of the foot etc.

Then making a basic bottom for the shoe with an effective support for the heel, then making off-loadings of the ulcer area. Then form the upper part of the shoe in thermoplastic materials and cover the inside with a thin layer of foam. Then do the closing and fixation system made by Velcro-band (hook-and-wool-part). Then test gait-function together with the normal other shoe. At last giving information of use and calling the clinic if problems.

The methods need NO high-tech equipment at all. Only a grinding machine and a heating oven and thermo-elastic materials, foam, Velcro and glue.

Results: Patients have fewer days of bedlaying and are able to walk normally and the healing is shorter and better because the patient can walk and use his muscles. That lead to better blood-sugar regulation and gives a more normal social life and continuing job and work. In Pakistan have the number of amputation decreased 50% since 2016 when the method was introduced. In the Palestinian Augusta Victoria Hospital the method has been used in 1½ year.

Conclusions: The method is very useful in countries with low economy. Staff can be trained in 4 days if the grinding machine and heat-oven and thermoplastic materials are present. The shoe can be ready after 1½ hour of manybacturing.

P08.2-3

Use of dermal regeneration matrix, negative pressure system and skin graft for severe limb coverage defects in diabetic patients

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Aim The aim of our study is to describe the results obtained in the treatment of diabetic patients by combining the use of dermal regenerate templates (DRT) with the negative pressure system and later performing a free skin graft.

Methods We retrospectively reviewed all adult diabetic patients with severe coverage defects (exposure of neurovascular and/or tendon structures) at the distal level of the leg and foot, treated with DRT between January 2014 and July 2017 at our center.

Results Eight patients were identified. DRT was used to manage a variety of acquired soft tissue lesions, including vascular ulcers, bullous cellulitis, ischemic ulcer, and pyoderma gangrenosum. The median age was 63 years RIQ(54-85). Closure of the coverage defect was partially achieved in 75% (6/8) of the patients and completed in 25% (2/8). The partially closed wounds were treated with advanced dressings. One patient required the local application of platelet-rich plasma, another completed the treatment with recombinant human growth factor, and three underwent seed skin graft. Complete wound closure was achieved in all patients, avoiding amputation of the affected limb.

Conclusion Leg and foot injuries in diabetic patients are considered a frequent and devastating complication, more than half of diabetic ulcers could become infected, and about 20% of these infections could end in amputation. Collagen-based skin substitutes are porous matrices that act as supporting tissue for skin regeneration and decrease donor site morbidity. Dermal matrices can help to accelerate the rate of healing, in non-infected and non-ischemic wounds, in patients with diabetes.

The use of DRT in combination with the negative pressure system and the subsequent performance of a free skin graft allows, in diabetic patients, the management of complex coverage defects in the lower third of the leg and foot with minimal donor site comorbidities. Although most patients required dressings to achieve complete wound closure, this would not have been possible without the initial coverage achieved with the use of DRT, accelerating the healing process.

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P08.2-4

Effect of modulating wound pH value on the healing of diabetic foot ulcers

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Aim: To evaluate the effect of wound pH value modulation in the treatment of diabetic foot ulcers.

Methods: 89 patients with diabetic foot ulcer attending the wound clinic at XXX Hospital, Shanghai, China were included and were randomly divided into the intervention group (n=44) and the control group (n=45). Both groups received diabetic foot specialist treatment, and the acid cleaning solution was used to modulate the wound pH value of the intervention group. The wound pH value, BWAT wound healing score, VAS score and wound healing rate were measured and compared between the two groups before and after treatment.

Results: The baseline pH of most of the wounds were in the alkaline range, up to 8.74. After treatment, the decrease of wound pH value in the intervention group was greater than that in the control group ($P<0.05$); During the treatment, the BWAT score of the two groups generally showed a downward trend, and the BWAT score of the intervention group was significantly lower than that of the control group ($P<0.05$); The rate of healing in the intervention group (55.8%) was higher than that in the control group (38.1%).

Conclusions: The wound pH value can be used as an important index to predict likelihood of wound healing, determine whether the wound is infected and evaluate the effect of wound treatment. Modulating the pH value of diabetic foot ulcer wound could improve the wound microenvironment, destroy the growth environment of specified bacteria, improve therapeutic effect, and promote the wound healing of patients.

P08.3-1

Effect of a Macrophage-regulating New Drug in Treatment of Diabetic Foot Ulcers: from Phase 3 RCT to Real-world

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Aim: Diabetic foot ulcers (DFUs) is a devastating disease with high morbidities and mortality, and is lack of effective drugs. The efficacy of a macrophage-regulating topical drug (ON101) in patients with Wagner grade 1 or 2 DFUs was assessed in a multinational Phase 3 randomized-controlled trial (RCT) and its efficacy in patients with Wagner grade 3 and 4 ulcers was assessed in a real-world setting.

Methods: A Phase 3 RCT (NCT01898923) randomized 1:1 eligible diabetic subjects with Wagner Grade 1 or 2 DFU(s) to receive ON101 or comparator for up to 16 weeks, followed by a 12-week follow-up. The primary endpoint is the incidence of complete healing, and the secondary endpoint is the time to complete ulcer healing. The real-world setting included diabetic patients with Wagner grade 3 and 4 ulcers who only received ON101(trade name: Fespixon®) in addition to debridement for DFU treatment. The healing of those patients was recorded.

Results: 236 diabetic subjects with Wagner grade 1/2 foot ulcers were enrolled to receive the study drug (n=122) or the control dressing (n=114) with balanced baseline characteristics between the two groups. 60.7% of patients in the study drug group reached complete healing versus 35.1% in the control group (p=0.0001). In a real-world scenario, four patients classified as Wagner grade 3 with bone or tendon exposure and two as Wagner grade 4 with local gangrene were suggested to undergo reconstructive operation or re-amputation. However, none of them decided to go through surgical procedure and instead, they switched to receive ON101. All those patients reached healing with only the topical application of ON101 plus necessary debridement.

Conclusions: Macrophage-regulating drug achieved superior therapeutic efficacy in a large Phase 3 RCT and has been demonstrated limb salvage outcomes in the real-world scenario where debrided Wagner grade 3 and 4 DFUs reached healing without reconstructive operation or re-amputation. This enlightens the future treatment in Wagner grade 1 to 4 DFUs by macrophage immunomodulation new drug as a promising solution.

P08.3-2

The value of a novel macrophage-regulating drug for diabetic foot ulcers: A cost-effectiveness analysis

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Aim: Diabetic foot ulcers (DFUs) and subsequent amputation incur enormous health and economic burdens to patients, healthcare systems, and societies. As a novel macrophage-regulating drug, ON101 is a breakthrough treatment for DFUs with proven significant efficacy among patients with DFUs in phase 3 randomized controlled trial. This study assesses the cost-effectiveness of ON101 cream added-on to general wound care (ON101+GWC) versus GWC for DFUs.

Methods: Cost and health outcomes associated with the ON101+GWC and GWC strategies were estimated by a Markov state-transition simulation model over a 5-year time horizon from the Taiwanese healthcare sector perspective, discounting costs and effectiveness at 3% annually. Data were sourced from the ON101 trial and supplemented from published literature. Deterministic and probabilistic sensitivity analyses also assessed the uncertainty of input parameters and the study's generalizability. DFU-related complications, costs, quality-adjusted life years (QALYs), and incremental cost-effectiveness ratio are the primary outcomes and measures for assessment. The study was designed and conducted from September 1, 2020, to January 31, 2022.

Results: Simulated over 5 years from the Taiwan healthcare sector perspective, the ON101+GWC strategy versus GWC yielded additional 0.038 QALYs at an incremental cost of US\$571, resulting in US\$14,922 per QALY gained. Financial results were most sensitive to healing efficacy, drug cost, and health utility of the healing state. The ON101+GWC group versus the GWC group experienced more healing events, stayed healing for a longer time, and had fewer infected DFUs, gangrene, and amputations. Cost-saving results were revealed in patient subgroups with poor glycemic control, larger ulcer sizes, longer ulcer durations, and current smokers. The ON101+GWC strategy was considered cost-effective in 60%-82% of model iterations against pre-defined willingness-to-pay thresholds of US\$32,787-\$98,361 per QALY gained.

Conclusions: The ON101+GWC strategy represented good value for money compared with GWC for patients with DFUs and may be considered in future standard wound care as well as prioritized to those with higher risks for disease progression of DFUs.

P08.3-3

Off-loading and compression therapy strategies to treat diabetic foot ulcers complicated by lower limb oedema: A scoping review

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Background Lower limb oedema is a common co-morbidity in those with diabetes and foot ulceration, which increases amputation risk¹. There is no current guidance for the treatment of concurrent diabetic foot ulcers and lower limb oedema, leading to uncertainty around the safety and efficacy of combination approaches incorporating offloading and compression therapies.

A scoping review was undertaken to map the evidence relating to off-loading and compression therapy strategies to treat both diabetic foot ulcers and lower limb oedema in combination; To determine indications and contraindications for such strategies and identify any other supplementary treatment approaches.

Methods Following the Joanna Briggs Institute (JBI) and PRISMA – ScR guidance, this review included published and unpublished literature from inception to April 2022. Two reviewers independently screened, extracted and mapped the data.

Results (see table 1)

Conclusions Most literature, focused on oedema management with compression therapy and agreed that compression therapy should be avoided in the presence of severe peripheral arterial disease. Less literature was found regarding off-loading strategies, but it was recommended that knee-high casts and walkers should be used with caution, when off-loading diabetic foot ulcers in those with lower limb oedema. Treatment options to manage both conditions concurrently, was identified as a research gap. Integrated working was the supplementary strategy most frequently recommended. As yet, no studies have been undertaken to evidence this further.

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Table 1. Summary of key results from searching, screening and literature mapping.

Searching and screening results.			
Total number of records found:		522	
Total no of records:		Included	51
		Excluded	471
Key Strategies identified and frequency in literature.		Sources of evidence.	
Compression therapy.	26 (51%)	Randomised controlled trial	2
Multi-layer bandaging	11	Prospective cohort study	1
Compression hosiery/wrap devices	10	Scoping review	1
Pneumatic compression devices	5	Case study	4
		Foundational sources*	18
Off-loading.	13 (25%)	Retrospective cohort study	1
Removable walking cast/boot	6	Case study	3
Total contact cast	5	Foundational sources*	9
Other devices	2		
Compression therapy and off-loading in combination.	3 (6%)	Case study	3
Supplementary strategies.	9 (18%)	National guidance documents	2
Integrated working	5	Observational study	1
Wound/limb triage tools	2	Case study	3
Patient specific care plans	2	Foundational sources*	3

* Foundational sources include: Clinical audit & reviews, best practice statements, literature reviews, expert opinion pieces, conference abstracts, medical industry information.

P08.3-4

Cost-effectiveness of TLC-NOSF dressing in the management of DFUS worldwide: an overview analysis

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Aims Diabetic foot ulcers (DFUs) are challenging wounds associated with delayed healing, high risk of infection and lower-limb amputation; and so, very high treatment costs.

TLC-NOSF dressing has proven its significant efficacy from a randomized, double-blind clinical trial, when compared with neutral dressings. Authors will report the results of the economic impact of using TLC-NOSF dressing in Europe, Asia and North America.

Methods In Europe, the studies involved a Markov-model cost-effectiveness design. From the study endpoint of 20 weeks, extrapolation to a base-case time horizon of 1 year was adopted in the UK and French models and 100 weeks for Germany. Deterministic and probabilistic sensitivity analyses were conducted to assess the robustness of the model parameters. In China and Canada, independent studies involving a Markov-model were conducted respectively on 10 000 and 1000 patients.

Results The NICE Guidance has recently supported the use of TLC-NOSF in the DFU treatment and reported an average annual cost-saving of £342 per patient in the UK; this treatment is also highly cost-effective in Germany (€3,767 cost savings) and in France (€3,345). The main cost driver was the time to heal. Furthermore, earlier the use of TLC-NOSF dressing, higher are efficacy and cost savings. In Canada, compared to conventional dressings, adding TLC-NOSF dressings resulted in an expected \$5,878 decrease in health care costs over 5 years.

Conclusions TLC-NOSF dressing compared with neutral dressings is the dominant treatment strategy in the management of DFUs, resulting in significant annual cost savings in European, Asian and North American Healthcare systems.

P08.4-1

Tissue Matrix Metalloproteinase-1 (MMP-1) Expression In Delayed Healing Of Neuropathic Diabetic Foot Ulcers

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Background/Aim: Matrix Metalloproteinases (MMPs) play a vital role in wound healing. Variability of Matrix Metalloproteinase-1 (MMP-1) in the serum or wound fluid was suggested to be responsible for delayed wound healing. The aim of this study is to assess immunoreactivity of tissue MMP-1 in relation to histopathological analysis in delayed healing of neuropathic diabetic foot ulcers (DFU).

Methods: This cross-section study involved twenty-one diabetic patients with neuropathic foot ulcers that did not achieve 50% reduction of ulcer surface area after 4 weeks of standard therapy (sharp debridement and proper offloading). Infected and Ischemic ulcers were excluded. After debridement two biopsies were taken one from the base and the other from the edge of the ulcer for histopathological analysis by an expert pathologist. Analysis included: cellularity (Fibroblast and macrophage), vascular proliferation, inflammation, and collagen. Assessment of immunoreactivity of MMP-1 was expressed as: 0: No staining, 1: Mild staining, 2: Moderate staining, 3: Strong staining

Results: MMP-1 was only expressed in the base of 6 (33.3%) and in the edge of 11 (52.4%) of the ulcers and most of the cases showed only mild staining (6,9 cases for the base and edge respectively). No case had strong staining. There was a statistically significant negative correlation between the ulcer surface area and tissue MMP-1 expression in ulcer base of studied cases ($r=-0.506$, $p=0.02$). Pathological assessment revealed only moderate cellularity (25-100 cells/ HPF) in both ulcer base and edge (85, 52% respectively). Vascular proliferation was mainly moderate (71, 52% in ulcer base and edge respectively). Absence of inflammatory cells in 38,76% of ulcer base and edge (respectively) with low prevalence in the remaining ulcers. Mature collagen was predominant at the base and edge of ulcers (85,100% respectively).

Conclusion: Lack of expression of tissue MMP-1 is linked to a delay in healing of diabetic foot ulcer. The delay was associated high level of mature collagen, decreased cellularity and inflammation. With recent experimental trials for MMP-1 application for wound healing, this result justifies more trials for treatment DFU with MMP-1.

P08.4-2

There is no blood for improvement: anemia cuts down healing chances in diabetic foot patients

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Aim - Anemia is considered a marker of severity of diabetes and diabetic foot (DF) but is still controversial if it can be taken as a predictor of negative outcomes in these patients. Our study aimed to evaluate if anemia could be associated with a reduction of healing chances in patients admitted for DF.

Methods - We retrospectively analysed all patients admitted in our Department in 2021 for DF, dividing them in two groups according to presence (Group A) or absence (Group B) of anemia, diagnosed on reduced level of both total Hemoglobin (HB) and red blood cells (RBC). We compared group for clinical, demographic characteristics, blood chemistry, procedures and clinical outcomes: healing rate (HR) and time (HT).

Results - We derived data of 196 patients: 116 patients in Group A [59.2%; age 70.9±10.8 yrs; male/female 74.1/25.9%; DM1/DM2 7.3/92.7%; Hba1c 57.2±18.5mmol/mol; diabetes duration (DD) 20.2±12.1 yrs] and 80 in Group B (40.8%; age 68.4±10.9 yrs; male/female 62.5/37.5%; DM1/DM2 10.3/89.7%; Hba1c 60.8±16.2mmol/mol; DD 16.6±11.8 yrs). Group A presented higher ($p<0.05$) male prevalence and shorter disease duration but no differences in comorbidities, and surgical or vascular procedures. Group A showed a lower healing rate (55.6% vs 77.5%, $p=0.0028$) with no differences in healing time (109±86 days vs 115±93 days, $p=ns$). In Cox logistic regression analysis only anemia negatively affected healing (HR 2.8, CI 95% 1.4-5.4, $p=0.0037$).

Conclusions - Anemia is associated to a reduction in healing chances in DF patients and represents an independent predictor of healing failure.

P08.4-3

Cold plasma treatment in a low-income country; a case series

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Aim: In low-income countries providing a good standard of wound care can be a challenge, especially at St. Maarten in the Caribbean. Lack of funds, resources and materials, capacity of qualified wound care providers and limited health education to the population are the reasons that chronic wounds presented at a local wound care clinic are far worse compared to wounds in the US or Western Europe. While the need for advanced therapies is high, these are hardly available due to financial restrictions. This case series describes the results of offering an innovative advanced wound therapy using cold atmospheric plasma to this population.

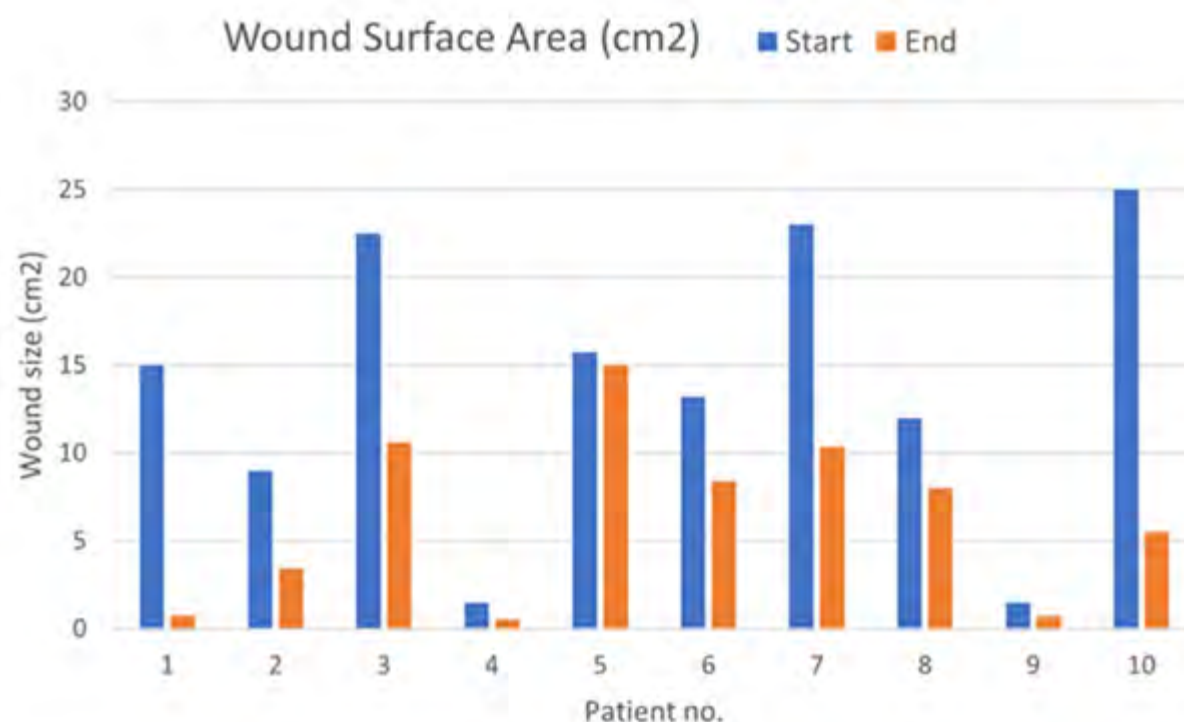
Methods: Cold plasma has proven to have a positive impact on wound healing by stimulation of cell migration and cell proliferation, improvement of microcirculation and inactivation of a broad spectrum of microorganisms, even if antibiotic resistant or in a biofilm.

10 Patients with non-healing diabetic foot ulcers, existing for a long time (> 1 year) participated in the study. Cultures were taken after debridement; most wounds were moderate to severely infected.

Cold plasma treatment was added to the regular standard of care that was given. Patients were treated twice a week for max. 4 weeks. Average number of plasma treatments was 5.

Results: After 4 weeks all wounds showed a significant reduction in wound surface (avg 65%) despite the long existence.

Conclusions: Adding innovative advanced technology can make a difference, even in a non-best practice environment. Especially when resources are limited, it is worth going the extra mile.



Wound surface area at start and end of treatment.

P08.4-4

Treatment of diabetic foot ulcers using high power radiofrequency technology with a c-boot device.

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Introduction: It is known that the application of Radiofrequency in wounds, improves vascularization and oxygenation of tissues, it has also been shown to increase the Epidermal and Vascular Growth Factors. It is known to be a safe and well tolerated treatment by the patient. In order to know the effect of this treatment on the Diabetic Foot Ulcers, this study was carried out, incorporating a C-Boot, designed to apply the radiofrequency treatment with a C 100 CAPENERGY for application in the foot ulcers.

Methodology: Four patients were treated with one or several ulcers where 10 minutes of capacitive electrode treatment was first applied in the area of the ulcer at a power of 50% of that delivered by the team. Then it was applied 20 minutes using the C-Boot with active and passive plate. The treatment was applied once a week. Ecosonography was performed to evaluate subcutaneous edema and a Visual Analogue Pain Scale.

Results: All patients noticed a decrease in the symptoms of edema and a decrease in pain from the first weeks, at the end of the treatment the ulcers were closed, improving the quality of life of these patients.

Conclusions: The application of Tecarterapia with the use of C-Boot has proven to be an effective treatment for the treatment of ulcer in the Diabetic Foot.

Diabetic Foot.jpg (could not be inserted)

Evolution of diabetic foot ulcer after RF treatment

P08.5-1

Impact of COVID-19 pandemic on diabetic foot ulcer healing time: A retrospective study between 2018-2022 (up to September)

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Background: It's well known that diabetic foot ulcer (DFU) is as significant medical condition that can lead to limb loss among diabetic population but it's generally assumed that regular and appropriate DFU management can reduce its burden. However, the high volume of DFU among Saudi diabetic population along with challenging times amid corona virus pandemic restrictions, limited appropriate wound care access restrictions might affect our DFU interventions. We sought then, to measure the impact of corona virus pandemic on our DFU healing outcomes.

Research Method and Design: At University Diabetes Center, we did assess 481 DFU healed patients data for neurological, vascular, dermatological, and biomechanical evaluation prior to our standard wound management protocol which are mainly, debridement, appropriate dressing, antibiotic therapy if required and adequate offloading if necessary with education.

Results: The table shows the result of our healing outcomes:

Year	Healing Rate	Healing Time
2018	82.72%	8.57 weeks
2019	81.49%	12.33 weeks
2020	82%	15.57 weeks
2021	83.75%	10.4 weeks
2022 (up to September)	82.41%	11 weeks

Conclusion: Corona virus pandemic didn't affect our wound healing rate outcomes but in contrary it did delay our healing times significantly due to access restrictions to DFU care amid COVID-19.

P08.5-2

The effect of antibiotic therapy on gut microbiome in patients with infected diabetic foot ulcers – DFIATIM study

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Human microbiome is often connected with obesity and inflammatory diseases and is influenced by factors such as race, gender, age, dietary intake, and medication (mainly antibiotics), method of delivery and whether the individual was breast-fed.

Aim: The aim of our study was to determine whether factors such as antibiotic therapy and body mass index (BMI) could qualitatively and quantitatively affect the gut microbiome. And finally, we detected percentage taxonomical composition of gut microbiome.

Methods: Twenty-five patients with diabetic foot ulcers, who underwent intravenously injected antibiotic therapy (ceftazidime or amoxicillin/clavulanic acid) were included in the study. Patients were born naturally and were breastfed, their diet was rational, and they were divided according to BMI into 5 groups: normal weight (number of stool samples = 3), overweight (n=19), 1stdegree obesity (n=22), 2nddegree obesity (n=12), 3rddegree obesity (n=2). Bacterial community structure in the fecal samples of diabetic patients was qualitatively and quantitatively examined for species richness, evenness, and phylogenetic diversity before antibiotic treatment (W0), after 1 week (W1) and after 10 weeks (W10) of antibiotic administration.

Results: Within groups W0, W1 and W10, we did not observed any significant differences in alfa diversity ($p>0.05$). On the other hand statistical analysis revealed significant differences between the samples after 1 week of treatment and the samples after 10 weeks of treatment ($p=0.049$). The species richness and evenness were significantly lower in the group of patients with normal weight, compared to the overweight patients, 1stdegree obesity and 2nddegree obesity patients. Also, the 1st degree obesity patients had significantly higher species richness and evenness compared to the patient with 2nddegree obesity ($p<0.05$). Besides, the phylogenetic diversity was significantly lower in the group of patients with normal weight, compared to the overweight patients, 1stdegree obesity and 2nddegree obesity patients ($p<0.05$). A total of 9 phyla were detected in the fecal samples including Firmicutes, Bacteroidota and Proteobacteria.

Conclusion: Our study showed significant differences of gut microbiota between the samples after 1 week of treatment and the samples after 10 weeks of treatment. These data were influenced also by BMI of study subjects.

P08.5-3

Timolol for diabetic foot ulcers: A randomized controlled pilot study

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Aims To evaluate the efficacy and safety of topical application of timolol in treating diabetic foot ulcers (DFUs) through a randomized controlled pilot study.

Methods According to the inclusion and exclusion criteria, patients with DFUs who attended at the diabetic foot care center of West China Hospital from January 2021 to July 2022 were included and randomly divided into the control group and the timolol group. Standard treatment was applied in the control group, and the timolol group was given 0.5% timolol maleate on the basis of standard treatment. Treatment was performed every other day in each group, and the ulcer area and healing rate were calculated before each treatment. The ulcer healing time was recorded when the ulcer was covered by the new epithelium completely. The adverse reactions were closely observed and recorded during the treatment.

Results 16 DFUs patients were included in this study, including 8 in the control group and 8 in the timolol group. Two patients withdrew after twice treatments, and the number of patients included in the final analysis in each group was 7. There were no statistical differences in baseline data between the control group and the timolol group (all $P > 0.05$). The ulcer healing rates on the D6, D12 and D18 after treatment in the timolol groups were $41.62 \pm 10.00\%$, $72.61 \pm 14.41\%$ and $93.76 \pm 6.04\%$ respectively, which were higher than those of the control group at the same time points ($40.40 \pm 6.80\%$, $64.22 \pm 10.49\%$ and $83.11 \pm 9.44\%$), but the differences were not statistically significant ($P = 0.804$; $P = 0.292$; $P = 0.078$). The healing time of the cured ulcers in the timolol group (41.50 ± 20.88 days) was shorter than that in the control group (58.50 ± 25.66 days), while the difference was not statistically significant ($P = 0.237$). During the treatment, no serious local or systemic adverse reactions occurred in both groups.

Conclusions Topical application of timolol in DFUs showed a trend of promoting ulcer healing, which did not reach statistical difference possibly due to the small sample size. It is necessary to further increase the sample size to confirm this.

P08.6-1

Benefits of Sucrose octasulfate dressings as first-line intention treatment, when part of SoC in patients with DFUs

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Background: Diabetic foot ulcers (DFUs) are frequent, characterised by delayed wound healing, high risk of infection, amputation and financial burden. Alongside with appropriate metabolic control, offloading, debridement and infection control measures, UrgoStart dressings are recommended by the National Institute for Health and Care Excellence (NICE) guidance to treat DFUs.

Aim: A service evaluation was conducted to assess the implementation of UrgoStart dressings as a first-line local treatment and integral part of usual standard of care for the local treatment of DFUs.

Methods: All patients presenting to our podiatric clinic over an 8-week period with a non-infected DFU were treated with the UrgoStart dressings range (Laboratoires Urgo). Primary outcome included wound closure rate by week 20.

Results: 23 patients with a DFU have been included (May to July 2021). Most wounds were seen for the first time and had just occurred (78% lasting for 1 week or less). By the final visit, wound closure was achieved in 16 patients (70%), with 81% of these closures occurring by the sixth week of treatment. A subgroup analysis showed that 85% of neuropathic DFU and 50% of the patients with peripheral arterial disease (PAD) healed after a median treatment period of 24 days and 43 days, respectively. During the study period, wound infections were reported in five patients (22%).

Conclusion: These results are consistent with previous clinical evidence, underlining the benefits of using TLC-NOSF dressings as a first-line local treatment and integral part of usual standard of care to treat DFUs since their onset.

P08.6-2

ScRNA-seq Reveals Long-Term Effects of ADM on Skin Cell Heterogeneity and Cellular Communication in Mouse Chronic Wound Window

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Acellular dermal matrix (ADM) could improve the wound healing. However, mechanisms for ADM impacting this highly coordinated and complex cascade of processes needs more details, including the cellular communications between epithelial and none-epithelial cells. We established a chronic wound window model, monitored the long-term effects of ADM on this wound, and acquired the tissue cells in the wound area at day 28 post wound introduction (28-PWI) for single cell RNA sequencing (ScRNA-seq) to explore the multiple functions of ADM during wound healing. We identified seven major skin cell types and nine epithelial subpopulations. ADM changed the skin cell homeostasis by increasing epithelial cells and decreasing immune cells. It activated the differentiation of epithelial stem cell (ESC) and hair follicle stem cell (HFSC) therefore altered the epithelial cell homeostasis. Coordinately both GO and KEGG pathway analysis revealed that ADM upregulated the genes related to keratinization, epidermal cell differentiation and epidermis development. On the contrary, ADM downregulated the inflammatory pathways, which was evidenced by the cell-cell communication between epithelial subpopulations and macrophages. In addition, ADM elevated the infiltrating macrophages and decreased the resident macrophages. The infiltrating macrophages were enriched with some well-known M2 macrophages markers. Hence we concluded that long-term ADM treatment significantly improved wound healing through activating skin stem cell differentiation and M1/M2 polarization, therefore finally changed the epithelial cell and macrophage homeostasis; cell-cell communication among the epithelial subpopulations and macrophages through inflammatory pathways were inhibited, which might play a critical role to benefit the re-epithelialization during wound healing.

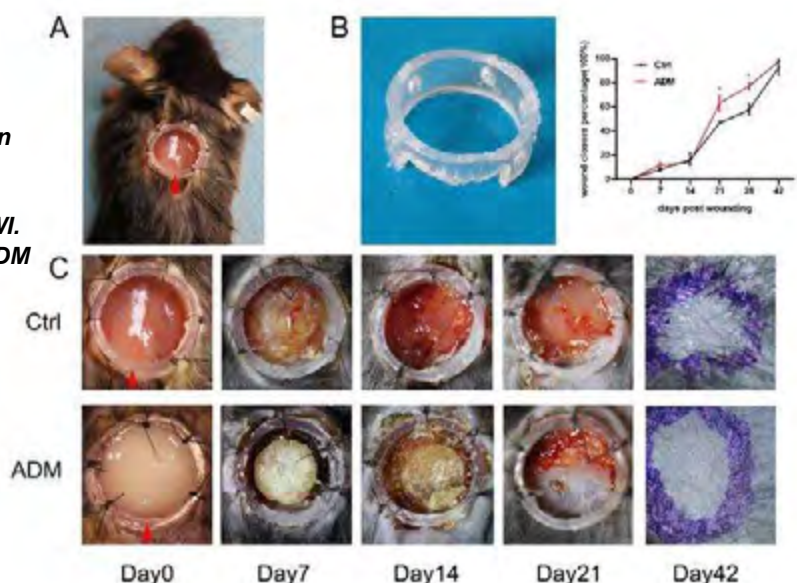
ADM Improves the Chronic Wound Healing

(A) Mouse model with dorsal wound window.

(B) A cylindrical silica frame applied in the model.

(C) Mouse models from day 0 post wound (0-PWI) induction till 42-PWI.

(D) Statistical analysis of effects of ADM on wound closure percentage.



P08.6-3

Use of oleic matrix – based gel releasing reactive oxygen species (ROS) in post-surgical tunneling diabetic foot wounds

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Aim: Postoperative wounds may arise from several etiologies including open partial pedal amputation, postoperative infection, and dehiscence of surgical sites from wound failure or patient compliance issues. If negative pressure wound therapy is the gold standard, its application in the toes area could be challenging as a consequence standard care is most likely used. Reactive oxygen species are a key part of the normal wound-healing process and we evaluate the use of a new oxygen-enriched oil-based product (gROS) in this kind of ulcers.

Method: A total of 22 diabetic patients with tunnelling post-surgical dehiscence of the foot (TUC IIA or IIIA) comprised the study population. Patients were randomised in two groups as follows: group 1 patients were treated with (gROS) and group 2 patients were treated with standard therapy. Primary outcome is healing rate. Secondary outcomes are new infections and side effects.

Results / Discussion: After 16 weeks wound closure occurred in 9 patients (75%) in group 1 and 4 (33%) in group 2 ($p=0,04$). New infections affected 2 patients (17%) in group 1 and 7 patients (58%) in group 2 ($p=0,05$) and, of these, six patients (50%) needed a new surgical debridement. No severe side effects were reported in group 1 and only in 1 patient (8%) perilesional maceration was observed. In standard therapy frequency of dressing was twice a week and in gROS once a week, reducing costs related to nursing time and hospital visits, responsible of 80-85% of the total cost.

Conclusion: Oleic matrix – based gel releasing Reactive Oxygen Species promising to be effective, safe and efficient in tunnelling post-surgical dehiscence in diabetic foot.

P08.6-4

Skin invisible damage and Wnt/ β -catenin signaling pathways changes induced by diabetes

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Aim: This work aimed to compare morphological differences and changes in Wnt/ β -catenin signaling pathways of non-injured skin and granulation tissues between non-diabetic and diabetic pigs.

Methods: The tissue used for this study was extracted from diabetic pigs induced by streptozotocin and non-diabetic pigs. After establishing the diabetic status, circular full-thickness skin samples from buttocks, and granulation tissues in the wound center 12 days after trauma were harvested for subsequent analysis of alterations (thickness of epidermis and dermis, collagen expression, microvascular density, and expression of Wnt/ β -catenin signaling pathways) caused by diabetes.

Results: Our results demonstrated that diabetes could lead to a thinner epidermis and dermis and less collagen expression in non-injured skin compared to non-diabetic pigs, but there was no significant difference in microvascular density between the two groups. In addition, collagen expression and vascular density in granulation tissues were lower in diabetic pigs. In the non-injured skin and granulation tissues of diabetic pigs, the relative mRNA or protein levels of Wnt3a, β -catenin, Fzd6, DVL1, CyclinD1, and c-Myc were significantly lower than those in non-diabetic pigs, except for higher Axin2.

Conclusion: Changes in non-injured skin and granulation tissues caused by diabetes might be related to suppressed Wnt/ β -catenin signaling pathways in diabetic pigs.

P08.6-5

Pathological and bacterial characteristics of preserved bone stump in patients with diabetic foot osteomyelitis and its effect on wound healing.

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¹Department of Diabetic Foot, Chu Hsien-I Memorial Hospital, Tianjin Medical University, Tianjin, China

Aim: After surgical treatment of diabetic foot osteomyelitis (DFO), the pathology and bacterial status of the “normal” of bone stump are of great significance the prognosis of foot wound, but there are few studies and there is urgent clinical need.

Methods: 49 inpatients with DFO from 2021.1 to 2021.12 were collected, all of whom had osteomyelitis of phalanges and metatarsal, underwent conservative surgery. After the surgical removal of necrotic bone, the material was taken from the “normal” metatarsal stump. The bones were cultured, did antibiotics susceptibility test and pathology. Analyzing the pathological and bacterial characteristics of preserved “normal” bone stump and its effect on wound healing.

Results: The agreement rate between deep soft tissue culture results and infected bone culture was only 27.1%. The pathology of infected bone was consistent with culture at 87.5%. The infected bone were mainly gram-negative bacteria (81.4%). *Acinetobacter baumannii* (8) and *Pseudomonas aeruginosa* (8) tied for the first, and the third was *Proteus mirabilis* (7). Only 9 cases bone stump were without osteomyelitis (18.4%). There were 20 cases of double positive, 17 cases only pathological positive, and 3 cases only culture positive. The bacteria in the bone stump were also dominated by gram-negative bacteria (78.2%). *Acinetobacter baumannii* (5) and *Pseudomonas aeruginosa* (5) tied for first, then *Enterococcus faecalis*, *Enterococcus avium* and *Proteus mirabilis* (each 3). Bacteria in bone stump was 91.3% consistent with that in infected bone, but reducing the variety of bacteria. The wound healing time of patients with ABI ≥ 0.7 was not affected by whether the bone stump was positive or not, but the negative bone stump of patients with ABI < 0.7 was shorter than that of the corresponding positive patient (40 ± 10 days vs 51 ± 9 days, $p < 0.05$). Antibiotic should cover soft and bone tissue bacteria and required multiple debridement even minor amputation. One of the 49 patients died, and the remaining 48 patients eventually wound healing without major amputation.

Conclusion: Although most of the “normal” residual bone has been invaded by bacteria, the stump can be preserved and the wound eventually be healed.

P09.2-1

Patient reported outcomes from a pilot trial of REDUCE: a complex psychological and behavioural intervention targeting ulcer recurrence and healing

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Background: REDUCE is a complex intervention targeting psychological and behavioural factors associated with ulcer recurrence and healing. REDUCE consists of eight 1:1 sessions with trained health care professionals, delivered remotely, and access to an ongoing package of online and offline maintenance support. Here we describe patient reported outcomes (PROMs) from a pilot trial of REDUCE.

Methods: Parallel, randomised controlled pilot trial. 20 participants with a recently healed diabetic foot ulcer were randomised (2:1) to receive REDUCE plus usual care or usual care alone. A range of validated PROMs were collected at baseline, 6 weeks and 3 months including foot care behaviours (NAFF), illness beliefs (B-IQQ, CBRQ), psychological health (GAD-7, PHQ-9, SPANE-P), social isolation (SPS) and physical activity (IPAQ-E-SF).

Results: All 20 participants completed PROMs at baseline, 16 returned questionnaires at 6 weeks (80%) and 15 at 3 months (75%). Descriptive summaries indicate those receiving usual care alone showed relatively stable PROMs scores across all time points. Participants randomised to REDUCE showed beneficial changes in some PROMs at 6 weeks, such as better foot care behaviours [NAFF: M=55.5 (8.1) to M=62.6 (6.3)] and reduced negative illness beliefs [e.g., CBRQ-Fear Avoidance: M=11.7 (4.5) to M=9.3 (6.0)], which were broadly maintained, but slightly attenuated at 3 months. There was little evidence of change for some other PROMs (e.g., social isolation).

These pilot trial results indicate acceptable levels of PROMs completion, in line with pre-trial expectations. Early signals from these PROMs suggest REDUCE is influencing some behavioural and psychological factors associated with ulcer recurrence and healing in the expected directions, albeit only tentative conclusions can be drawn from this pilot study. A definitive trial is now underway.

Funded by National Institute for Health Research Programme Grant for Applied Research Reference: RP-PG-0618-20001

P09.2-2

Assessment of cognitive function, health literacy and selfcare in adults with diabetic foot ulcers: An explorative case-series study.

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Background/Aim It remains unknown whether difficulties with health literacy and potential declined cognitive function affect the capability to recall and comply with the foot-self-care recommendations among adults with DFU. One way of getting insights into a population's knowledge, myths, attitudes, beliefs, and behaviors related to a specific health-related topic is to use combined knowledge, attitude, and practice examinations. The aim of this study was to investigate the cognitive function, knowledge-, attitude- and practice of foot self-care among people with an active diabetes foot ulcer.

Methods Twelve participants were recruited for the present study. Cognitive function was assessed using Addenbrooke's Cognitive Examination and health literacy using the European Health Literacy Survey Questionnaire. A semi-structured interview guide was developed to evaluate the participant's knowledge, attitude, and foot self-care practice. The qualitative data was analyzed with a deductive approach based on Thematic Analysis described by Braun & Clarke.

Results The participants were evenly distributed between the three cognitive scoring categories (normal n=4, inclusive n=4, and abnormal n=4). Fluency and memory were the two domains' the participants had the most errors. The qualitative findings represent the following themes: Knowledge, Attitude, and Behavior. The findings refer to the participants' understanding of diabetes and its relation to diabetic foot ulcer. It also provides insight into the participants' feelings toward diabetic foot ulcer and their thoughts about their self-image. The findings illustrate how the participants demonstrate their knowledge and attitude through their foot self-care practices. There was no clear pattern between the cognitive and health literacy scores. Some participants with low cognitive scores had good knowledge, while the opposite was also observed.

Conclusions The present study indicates that some persons with diabetes and an active DFU are well informed regarding DM foot self-care, whereas others are not. The combined methods revealed that a low cognitive score did not necessarily translate into poor KAP towards DM foot self-care. Further investigation into how to target and educate people with DM individually is warranted.

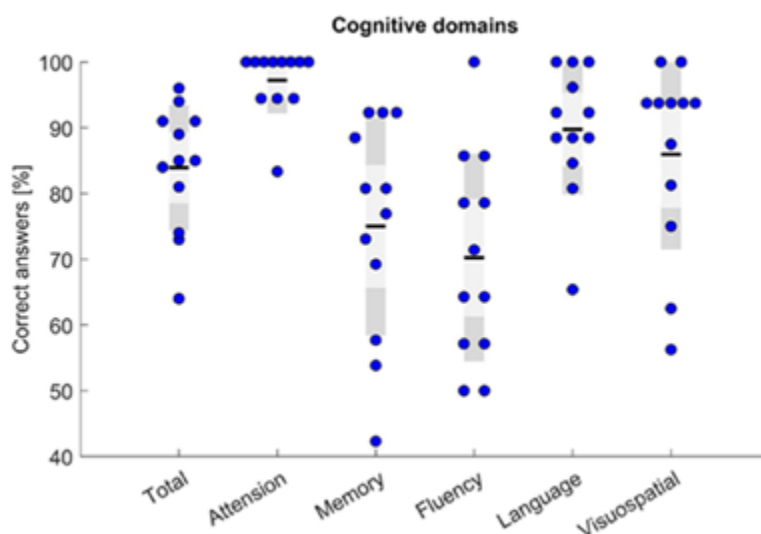


Fig 2 Cognitive domains

P09.2-3

Long-term effect of motivational interviewing on adherence to wearing orthopaedic shoes in people with diabetes: a multicentre cluster-randomized controlled trial

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Background/aim: Adherence to wearing orthopaedic shoes is a known problem in people with diabetes. Interventions to improve footwear adherence are needed. Motivational interviewing (MI) has been suggested, but never tested beyond pilot studies. The aim of this randomized controlled trial was to evaluate the effectiveness of MI performed by a MI-trained podiatrist, in improving adherence to wearing orthopaedic shoes in people with diabetes at low-to-high risk of ulceration.

Methods: People with diabetes type 1 and 2 with either loss of protective sensation or peripheral artery disease and prescribed with orthopaedic shoes were included. Participants in the intervention group received usual care plus MI-conversation. Wearing time was continuously measured using a temperature microsensor inside the footwear. Participants wore a wrist activity tracker for seven consecutive days at 3 months and 6 months after microsensor placement. Adherence was determined as the percentage of steps taken while wearing the footwear. Participants were considered adherent when $\geq 80\%$ of steps were taken in their orthopaedic shoes. Analysis of the proportion participants adhered to wearing their orthopaedic shoes used chi-square tests and differences in adherence percentages used independent T-tests.

Results: 121 participants were included, whereof 4 (3.3%) had International Working Group on the Diabetic Foot (IWGDF) risk 1, 44 (36.4%) had IWGDF risk 2, and 73 (60.3%) IWGDF had risk 3 (mean (SD) age: 68.5 (8.3) years; females: n=38; type 2 diabetes: n=109). 68 were allocated to the control group and 53 to the intervention group. Percentage adherent in the control group was higher than in the intervention group at 3 months (30.9% (21/68) versus 15.1% (8/53); $P=0.044$), and at 6 months (22.1% (15/68) versus 13.2% (7/53); $P=0.210$). Mean adherence percentage was also higher in the control group than in the intervention group at 3 months (60.9% versus 50.9%; $P=0.029$), and at 6 months (59.9% versus 49.5%; $P=0.025$).

Conclusions: The current implementation of MI did not result in higher adherence to wearing orthopaedic shoes in comparison to usual care in people with diabetes at low-to-high risk of ulceration.

Acknowledgements: This trial was funded by ZonMw (the Netherlands Organization for Health Research and Development, project no. 8530001101).

P09.2-4

Patient beliefs after minor amputation, an explorative qualitative study

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Background: Although the term ‘minor’ amputation refers to the removal of ‘only’ a small part of the body, this amputation may have a significant impact on patient’s well-being.

Aim: to explore patients emotional impact when they underwent a minor amputation.

Methods: research design: a qualitative study with semi-structured interviews. Population: all patients who underwent a minor foot amputation between 2022 – 2023 in a secondary referral hospital in the Netherlands.

Results: Twenty patients were interviewed, eighteen of whom had diabetes mellitus. The majority of patients were men (90 %). Most patients reported that they did not expected/anticipated that they needed an amputation (n 18= 90 %). The main reactions were anxiety of the unknown “what will be next?” In addition, patients frequently underestimated the severity of their (diabetic) foot problems and anticipated no healing problems at all. Several patients report that physicians underestimated the psychological impact of being told to need a toe amputation. For most patients religion was not a factor of influence regarding their attitude towards a toe amputation.

Conclusions: Patients experience different thoughts and feelings about minor amputations. Physicians knowledge about the psychological impact of minor amputation must be updated/better aligned with the patient (perspective), subsequently physicians should be trained to give patient education tailored to patients’ needs.

P09.2-5

Sharing experiences of patients with diabetic foot ulcers through emotional mapping; a single centre United Kingdom experience

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Diabetic foot ulceration (DFU) is challenging to manage and necessitates a well-coordinated multi-disciplinary approach to improve outcomes. However, patients' often experience poor coordination and continuity in their care, ultimately leading to poorer health outcomes. We aimed to consider the patients' perspectives of their care and identify aspects of the healthcare system that can be improved to create a more user-friendly and accessible service.

Semi-structured interviews were conducted with patients who had a history of DFU and healthcare professionals (HCPs) working in diabetic foot services. We explored patient experiences of accessing diabetic footcare in community and hospital-based settings, which we termed service 'touchpoints', using an emotional mapping exercise. Emotional maps were co-created with each participant to capture the positive and negative experiences and emotions associated with navigating these 'touchpoints' along their health journey. The interviews were analysed using an inductive approach to thematic analysis.

Nineteen patients (5 female, mean age 59.6) and seven HCPs were interviewed. Key themes identified from patients included that they judged the quality of footcare based on the "friendliness" of HCPs, that social support heavily impacted emotional wellbeing and that DFU education was inadequate. Key themes identified from HCPs were that language barriers and cognitive impairment acted as significant barriers to effective information comprehension, and that some patients disregarded medical advice. We observed, that as patients moved along 'touchpoints' within the diabetic foot service towards more specialist care, the number of positive experiences and emotions increased, whilst their negative experiences and emotions decreased. Patients emphasised the attention and expertise they felt in specialist care.

The communication style of HCPs and the HCP-patient relationship are key factors in how patients perceive the quality of their care. More attention needs to be directed to identifying patients who need additional educational or social support to detect those more vulnerable to direct DFU complications as well as the potential social and emotional consequences of this condition. Particular focus on improving the experiences of patients in the community through patient-led support groups and better access to primary care will considerably impact overall patient emotional and physical wellbeing.

P09.2-6

Validation of the Flemish-Dutch diabetic foot ulcer scale short form (DFS-SF) questionnaire for diabetic foot ulcers

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Background/Aims: Diabetic foot ulcers (DFU) negatively affect the quality of life (QoL) of people with diabetes. The DFU Scale Short Form (DFS-SF) is a validated disease-specific patient-reported outcome measure (PROM) for measuring health-related quality of life among DFU patients. It consists of 29 items in 6 subscales: leisure, physical health, dependence/daily life, negative emotions, worried about ulcers and bothered by ulcer care. This study aimed to validate the DFS-SF questionnaire for Flemish Dutch-speaking patients with DFU in Belgium.

Methods: This observational cohort study included 100 patients with DFU from the multidisciplinary diabetic foot clinic of Onze-Lieve-Vrouw Hospital Aalst, Belgium. DFS-SF items were reverse-coded so that high DFS-SF scores indicate better quality of life. Reliability was assessed through the test-retest reliability (intraclass correlation coefficient (ICC)), internal consistency (Cronbach's alpha) and measurement error (agreement). Spearman's correlations and known-group comparisons were conducted to examine construct validity. Correlation with EQ-5D-5L was used to test criterion validity. The full study protocol has been published earlier (Rezaie et al. 2019. doi:10.1136/bmjopen-2019-034491).

Results: The majority of the patients were men (71.1%), with a mean age of 67.7±10.3 years and mean diabetes duration of 20.1±12.5 years. 81 patients (83.5%) had type 2 diabetes. Ischemia was present in 31.7% of the patients, neuropathy in 88.5%. Most DFU were deep (93.2%) and showed signs of infection (60.6%). ICC of the different DFS-SF subscales ranged from 0.36 to 0.84. Cronbach's alpha was between 0.70 and 0.92 for all subscales. Agreement varied between 2.83 and 14.52. A ceiling effect was observed in the subscales leisure, dependence/daily life, negative emotions and bothered by ulcer care. None of the 6 predefined hypotheses to determine the construct validity was confirmed. The different DFS-SF subscales showed a moderate to strong correlation with the EQ-5D-5L index value. The DFS-SF subscales were not sensitive to ulcer changes over time.

Conclusions: The psychometric properties of the Flemish-Dutch version of the DFS-SF questionnaire were not confirmed nor showed a good sensitivity to ulcer changes in our patient population. The disease-specific DFS-SF provided no relevant additional information on quality of life beyond the general EQ-5D-5L.

P09.3-1

Patients and healthcare professionals experiences of digital foot examination versus traditional foot examination– a randomised controlled study

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Background: Digital solutions in healthcare can facilitate and improve care. However, the experiences and usefulness of using either digital foot examination or traditional foot examination needed to be evaluated.

The aims of the study were to evaluate:

- 1) differences of patient's experiences, being foot examined supported by the use Clinical Decision Support System (CDSS) as compared with being foot examined in traditional practise,
- 2) how healthcare professionals (HCP), by using the CDSS, experienced the routine as compared to make the foot examination as in traditional practise.

Methods Out of a total of 141 patient, 100 patients with diabetes, was single-blind digital randomized, to one of two parallel arms: being foot examined of HCP using a clinical decision support (CDSS) (n=47) or to be foot examined as in traditional practice (n=53) at the department of prosthetics and orthotics (DPO) at Sahlgrenska University Hospital, Gothenburg, Sweden. Patients filled in a modified version of the National Patient Survey (NPS) and the Orthotic and Prosthetics User's Survey (OPUS) at study end. Two HCP, working at a the DPO answered surveys regarding the interaction between patient and the CPO.

Results: Patients, 65±14 years, perceived a high level of satisfaction with the service at the department regardless method used. No significant differences between groups were found evaluated with 27 questions in the NPS, nor the OPUS (scores 67.17±12.18 vs. 66.35 ±16.52 (p= 0.78)) for the intervention and control group respectively. Hundred percent of the patients were risk classified in the intervention group as vs, 2%, in the control group.

Conclusions: Patients perceived a high level of satisfaction with the services at the DPO regardless method used for the foot examination. All patients were risk classified in the intervention group. The HCP experienced that by using the CDSS the foot examination was structured and followed clinical guidelines. Furthermore, the documentation in the electrical health record was thoroughly, however further improvements, e.g., integration with co-existing health record systems was requested. Supported by CDSS, that are useful for HCP, can improve care and facilitate the implementation of national clinical guidelines, thereby improving the prevention and care of DFU

P09.3-2

Sensor controlled diabetic foot ulcer therapy enhances wound closure significantly – a randomized controlled trial

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Aim: We developed a complex, e-health integrating approach to optimize offloading diabetic foot ulcers (DFU) in order to preserve mobility and accelerate ulcer closure. We monitored pressure, temperature, humidity, and steps; used smartwatch and web applications to alert patients and their therapists when pressure limits exceeded. We selectively offloaded DFU using customized, non-removable offloading soles made of felt or felt plus fibreglass or a total contact cast. Patients should not limit the number of steps. To our knowledge, the effects of sensors on time to DFU closure are published for the first time.

Methods: In a randomized, controlled, multicentre trial, patients with diabetic plantar pressure ulcers who used the entire system were compared to a control group without information provided to patients and staff. Patients were asked to walk as much as they usually did before pressure ulcer onset. If necessary, PAD had to have been previously corrected and the ulcer surgically debrided.

Results: 20 patients participated in the study (12 intervention, 8 control). 3 had to be excluded because they did not use the system within the first 2 weeks (2 intervention, 1 control). 15 of 80 intervals between visits showed worsening, significantly less in the intervention group (4/42 vs. 11/38, $p = 0.026$). Median time to ulcer closure was reduced (232 to 40.5 days, $p=0.03$). The individual average of steps per day (mean 2,146, SD 1,427) corresponded to independent living and normal activity for many patients. Observed optimizations were related to offloading devices at the time of initial application and later after dressing changes, and behavioural changes of patients responding to alarms.

Conclusions: Integration of optimized offloading devices, sensor control, and alerts for patients and staff enabled rapid closure of plantar foot ulcers without limiting the number of steps by optimizing medical staff performance and improving patient's health-related behaviours.

P09.3-3

Evaluation of the effectiveness of remote foot temperature monitoring for prevention of amputation in a large integrated healthcare system

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Background/Aim: This study aimed to evaluate the effectiveness of remote foot temperature monitoring (RTM) in a large, national healthcare system in terms of lower extremity amputation (LEA), all-cause hospitalization, and death.

Methods: We conducted a matched retrospective cohort study including patients receiving care from the United States Department of Veterans Affairs healthcare system. Patients were considered eligible if they were at high risk for ulceration and amputation (i.e., due to history of a recent diabetic foot ulcer, LEA, osteomyelitis, or Charcot foot) and did not have any of the exclusion criteria. RTM involved home use of a SmartMat and notification if temperature asymmetries exceeded 2.2°C over two consecutive scans. Eligible patients enrolled in RTM between 2019 and 2021 were matched up to 3:1 to non-RTM patients. Follow-up was through August 2021. We used conditional Cox regression (with death as a competing event) to account for matched data and estimate unadjusted and adjusted cause-specific hazard ratios (HR) and corresponding 95% confidence intervals (CI) for LEA (primary outcome) and all-cause hospitalization and death (secondary outcomes).

Results: The study included 924 patients enrolled in RTM and a comparison group of 2757 non-RTM patients. Almost all (>98%) patients were over 50 years of age, with nearly half were between 70 and 79 years, 16% were Black, and 76% were white. After adjusting for covariates (race, hemoglobin A1c, osteomyelitis, Charcot foot, kidney disease, Gagne comorbidity index, drive time to specialty care, and emergency room/urgent care visits), RTM was not inversely associated with LEA incidence (adjusted HR= 0.92, 95% CI 0.62-1.37) or all-cause hospitalization (adjusted HR = 0.97, 95% CI 0.82-1.14), but was inversely associated with death (adjusted HR=0.63, 95% CI 0.49-0.82).

Conclusions: This study does not provide support that RTM reduced the risk of LEA or all-cause hospitalization in individuals with a history of diabetic foot ulcer, though risk of death was reduced. Randomized controlled trials can overcome important limitations, help identify those most likely to benefit, and detect gaps in implementation that can be filled to improve effectiveness.

Acknowledgements: This work was supported by funding from Department of Veterans Affairs (CIN 13-402).

P09.3-4

Assessing equity in the uptake of remote foot temperature monitoring in a large integrated US healthcare system

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Background/Aim: The objective of this study was to assess equity in the uptake of remote foot temperature monitoring (RTM) in the United States Department of Veterans Health Affairs (VHA), including comparisons across facilities and between patients enrolled and eligible patients not enrolled in RTM.

Methods: Using national electronic medical records, we measured demographic, geographic, clinical, and utilization characteristics prior to baseline among 1066 patients enrolled in RTM and 45,228 non-enrolled eligible patients. To assess whether there was equitable use of RTM across facilities, we compared characteristics of facilities based on the number of patients enrolled in RTM (e.g., no RTM use, and low, moderate, and high RTM use). To evaluate the association of patient characteristics with enrollment, we fit a logistic regression model including only patients from facilities using RTM.

Results: RTM use increased substantially from 2019 to 2021 (from 84 patients in the first 7.5-month period to 202, 463, and 317 in the final period); growth was concentrated in a few high-volume facilities. High-volume RTM facilities had higher complexity and a lower ratio of patients per podiatrist but did not have consistent evidence of better footcare process measures. Fewer than 1 in 25 (3.7%) eligible patients at facilities where at least one patient enrolled in RTM were enrolled in RTM. Furthermore, at these facilities, being aged 80+ years (vs. 70-79), Black race (vs. white), low income, living far from specialty care, and in the highest quartiles of telehealth use prior to enrollment was inversely associated with enrollment. Enrollment was positively associated with having osteomyelitis, Charcot foot, a partial foot amputation, BMI>30 kg/m², and high outpatient utilization.

Conclusions: RTM growth was concentrated in a small number of higher-resourced facilities, and there was evidence of lower use among those who were Black and lived farther from specialty care. Future studies are needed to identify and address barriers to RTM use by smaller, less-resourced facilities as well as facilities with a high proportion of Black and rural patients to prevent exacerbating existing ulceration and amputation disparities.

Acknowledgements: This work was supported in part by funding from Department of Veterans Affairs (CIN 13-402).

P09.3-5

Plantar Foot Assessment Using Liquid Crystal Thermography

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Background/aim. Thermography can be a powerful tool to monitor foot health. In particular in the area of diabetes research suggests that frequent thermographic assessment may be able to detect and prevent potentially deadly complications such as those arising from diabetic foot ulcers [1].

Method. This contribution introduces a device for professional use that is based on the well established liquid crystal technology within the workflow of clinical examination protocols for over 40 years [2]. A second version of the device is introduced that satisfies the need for frequent assessment at home. In contrast to thermal camera based approaches this device is usable daily by patients themselves without the constraints of the strict examination protocols that are usually required for such examinations [3]. Relaxing protocol constraints means that assessments based on absolute temperatures cannot be used because some parameters under which the thermograms are taken are variable, unknown or not repeatable. The authors therefore suggest a set of measures based on relative temperatures and thermal patterns that are assumed to be more resilient to such variable conditions. Amongst these are contralateral symmetry [4], thermal patterns [5] and hot spots.

Results. Using case studies as examples this contribution examines the advantages and disadvantages of the proposed measures. The examples demonstrate that thermographic thermal mapping of the foot can help clinicians to educate their patients and to improve compliance. The technology is suitable for detecting a range of foot conditions and in many cases helps to prevent further deterioration by aiding treatment decisions and consecutive monitoring. The technology used makes the assessment process repeatable. The ability of the devices to send all data to a central server for remote inspection enables a community based approach to patient care, although the logistical challenges and the need for semi-automated data interpretation that are associated with this approach remain largely unresolved.

Conclusion. The liquid crystal based thermography devices introduced in this contribution have demonstrated high utility and effectiveness in use by patients at home and in clinic. Challenges remain in the areas of data interpretation and organising deployment.

P09.3-6

Infrared thermometry as a diagnostic tool in the discernment of diabetic foot infection

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Background Diabetic foot infection is a cause of significant morbidity and is associated with the need for lower extremity amputation. The diagnosis of infection is a clinical one and the classical signs of infection are often absent in those with DM due to concomitant immunopathy (Glaudemans et al 2015).

Methods We utilised the FLIR E6 infrared camera to assist in the clinical diagnosis of foot infections across 20 patients with suspected signs of infection in order to confirm diagnosis and guide therapy. In those where the diagnosis of clinical infection was not clear, we utilised infra-red thermometry to aid in the clinical diagnosis. We utilised a 2.2°C temperature difference between feet in order to aid the clinical decision making. When the diagnosis was still unclear we referred onwards for inflammatory marker testing.

Results We found that the use of infrared thermometry was a good clinical aid in those who did not have overt signs of infection. In (n=17) patients no further need for assessment of systemic inflammatory markers was required to confirm or refute the clinical diagnosis. By utilising this point of care test we were able to reduce the number of patients referred for blood tests to confirm or refute diagnosis.

Conclusion The use of infrared thermometry is a useful diagnostic aid for the presence of DFI in those where the clinical diagnosis is uncertain reducing the need for further testing of inflammatory biomarkers.



Infrared image showing increased temperature

P09.4-1

Sharing experiences of patients with diabetes related foot disease through emotional mapping

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Background: Diabetes affects 4.6 million people in the United Kingdom (UK) and up to a quarter of these will develop diabetic foot ulcers (DFU). DFUs are associated with a poor quality of life and high rates of amputation.

DFUs are managed by multi-disciplinary teams including healthcare professionals (HCPs) such as podiatrists. Patients with DFUs can experience poor coordination and continuity in their care ultimately leading to poorer health outcomes. Considering patients' experiences when improving aspects of the healthcare system creates a more user-friendly and accessible service.

Methods: The aim of this study was to gain a better understanding of the experience of patients navigating diabetic foot services through an emotional mapping exercise. This established methodology allows us to capture positive and negative experiences and emotions at various 'touchpoints' within the healthcare service along a patient's personal health journey.

Semi-structured interviews were conducted with DFU patients and HCPs. Emotional maps were completed with patients. The interviews were analysed using an inductive approach to thematic analysis.

Results: 19 patients and 7 HCPs were interviewed. Key themes identified from patients included that they judged the quality of foot care according to the friendliness of HCPs, social support heavily impacted emotional wellbeing and DFU education was inadequate. Key themes identified from HCPs included that language barriers and cognitive impairment form the largest obstacles to effective information comprehension and patients disregard medical advice.

Discussion: HCPs must work alongside patients with DFUs to overcome barriers to effective care by focusing on health literacy. Better DFU education will considerably impact overall patient emotional and physical wellbeing.

Conclusion: The approach of DFU services to patient education should be improved, and strategies to improve patients' adherence to medical advice should be implemented. These recommendations can help redirect HCPs attitudes and DFU education for better patient outcomes.

P09.4-2

The impact of at-home foot temperature monitoring for ulcer prevention on quality of life: longitudinal results from the DIATEMP study

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Background The DIATEMP trial showed that daily at-home foot temperature monitoring is cost-effective over usual care in preventing recurrent foot ulcers, but at the cost of reduced health-related quality of life (HRQoL). We aimed to investigate this negative impact on HRQoL.

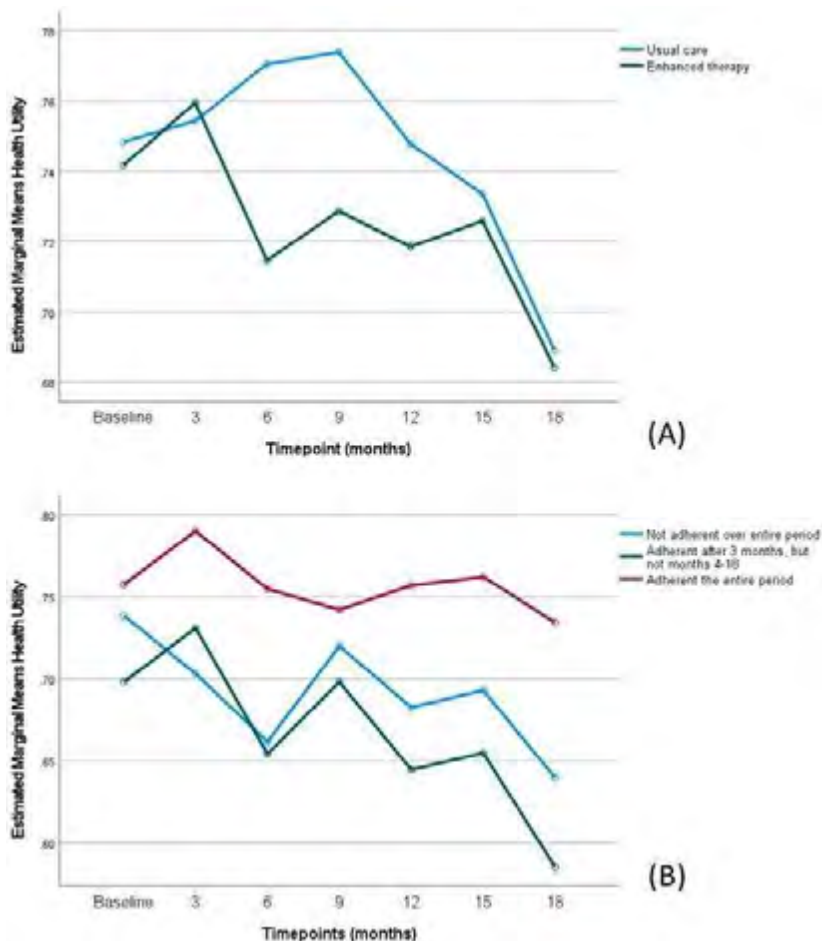
Methods DIATEMP enrolled 304 participants, 151 randomly assigned to enhanced therapy (daily at-home foot temperature monitoring) and 153 to usual care. Participants completed the HRQoL-questionnaire EQ-5D-3L at baseline and every 3 months during the study. Health utilities associated with the EQ-5D-3L scores were determined to calculate quality-adjusted life years (QALY). Patterns of change in health utilities were analysed using mixed-model repeated measured ANOVAs. Factors associated with QALY in the enhanced therapy group were investigated with multiple regression.

Results A significant drop in health utilities after 3 months was found for enhanced therapy compared to usual care ($p < 0.01$, Fig.1A). Health utility patterns differed according to participant adherence to temperature monitoring, with the largest drops for those who first adhered and then quit self-monitoring (Fig.1B). In enhanced therapy group, use of a walking aid ($p < 0.001$) and smoking ($p = 0.03$) were associated with lower QALY, and also showed a drop in health utilities after 3 months.

Conclusions There is a significant drop in HRQoL after 3 months of undertaking daily at-home foot temperature monitoring, especially in people who first adhere and then stop self-monitoring. Clinicians should carefully consider the benefits and harms of recommending temperature monitoring.

Acknowledgements Funding bodies: ZonMw, NVvP, ProVoet

Figure 1: The pattern of change for health utilities according to group allocation for $n=304$ (A); and for those in the enhanced therapy group according to levels of adherence (B).



P09.4-3

Gender differences in quality of life in a group of patients diagnosed with diabetes

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Background/aim To be diagnosed with diabetes is a profound change in life. Daily life is changed as for instance dietary adaptations, regular control of blood glucose and self-care of the feet. Little is known of how Quality of Life (QoL) differs over a longer time-period between women and men living with diabetes. The aim was to evaluate differences in QoL between groups of women and men living with diabetes.

Methods Patients were recruited from the waiting list from the Department of Prosthetics and Orthotics at Sahlgrenska University Hospital, Gothenburg. At baseline 114 patients with diabetes were included, 61 men and 53 women. Inclusion criteria were diabetes, over 18 years of age; ability to walk independently and to understand Swedish language. Exclusion criteria were foot ulcers.

SF-36 was used to measure self-perceived QoL at 6 scheduled appointments. At baseline and at every 6 months until 24 months were reached. In addition, a further follow-up was carried out after another 10 years. For statistical calculations, Mann Whitney U test was used to analyse differences of QoL for the two groups respectively at baseline, 24 month and at 10 years follow-up.

Results At baseline there was no statistically significant difference between men and women regarding QoL. At the 24 months follow-up there was a difference in the domain body pain where women scored significantly lower: women: median=62 (range 41 to 84), and men: 79 (range 62 to 100), $p=0.049$. At the 10-year follow-up there was no statistically significant difference of QoL.

Conclusions Women scored lower QoL in the domain pain at 24 months follow-up. However, the results should be interpreted with caution as the results have not been adjusted for multiple comparisons nor being analysed regarding other factors that might influence QoL, such as age. In future studies, it is recommended to investigate a) if pain is more often present in groups of women living with diabetes as compared with groups of men, b) details regarding localisation and reasons for pain, c) how other factors such as type of diabetes, diabetes duration, age, BMI, and comorbidities impact on QoL.

Figure caption

Gender differences in quality of life in a group of patients diagnosed with diabetes

P09.4-4

Validation of the Flemish-Dutch Lower Extremity Functional Scale (LEFS) questionnaire for diabetic foot ulcers

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Background/Aims: Diabetic foot ulcers (DFU) negatively affect the quality of life (QoL) of people with diabetes. The Lower Extremity Functional Scale (LEFS) is a patient-reported outcome measure (PROM) for measuring physical functioning in patients with lower extremity disorders. It consists of 20 items and can distinguish between pain and function. To date, the LEFS is not yet validated for assessing functional impairment of foot and ankle in diabetic foot conditions. This study aimed to validate the LEFS questionnaire for Flemish Dutch-speaking patients with DFU in Belgium.

Methods: This observational cohort study included 100 patients with DFU from the multidisciplinary diabetic foot clinic of Onze-Lieve-Vrouw Hospital Aalst, Belgium. Reliability was assessed through the test-retest reliability (intraclass correlation coefficient (ICC)), internal consistency (Cronbach's alpha) and measurement error (agreement). Spearman's correlations and known-group comparisons were conducted to examine construct validity. Correlation with EQ-5D-5L was used to test criterion validity. The full study protocol has been published earlier (Rezaie et al. 2019. doi:10.1136/bmjopen-2019-034491).

Results: The majority of the patients were men (71.1%), with a mean age of 67.7±10.3 years and mean diabetes duration of 20.1±12.5 years. 81 patients (83.5%) had type 2 diabetes. Ischemia was present in 31.7% of the patients, neuropathy in 88.5%. Most DFU were deep (93.2%) and showed signs of infection (60.6%). ICC of the LEFS questionnaire was 0.85 (95% CI 0.75-0.91). Cronbach's alpha equaled 0.95. Agreement was 4.55. No floor or ceiling effect was observed. Only 1 of the 6 predefined hypotheses to determine the construct validity of LEFS was confirmed (17%). The LEFS score showed a strong correlation with the EQ-5D-5L index value ($p<0.0001$) and a moderate correlation with the EQ-5D-5L visual analytical scale ($p<0.0001$). The LEFS score was not sensitive to ulcer changes over time.

Conclusions: The Flemish-Dutch version of the LEFS questionnaire has good reliability properties and criterion validity could be confirmed. However, the construct validity was not optimal and the scale was not sensitive to ulcer change during follow-up in our patient population. The LEFS provided only minor relevant additional information on quality of life beyond the general EQ-5D-5L.

P09.4-5

User perceptions of innovative shoes designed to improve comfort: older adults with and without type II diabetes

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Background: Perceptions surrounding shoe designs can help inform considerations to promote adherence to proper shoe wear in older adults with type II diabetes.[1-3] This study compared perceptions of a novel shoe design in older adults with type II diabetes to those without type II diabetes.[4]

Methods: Participants were asked to wear the shoes for 6 weeks. At 6 weeks, they completed a 15-item questionnaire based on the Technology Acceptance Model (TAM) with a 5-point Likert scale from "strongly agree" to "strongly disagree," along with open-ended questions. [5] Chi-Squared tests were performed to compare TAM ratings of older adults with and without type II diabetes.

Results: 29 older adults with self-reported foot pain participated (11 with type II diabetes, age 64.8 ± 7.6 years, 38.5% male; 18 without type II diabetes, age 67.4 ± 2.3 years, 22.2% male). Older adults with type II diabetes, compared to those without, reported: their back, hip, knee, and ankle joints hurt less ($p=0.043$), they would recommend the shoes to a friend ($p=0.034$), the shoes were easy to take on and off ($p=0.012$), the shoes were comfortable to wear ($p=0.042$), and the shoes caused them to trip more ($p=0.043$). Comments of older adults with type II diabetes included shoe heaviness, decreased foot pain, and increased muscle strength and support compared to their everyday shoes.

Conclusions: Perceptions of the innovative shoes tended to be more favorable in older adults with type II diabetes, except reporting the shoes caused them to trip more. Potential explanations for this include comments on perceived weight of the shoes or neuropathy. Future research can examine influences of design considerations, such as perceived shoe weight, on promoting adherence to proper shoe wear in this population.

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Acknowledgements: Thanks to Josh White and Ron Bar for providing the shoes.

P09.5-1

Infrared thermography for monitoring the severity and treatment of diabetic foot infections

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Background / Aim: Monitoring of the severity of diabetic foot infections (DFIs) is largely based on clinical assessment, which is limited by moderate reliability. A potential aid for monitoring the severity of DFIs is infrared thermography. Using infrared thermography, increased temperatures can be assessed as markers of tissue inflammation. Infrared thermography devices have been studied for the monitoring of the severity of DFIs before, showing no additional benefit. However, an advanced thermography setup that enables simultaneous temperature measurements of the entire plantar surfaces of patients' feet has not been investigated for this purpose before. We conducted a prospective study to explore the monitoring of thermal asymmetry (difference between mean plantar temperature of the affected and unaffected foot) for the assessment of severity of DFIs during in-hospital treatment.

Methods: We prospectively investigated patients who were hospitalized due to moderate or severe DFIs (International Working Group on the Diabetic Foot infection-grades 3 or 4). In these patients, we measured thermal asymmetry with an advanced infrared thermography setup during the first four to five days of in-hospital treatment. Besides measuring thermal asymmetry, we performed clinical assessments and tests of serum inflammatory markers (white blood cell counts and C-reactive protein levels). We assessed the change in thermal asymmetry from baseline to final assessment, and investigated its association with infection-grades and serum inflammatory markers.

Results: In seven patients, thermal asymmetry decreased from median 1.8°C [range: -0.6-8.4] at baseline to 1.5°C [range: -0.1-5.1] at final assessment ($p=0.625$) (Figure 1). In three patients who improved to infection-grade 2, thermal asymmetry at baseline (median 1.6°C [range: -0.6-1.6]) and final assessment (1.5°C [range: 0.4-5.1]) remained similar ($p=0.285$). In four patients who did not improve to infection-grade 2, thermal asymmetry decreased from median 4.3°C [range: 1.8-8.4] to 1.9°C [range: -0.1-4.4] ($p=0.197$). No correlations were found between thermal asymmetry and infection-grades, ($r=-0.347$; $p=0.445$), C-reactive protein levels ($r=0.321$; $p=0.482$) or white blood cell counts ($r=-0.250$; $p=0.589$) during the first four to five days of in-hospital treatment.

Conclusions: Based on these explorative findings, infrared thermography seems to have limited value for monitoring of the severity of DFIs during in-hospital treatment.

P09.5-2

Evaluation and Longitudinal Tracking of Wound Infections with a novel Autofluorescence Imaging Device and Comparison with Metagenome Sequencing

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Aim To evaluate the accuracy and efficacy of a novel multispectral imaging device for bioburden assessment, longitudinal tracking and to correlate bacterial bioburden levels with metagenome sequencing.

Method In the present approved clinical study, we assessed clinical efficacy and accuracy of this novel device in diabetic foot ulcer patients. Wounds post-debridement were imaged using this device and the report, containing spatially mapped regions of bacterial burden along with their bacterial gram type was compared with the results obtained using 16S rRNA metagenome sequencing of the patient samples. In addition, few patients are also tracked longitudinally to assess the changes in bacterial bioburden with treatment.

Results A total of 157 patients' wounds were imaged, and the colour-coded regions (Gram Positive/ Gram Negative infected) were identified by the machine learning algorithm. A guided tissue biopsy was performed and 26 patient samples were sent for both culture test and 16S rRNA metagenome sequencing. Of these, cultures were positive in 17 cases and correlated with the major species identified through 16S rRNA results in 16 cases. However, culture test missed detection of major species in 5 cases. Interestingly, this device could detect the presence of bacteria in 4 of these 5 cases as confirmed by 16S rRNA results (using 50 reads as a cut-off) and thus is a more sensitive method. This device can be used as an adjunct tool for assessing and monitoring diabetic wounds' bacterial burden over time.

Conclusions This novel device, is a first of its kind multispectral autofluorescence imaging device to detect and track bacterial bioburden in wounds rapidly (< 2minutes) and effectively.

P09.5-3

Compliance with remote foot temperature monitoring for prevention of amputation in a large integrated healthcare system

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Background/Aim: Remote foot temperature monitoring (RTM) devices have great potential to prevent re-ulceration and amputation through early detection of problems. Technologies like this may help to reduce disparities by race and rurality. However, failure to use the device as intended may limit potential benefits. Thus, the aim of this study was to assess the extent to which sociodemographic, clinical, and behavioral characteristics, and access to care are associated with non-compliance with RTM.

Methods: We conducted a cohort study including patients receiving care from the United States Department of Veterans Affairs healthcare system who were enrolled in RTM with a thermometric SmartMat. Non-compliance was defined as using the device <2 times per week during at least 75% of the months of follow-up (maximum of 12 months). We obtained data on average weekly SmartMat use for patients enrolled in RTM between January 2019 and August 2021. Sociodemographic characteristics, clinical diagnoses and procedures, behavioral factors, and utilization were obtained from electronic health records. We fit a logistic regression model to evaluate associations via odds ratios (ORs) between patient characteristics with RTM non-compliance.

Results: The study included 1138 patients enrolled in RTM, of whom >98% were men and >50 years of age, 73% were white, 20% were Black, and 25% were rural/highly rural. Overall, 38% of the population was non-compliant. In a multivariable model, poor blood glucose control (hemoglobin A1c >10 vs. <5.7, OR=2.5, 95% CI 1.2-5.3) and current (OR=1.91, 95% CI 1.24, 2.96) vs. never smoking were associated with non-compliance as was high overall comorbidity burden as measured by the Gagne comorbidity index (>4 vs. ≤0, OR=1.9, 95% CI 1.2, 2.9). Neither race nor rurality were statistically significantly associated with non-compliance.

Conclusions: This study contributes to our understanding of factors independently associated with non-compliance and suggests that those who struggle to manage blood sugar or to quit smoking or who have a high comorbidity burden may need additional support to use the SmartMat as directed.

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P09.5-4

Smart Offloading for Diabetic Foot Ulcers: Defining the Adherence with Offloading Boots using Smart Sensor

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Background/Aim: Diabetic Foot Ulcers (DFU) remain one of the most serious and most morbid outcomes of diabetes. Offloading devices have been shown to have the most effectiveness for healing of DFU. To provide consistent adherence for successful healing, non-removable offloading devices are accepted as the gold standard. However, these devices are not generally used as intended by the patients due to the discomfort caused by irremovability¹. To overcome this limitation, removable offloading boots are offered as a compromise. But, since they are removable, their compliance needs to be monitored carefully. Recent literature suggests that using the removable boot for 7 hours a day or 80% of daytime demonstrates high compliance with the boot. However, this definition does not include the measurement of patient's activity, the number of steps taken while the boot on/off and the consistency of boot use.

Methods: To determine the impact of activity and number of the steps on healing, boot on/off time, activity/resting time with/without boot, total number of steps, number of steps taken with/without boot were collected from 15 participants using a device² integrated on the boot, providing Inertial Measurement Unit (IMU) capabilities. By analyzing these data, the number of steps taken per hour was calculated and boot use adherence was determined.

Results: We noticed that the participants who wore their boot less than 7 hours also tended to be less active and more consistent. On the other hand, participants who wore the boot more than 7 hours were more active but more inconsistent. (Shown in the table, one week data from two participants) Therefore, our preliminary results suggest that the duration of wear time is not enough itself to determine the level of adherence.

Pt1 (not adherent)		Pt2 (adherent)	
# steps/h	Bon	# steps/h	Bon
532.99	6.03	203.05	0.97
491.46	3.86	117.87	6.84
704.82	10.94	113.47	11.09
1,907.42	3.53	91.32	12.07
516.83	1.96	72.51	9.46
677.22	9.81	336.02	5.03
929.56	4.63	0.00	0.00
29,249.33	0.19	289.36	3.89

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²Sensoria Health. 2022. Sensoria Core.

P09.5-5

The use of Infrared thermometry in the identification of diabetic foot ulceration

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Purpose Research has shown that using thermometry in those with a history of diabetic foot ulceration (DFU) can reduce the rates of recurrent DFU. This study considered whether thermometry can identify early tissue damage and inform clinical practice.

Methods In this prospective observational study temperature measurements using the Flir E6 Infra-red camera were taken from 216 individuals attending outpatient diabetes clinics in a large urban teaching hospital in Ireland as part of a comprehensive diabetic foot assessment. Measurements were taken at foot sites associated with ulceration namely the plantar hallux, the 1st and 5th plantar metatarsal heads and the heel. Those identified at increased risk at baseline using a standard assessment received repeat temperature measurement on 2 subsequent occasions in the following week. The rate of ulceration was subsequently recorded.

Results Of the 216 participants, 4% (n=9) developed ulceration within 7 days. All of these had been identified at high risk at baseline assessment and had a history of foot disease. A temperature differential of ≥ 2.2 degrees between sites of interest was recorded. Temperature ranges varied from 29.1 degrees Celsius to 37.6 degrees Celsius. High temperature was considered if over 35 degrees Celsius.

Temperature	DFU	No DFU	
Low (<30)			
Normal (30.0-34.9)			
High (≥ 35)	0		
2 (22%)			
7 (78%)	21 (10%)		
111 (54%)			
75 (36%)			

	Temperature >2.2	Temperature >2.2	p-value
Baseline, n=216			
Any location	5(56)	45(23)	0.041
Plantar Hallux	4 (67%)	16(9%)	0.001
1st MTPJ	4(44)	20(11)	0.018
5th MTPJ	2(29)	17(10)	0.158
Heel	1(13)	16(9)	0.539
Follow-up 1, n=54			
Any location	6(67)	10(24)	0.020
Plantar Hallux	3(60)	2(6)	0.011
1st MTPJ	2(33)	2(6)	0.091
5th MTPJ	4(44)	4(11)	0.033
Heel	1(14)	5(14)	0.999
Follow-up 2, n=47			
Any location	5(63)	11(29)	0.105
Plantar Hallux	3(75)	4(13)	0.018
1st MTPJ	4(67)	6(17)	0.024
5th MTPJ	3(43)	4(13)	0.094
Heel	0	4(11)	0.517

Conclusion Initial analysis suggests that neither the 35 degree Celsius threshold nor a 2.2 degree Celsius temperature difference is indicative of inevitable tissue damage in this population in remission from DFU. Wide variability in temperature between individuals and further investigation across larger cohorts is needed.

P09.5-6

Electrical Stimulation to Regain Lower-Extremity Muscle-Perfusion and Endurance in Patients with Post-Acute Sequelae of SARS CoV-2: A Randomized Control Trial

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Background: COVID-19 patients with previous severe illness can experience long-term symptoms of muscle-deconditioning and impaired vascular-function in the lower extremity (LE). This condition is a subset of Post-Acute Sequelae of Sars-CoV-2 (PASC) that do not have evidence-based treatment. In this double-blinded randomized control trial, we examined the efficacy of LE electrical stimulation (E-Stim) to regain muscle-perfusion and endurance in individuals with PASC experiencing LE muscle-deconditioning symptoms.

Methods: Participants were assigned to control (CG) or intervention (IG) group to self-apply daily one-hour E-Stim for 4-weeks on both gastrocnemius muscles (GNM). The device* was functional in the IG and non-functional in the CG. Changes in plantar oxyhemoglobin (Δ OxyHb) in response to E-Stim was assessed with near-infrared-spectroscopy at 0min (t0), 60min (t60), and 10min after stopping the therapy (t70). Changes in GNM-endurance (Δ GNMe) in response to E-Stim was recorded using surface electromyography at two intervals: 0–5min (Intv1), and 55–60min (Intv2). Outcomes were measured at baseline and 4-weeks.

Results: Thirty-six (IG=20, CG=16) lower extremities in 18 patients were independently assessed. Baseline OxyHb in response to one-hour E-Stim decreased at t60 (-2.44%, $p < 0.05$) and t70 in both groups (IG: -5.97%, $p = 0.021$; CG: -5.11%, $p = 0.06$). At 4-weeks, the IG's OxyHb increased at t70 (+2.35%, $p = 0.040$), whereas the CG's OxyHb decreased (-4.44%, $p < 0.001$). Normalized values to %change showed the IG's OxyHb was higher than the CG at t70 ($p = 0.014$). Additionally, baseline GNMe did not show significant changes between Intv1 and Intv2 within and between groups. At 4-weeks, the IG's GNMe had a significant increase from Intv1 to Intv2 (+0.87%, $p = 0.031$), whereas no significant change occurred in the CG ($p > 0.05$). Moreover, the IG showed a significant association between Δ GNMe and Δ OxyHb ($r = 0.628$, $p = 0.003$) at 4-weeks.

Conclusion: A 4-weeks daily one-hour self-administered E-Stim therapy may lead to recovery of muscle-perfusion and endurance in individuals with LE musculoskeletal PASC. This practical therapy may provide a potential benefit for GNM vascular improvement. A larger sample size is warranted to confirm these findings.

Acknowledgements *Tennant Biomodulator® (Avazzia Inc, TX, USA). This study was partially supported by the device manufacturer.

P09.6-1

Does quality of life differ between patients with diabetes type 1 and patients with diabetes type 2 over time?

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Background Diabetes is a rapidly growing disease that affected 537 million people worldwide in 2021 and is expected to increase according to the International Diabetes Federation (IDF). IDF states that it is crucial to evaluate the Quality of Life (QoL) for people with diabetes to increase the knowledge of how the disease and its complications impact the life of persons living with diabetes.

The aim was to evaluate if there were differences in QoL between patients with diabetes type 1 and patients with diabetes type 2 over a ten year period.

Methods Patients with diabetes (n=114) answered the Short Form Health Survey (SF-36), a self-assessment questionnaire that measures health-related QoL and consists of eight health domains. SF-36 was answered at baseline and at the follow-ups, every 6 months, until 24 months was reached. After 10 years, an additional follow-up was done. Inclusion criteria: >18 years, diagnosed diabetes without previous foot ulcers, being able to walk without walking aids and being first-time visitors at the Department of Prosthetics and Orthotics Sahlgrenska University Hospital, Gothenburg.

Results At baseline, n=31 had diabetes type 1 (T1) and n=83 had diabetes type 2 (T2).

Group T1 scored higher compared to group T2 in the domains physical functioning (PF), role functioning physical (RP) and role functioning emotional (RE) at baseline as follows: PF: T1=90 (80-100), T2=75 (65-90), $p<0.001$; RP: T1=100 (75-100), T2=75 (19-100) $p=0.004$; RE: T1=100 (100-100), T2=100 (67-100) $p=0.025$. After 24 months (n=24, 56) none of the eight domains showed any statistically significant differences. At the 10-year follow-up (n=9, 24) group T1 scored higher vs. group T2 in PF (T1= 90 (88-98), T2= 75 (65-85) $p=0.025$).

Conclusions These results show that there is a difference in self-perceived QoL for patients with diabetes type 1 vs. patients with diabetes type 2. Further research is needed to evaluate if differences in QoL exist depending on type of diabetes. A limitation is that the sample was small and only 29% of the participants participated in the 10-year follow-up.

P09.6-2

Factors related to illness perception of individuals with diabetic foot ulcers: A structural equation model

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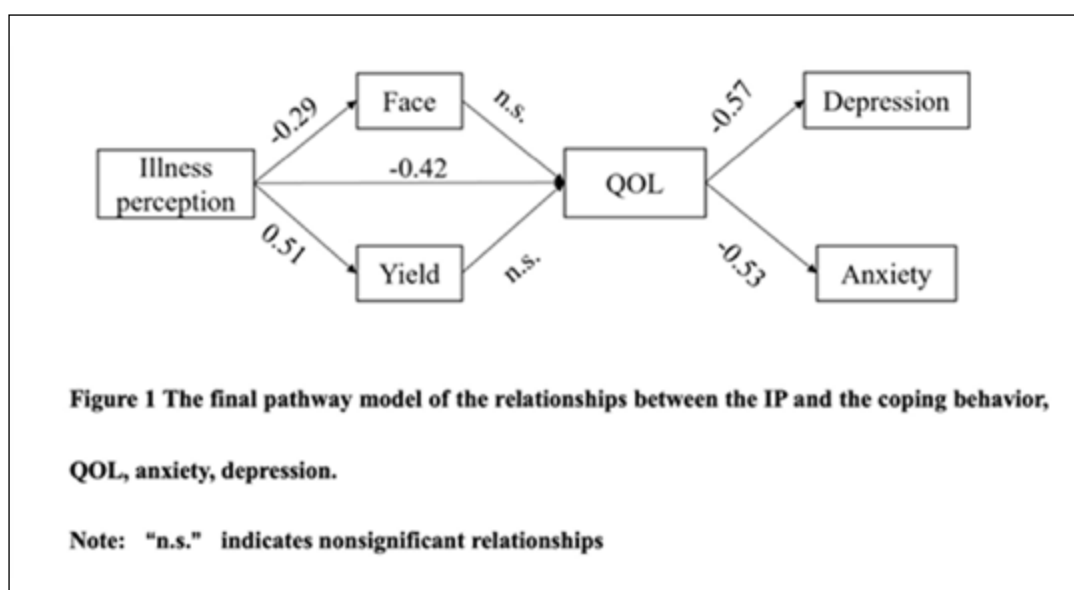
Aims and objectives: To explore the factors that correlated with illness perception and to structure an illness perception model to direct better management of patients with diabetic foot ulcers (DFUs). Background: DFUs are a common severe complication of diabetes, limiting movement, emotional distress, and quality of life. Illness perception was introduced to improve the psychological status and quality of life of patients with DFUs.

Design: This multicentered cross-sectional study followed the STROBE guidelines.

Methods: Patients with DFUs from six hospitals were recruited for the study from April 2021 to February 2022. Data collection included the general characteristics and instruments about illness perception, coping behavior, emotional status and quality of life.

Results: The final structured equation model of illness perception fit well: $\chi^2 = 7.484$ ($P > 0.05$), $\chi^2/df = 1.871$, CFI = 0.993, IFI = 0.994, RFI = 0.929, NFI = 0.986, TFI = 0.966, and RMSEA = 0.065. Illness perception was negatively related to coping behaviour ($r = -0.290$, $P < 0.01$) and quality of life ($r = -0.504$, $P < 0.01$), and it had a positive relationship with yield-coping behaviour ($r = 0.513$, $P < 0.01$), anxiety ($r = 0.470$, $P < 0.01$) and depression ($r = 0.470$, $P < 0.01$). The factors influencing illness perception in DFUs were pain, diabetes duration, quality of life, yield-coping strategy and sex ($P < 0.05$).

Conclusion: The structural equation model of the correlation between illness perception and depression, anxiety, quality of life, and coping behavior is fit well. Illness perception can be considered a predictor of quality of life, depression and anxiety.



The final pathway model of the relationships between the IP and the coping behavior, QOL, anxiety, depression.

P09.6-3

The Number of Risk Factors Predict All-Cause Mortality in Patients with Diabetic Foot Ulcer: A Retrospective Cohort Study

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Background: Patients with diabetic foot ulcer (DFU) have high risk of death. We aimed to investigate the influence of each risk factor and the number of risk factors on all-cause mortality in patients with DFU.

Methods: This was a retrospective cohort study included 1076 patients with DFU in a tertiary academic hospital between 2015 and 2022. Five risk factors were included: body mass index, blood pressure, glycated hemoglobin, total cholesterol/HDL cholesterol ratio and estimated glomerular filtration rate (eGFR). Cox regression was used to assess the risk of all-cause mortality associated with each risk-factor variable and number of risk-factor variables.

Results: A total of 127 deaths occurred during a median follow-up of 28.0 months. Patients with less favorable BMI levels of ≤ 22.2 kg/m² had higher risk of all-cause mortality than those with more favorable BMI (HR, 1.348 [95%CI, 1.001-1.817]). Patients with eGFR levels of ≤ 68.5 ml/min/1.73m² had an 86.2% higher risk of all-cause mortality than patients with higher eGFR (HR, 1.862 [95%CI, 1.399-2.479]). A dose-dependent relationship was found between the number of risk-factor variables and all-cause mortality (ptrend <0.001). Patients with 3 to 5 risk-factor variables had an HR of 1.833 (95% CI, 1.563-2.150), adjusted for age, sex and severe DFU, compared with the 0 to 1 risk-factor variable group. Restricted cubic spline analyses suggested that the higher levels of systolic blood pressure, as well as lower eGFR, were associated with higher risk of all-cause death.

Conclusions: Among patients with DFU, excess risk of death from any cause increased stepwise for a higher number of risk-factor variables. (Supported by Zhejiang Provincial Medical Science and Technology Plan, Grant 2019-M-18.)

P09.6-4

Degree of independent living after lower extremity amputation in Belgium: impact of amputation level, diabetes, age and gender

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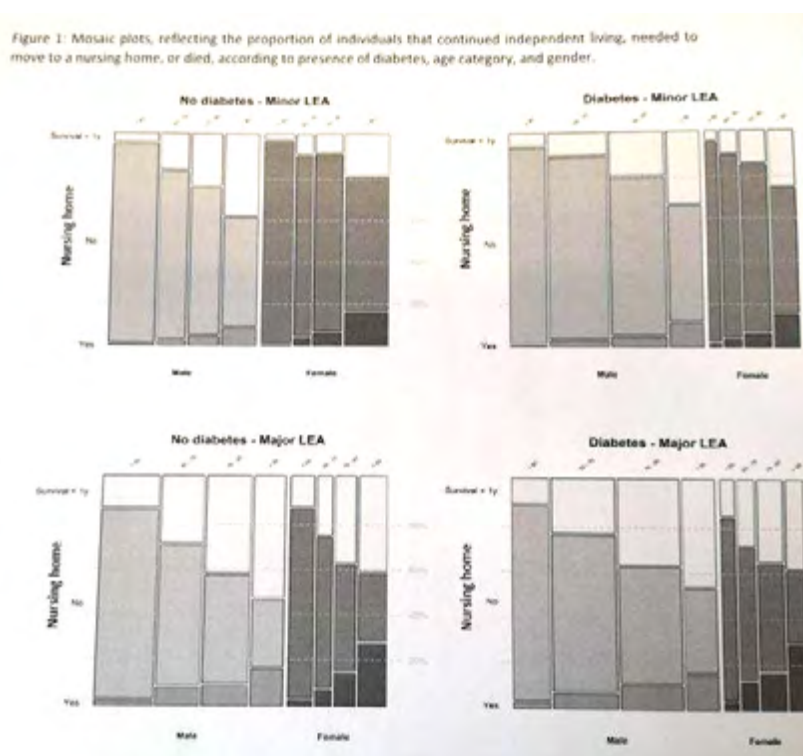
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Background/Aim. Lower extremity amputation (LEA) has a high impact on mobility, and hence (in) dependent living. Present study aimed to determine how many individuals lost the ability of independent living, and needed to move to a nursing home in the first year after LEA in Belgium.

Methods. Nationwide data including all individuals undergoing LEA from 2009 to 2018 were collected. Regression analysis determined the independent effect of amputation level, diabetes, age and gender on independent living after minor and major LEA. Patients that already lived in residential care before the LEA, were excluded.

Results. In the study period, 26 526 individuals underwent one or more LEA; 3 563 of these already lived in residential care. Another 1 652 individuals (7%) changed from independent living to living in a nursing home. The included mosaic plots (Figure 1) reflect the proportion of individuals that continued independent living, needed to move to a nursing home, or died, after minor and major LEA. Diabetes did not impact on moving to a nursing home after minor (OR 1.10, 95%CI 0.94-1.29, $p=0.22$) or major LEA (OR 1.01, 95%CI 0.86-1.18, $p=0.89$). Need for a nursing home increased with older age. Women had a significant higher risk of moving to a nursing home (OR 1.50, 95%CI 1.35-1.68, $p<0.001$), irrespective of amputation level, presence of diabetes, and age category.

Conclusions. After a LEA, the necessity to move to a nursing home is mainly related to higher age and female gender. Diabetes is not associated with a higher loss of independency.



P09.6-5

Prescription of a functional prosthesis after major lower extremity amputation in Belgium

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Background/Aim: Major lower extremity amputation (LEA) is associated with a significant loss in quality of life, at least partially related to reduced mobility. Present study aimed to determine how many individuals in Belgium were provided with a functional prosthetic limb in the first year after major LEA, in the period 2009–2018.

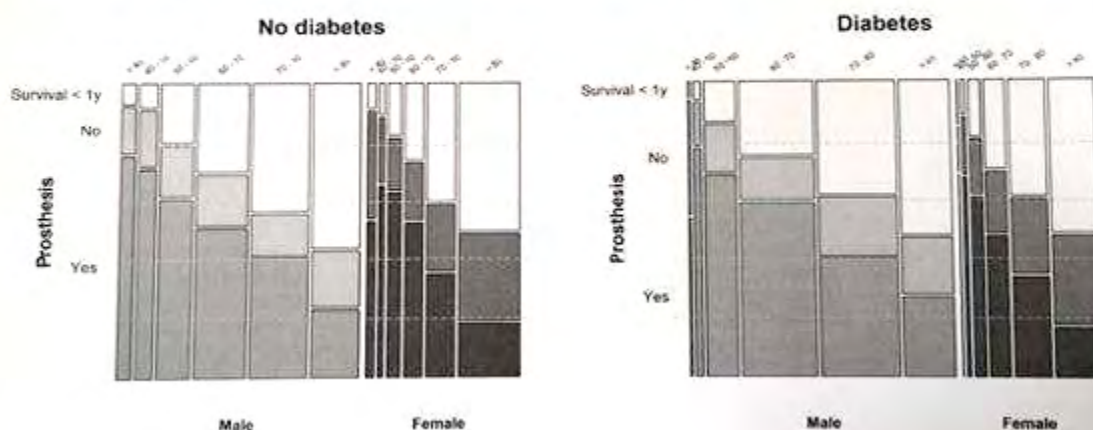
Methods. All Belgian citizens undergoing major LEA in the decade 2009-2018 were identified. Major LEA was defined as any amputation above the level of the tarsus. Prescription of a prosthetic limb intended for rehabilitation and mortality were registered one year after amputation. Logistic regression analysis determined the independent effect of diabetes, age and gender on prescription of a prosthesis.

Results. 10 474 Belgian citizens underwent major LEA (5 765 with and 4 709 without diabetes). Twelve months after major LEA, prosthetic prescription and mortality rates were very similar between individuals with and without diabetes (prosthetic prescription: 44 versus 42%; no prosthetic prescription: 21 versus 21%; mortality 36 versus 37%; diabetes versus no diabetes). Diabetes did not affect prosthesis prescription (OR 0.98, 95%CI 0.88-1.10, $p=0.78$). Prosthesis prescription diminished with older age, with especially sharply reduced prosthesis prescription rates in individuals older than 70 years. Women had significantly less prostheses prescribed compared to men (OR 0.45, 95%CI 0.27-0.74, $p=0.002$).

Conclusions. Prescription of a functional prosthesis, intended for rehabilitation, is mainly related to younger age and male gender. Diabetes does not affect prescription of a prosthesis.

Figure 1: Mosaic plots, reflecting the proportion of individuals having a functional prosthesis prescribed, not having a functional prosthesis prescribed.

or dying in the year following major LEA, according to presence of diabetes, age category, and gender.



P10.1-1

Application of one-step swine acellular dermal matrix microparticles combined with autologous microparticle skin grafting for the treatment of diabetic foot

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Objective To explore the clinical value of one-step swine acellular dermal matrix (ADM) microparticles combined with autologous microparticle skin grafting for the treatment of diabetic foot.

Methods According to the inclusion and exclusion criteria, 15 patients with good growth of granulation tissue after debridement of diabetic foot were selected. One-step swine ADM microparticles combined with autologous microparticle skin grafting were used to repair the wound. Then the wound healing time was observed, and the local tissues were taken after healing, for observing pathological sections.

Results Five patients with diabetic foot healed well, with a healing time (from the day of the one-step surgery to the complete healing of the wound) of 33-78 days, and the average days is 47. The result of the pathological examination is: the continuous tissue is visible in the tissue, indicating that the wound has healed. It can be seen that the formation of blood vessels and the proliferation of skin cells can also be seen in the outermost ADM structure.

Conclusions One-step swine ADM microparticles combined with autologous microparticle skin grafting is an effective method for the treatment of diabetic foot.



The wound healed completely 54 days after one-step operation. A shows the first day, given surgical treatment, intraoperative debridement to visible good red granulation tissue; B shows the first day, given surgical treatment, visible white type A ADM covered on the wound; C shows the 8th day, the first postoperative dressing, visible wound yellow granulation tissue; D showed that on the 13th day, the patient's wound was dry, and new and old granulation tissues were visible; E showed that on the 21st day, the wound was partially healed, and fresh granulation tissue was seen in the unhealed wound; F showed that the wound healed completely on the 54th day

P10.1-2

Distal Minimally Invasive Metatarsal Osteotomy for offloading of Diabetic Foot Ulcers

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Aim The aim of our study is to describe the clinical results obtained with minimally invasive distal metatarsal osteotomy (DMMO) in diabetic patients with neuropathic ulcers in the forefoot.

Methods This is a retrospective study. Clinical records between January 2012 and December 2021 were analyzed. Diabetic patients older than 18 years old with a neuropathic ulcer in the forefoot that did not heal with standard treatment and was treated with a percutaneous distal metatarsal osteotomy were included.

Results Ten patients were included, all were men. The median age was 62.5 RIQ(51-72.5). All patients had peripheral neuropathy and no significant vascular disease. No ulcer had a positive probe to bone test. We ruled out osteomyelitis by MRI or biopsy in cases with bone edema. The median ulcer diameter was 8 mm (6,25-10). In 4 cases, a unique osteotomy was performed in the distal 5th metatarsal; in 6 cases, two or more osteotomies were performed to produce the ulcer discharge and a balanced metatarsal formula. All patients cured their ulcers in an average time of 4.1 weeks ST(2,46). One patient developed an infected transfer ulcer and needed the resection of the fifth metatarsal head. The median Glycosylated Hemoglobin was 7.75 RIQ(7.025-9.125). All patients started with early controlled ambulation in a post-surgical shoe.

Conclusion In diabetic persons with loss of protective sensation flexion deformities under the heads of the metatarsals cause heightened local pressure, being a risk factor for ulceration. Primary off-loading using a cast is an efficient treatment. Special footwear and orthotics are prescribed to prevent recurrence. Difficulties or poor adherence can sometimes cause these conservative tactics to fail. Then, surgical off-loading might be advised to reduce plantar pressure on the metatarsal head that is injured.

In diabetic patients with neuropathic ulcers in the forefoot with heightened metatarsal local pressure, that conservative treatment failed without significant vascular disease and ruled out osteomyelitis, percutaneous distal metatarsal osteotomies could be a procedure of choice for faster resolution and less time immobilizing the limb and allowing controlled ambulation.

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P10.1-3

Development and implementation of the Day Case Pathway - reducing length-of-stay for amputation resulting from diabetes-related foot complications.

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Aim: Develop and implement an alternative day procedure pathway for surgical intervention for diabetes-related foot complications to reduce the duration of inpatient stay at a tertiary hospital.

Background: Trans-phalangeal or minor digital amputations, are an important component to preserving limb and life. Traditionally these procedures have required acute hospitalisation, a finite resource which is becoming increasingly overloaded.

Method: In conjunction with the Podiatry and Vascular departments, an administrative and treatment pathway was developed to avoid an overnight stay for select vascular procedures. Eligibility criteria included being medically stable (e.g., no systemic features of infection, toe pressure > 50 mmHg) and undergoing a digital amputation, local surgical debridement, or biodegradable temporizing matrix application. All patients completed a pre-operative questionnaire which was assessed and triaged by the anaesthetics team for consideration of further anaesthetic review. Patients were scheduled to attend the day admission suite. Discharge criteria included review in recovery by nursing and podiatry, and where appropriate offloading and a 7-day course of prophylactic antibiotics were provided. Contraindication to discharge included excessive pain, bleeding, or medical instability. Patients were then reviewed in an outpatient clinic 48 hours post-operatively with a podiatrist and nurse, and oversight by a vascular consultant. Subsequent follow up was determined at this review – either with podiatry, vascular, multi-disciplinary foot, or telehealth outpatient appointment as appropriate.

Results: There was a marked reduction in the average length of stay when comparing pre (6.4 days) vs post (1.0 days; N = 17) implementation of the day case model. This resulted in a six-fold cost reduction per patient when compared to pre-implementation of the model (pre = \$5,446; post = \$851). At 3-months post operation 85% of patients were healed.

Conclusion: The day case pathway reduces the length of stay and cost of surgical procedures. This model is of great benefit to the organisation and community by providing more access to acute beds, as well as personal benefits to patients.

P10.1-4

A systematic review of minimally invasive surgery for Charcot foot reconstruction

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Introduction: The use of minimally invasive surgery (MIS) is becoming more popular in foot and ankle surgery due to its reduced wound complications and faster recovery time. Since Charcot foot patients have a higher risk of soft tissue compromise, MIS surgery is relevant to this group of patients. MIS techniques for Charcot foot reconstruction include percutaneous fixation through the intramedullary beam- ing, mini-incision osteotomy, or release of the Achilles tendon percutaneously. In this study, we examine the current trend of MIS surgery usage for Charcot foot reconstruction and evaluate the outcomes of such surgery.

Methods: This study was done in accordance with the PRISMA (Preferred Reporting Items for System- atic Reviews and Meta-analysis). A literature search was done on Pubmed, Embase, Cochrane Library, and Clinicaltrials.gov. The search was done using keywords (percutaneous OR “minimally invasive”) AND (“Charcot foot” OR “Charcot arthropathy” OR “Charcot joint” OR “Charcot neuroarthropathy”).

Results: Five studies were included, including two case series and three review articles, after screening 32 articles. In the two case series, there were only 21 cases. Both studies involved the reconstruction of both hindfoot and midfoot Charcot arthropathy. Amputation rate, non-union rate, and revision rate were all zero in both studies.

Conclusion: In the field of Charcot foot reconstruction, there is still a limited amount of literature on the use of MIS surgery. It is possible that this occurs due to the difficulty of performing MIS surgery on patients with severe Charcot deformities and the unfamiliarity of most surgeons with these techniques. The limited literature we found, however, showed excellent outcomes for patients.

P10.1-5

No increased risk for treatment failure and revisions for conservative surgery in diabetic foot osteomyelitis

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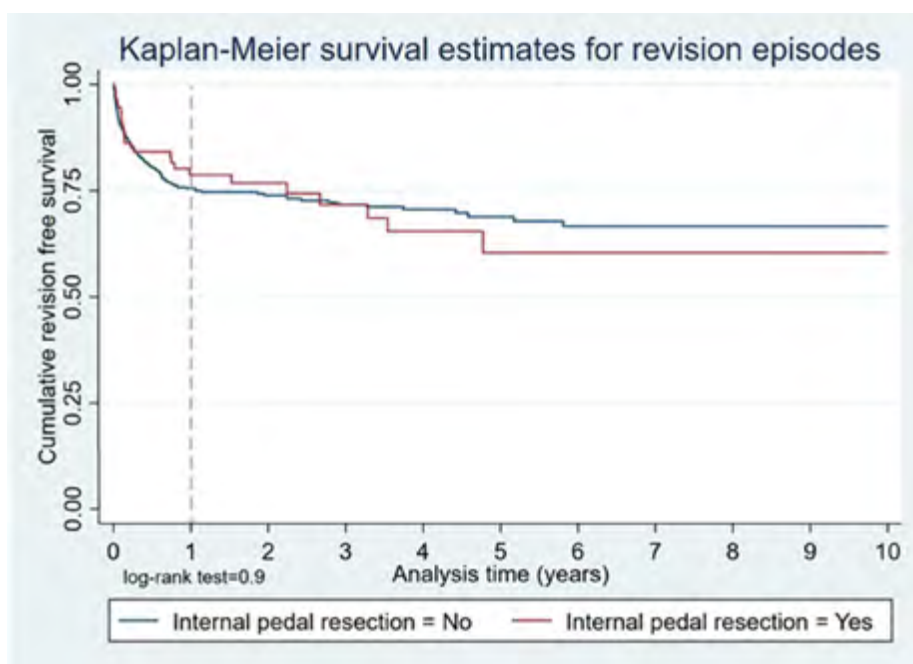
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Background: The optimal treatment strategy for diabetic foot osteomyelitis (DFO) remains debated in the literature. Conservative surgery, meaning resection of infected bone and soft tissues without amputation, continues to gain importance. This study compared the treatment failure proportions between patients treated with conservative surgery and with minor amputation.

Methods: Single-center, retrospective comparative study comparing 113 episodes of conservative surgery to 576 episodes of minor amputation in case of DFO. Multivariate Cox regression analysis and Kaplan Meier survival estimates were performed.

Results: The amount of clinical failures was not different with 24% in the conservative surgery group compared to 24% in the minor amputation group ($p = 0.93$). Clinical failure was associated with polymicrobial DFO (Hazard ratio (HR) 1.53, 95% confidence interval (CI) 1.01-2.34; $p = 0.05$) and age (HR 1.02 (95%CI 1.01-1.04; $p=0.05$). Conservative surgery was not associated with clinical failure (HR 0.98, 95% CI 0.65-1.47; $p = 0.91$). Microbiological recurrence was not different between both groups (conservative surgery 8%, minor amputation 5%; $p = 0.15$), as well. Revision free survival was no different between both groups throughout the follow-up (log rank test $p = 0.9$; Figure 1).

Conclusions: In diabetic foot osteomyelitis, conservative surgery can be used as the surgical treatment part with the same amount of clinical failures and microbiological recurrences at one year and with equal revision free survival, compared to minor amputations.



Kaplan Meier survival estimate for revision free survival, plotted for conservative surgeries and minor amputations

P10.2-1

Interrater reliability of sensory testing in patients with diabetic neuropathy

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Background: Degree of sensory loss is associated with the incidence of diabetic foot ulcers (DFU), making somatosensory testing, e.g., with the Rotterdam Diabetic Foot (RDF) study test battery, an important aspect of risk stratification. This study aims to assess its interrater reliability in diabetic patients with diabetic sensorimotor polyneuropathy (DSP).

Methods: The continuous and dichotomous 39- and 13-item RDF test batteries (RDF-39-C, RDF-39-D, RDF-13-D) assess incremental sensory loss and were executed by two examiners. Somatosensory modalities assessed included static and moving two-point discrimination, static one-point discrimination, vibration sense, perception of cold, Romberg's balance test, and information on complaints of numbness and a history of foot ulceration or amputation. Interrater agreement rates (IRA) and intraclass coefficients (ICC) were calculated to assess reliability.

Results: Sixty-five diabetic subjects with DSP were included. Interrater agreements were depended on the cut-off value and test battery (Table 1). ICCs were all >0.80, indicating high correlation.

DFU risk assessment using RDF-13-D, showed an acceptable level of agreement (rater 1 versus 2:

IRA=83.7%, 2 versus 3: IRA=78.6%) with a substantial to moderate level of agreement (1 versus 2: $\kappa=0.68$, $p<0.001$; 2 versus 3: $\kappa=0.57$, $p=0.018$). An almost perfect agreement was found for the RDF-39 (IRA=93.3%, $\kappa=0.82$, $p<0.001$).

We expect to double the number of comparisons by the time of the congress.

Conclusion: RDF test batteries show a low to high reliability between clinicians, highly dependent on the cut-off value used and the pair of raters. Standardized training across clinicians may improve its reliability.

Interrater reliability, reported as interrater agreement and intraclass correlation coefficients, of different test batteries.

	Interrater agreement				ICC (95% CI)
	Total agreement (%)	Rater difference of ≤ 1 points (%)	Rater difference of ≤ 2 points (%)	Rater difference of ≤ 3 points (%)	
RDF-39-C					
Rater 1 vs. 2 (n = 11)					
S2PD	86.4	90.0	94.5	95.5	
M2PD	79.5	86.4	88.6	92.0	
S1PD	28.2	64.5	83.6	92.7	
Vibration sense	52.3	90.9	100	-	
Cold perception	100	-	-	-	
Romberg's test	100	-	-	-	
Total test battery	69.0	84.6	92.1	95.3	
RDF-39-D					
Rater 1 vs. rater 2 (n = 30)					
S2PD	86.7	90.0	96.7	100	.022 (-.348-.380)
M2PD	73.3	90.0	93.3	100	.479 (.147-.713)
S1PD	83.3	86.7	100	-	.767 (.569-.881)
Vibration sense	76.7	83.3	100	-	.887 (.778-.944)
Cold perception	100	-	-	-	-
Romberg's test	100	-	-	-	-
Total test battery	60.0	73.3	90.0	93.3	.852 (.712-.927)
RDF-13-D					
Rater 1 vs. 2 (n = 40)					
S2PD (≤ 8 mm)	90.0	100	-	-	.291 (-.017-.549)
M2PD (≤ 8 mm)	95.0	100	-	-	-
S1PD (≤ 10 g)	87.5	100	-	-	.873 (.773-.931)
Vibration sense	65.0	85.0	97.5	100	.843 (.712-.915)
Romberg's test	100	-	-	-	-
Total test battery	40.0	82.5	97.5	100	.859 (.751-.923)
Rater 2 vs. 3 (n = 14)					
S2PD (≤ 8 mm)	42.9	100	-	-	.119 (-.445-.602)
M2PD (≤ 8 mm)	71.4	100	-	-	.188 (-.353-.638)
S1PD (≤ 10 g)	92.9	100	-	-	.649 (.217-.871)
Vibration sense	64.3	85.7	100	-	.870 (.646-.956)
Total test battery	42.9	64.3	92.9	100	.810 (.514-.935)

S/M2PD was defined aberrant when > 8 mm, S1PD was defined aberrant when > 10 g.

Abbreviations: RDF-39-C: continuous version of the 39-item Rotterdam Diabetic Foot Study test battery; n: number; S2PD: static two-point discrimination, M2PD: moving two-point discrimination, S1PD: static one-point discrimination.

P10.2-2

Predictors of Healing Of Diabetic Foot Ulcer in An Egyptian Diabetic Foot Clinic: Retrospective 10 Years' Study

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Background: Foot ulcers are common problems in diabetes. Studying the predictors of healing through years of work is important to improve the service of the clinic

Methods: Retrospective study of patient's data presenting with diabetic foot ulcer from year 2005 till 2015. Healing of Foot ulcer was the primary outcome with assessment of ulcer recurrence during this period. Data were analyzed to suggest predictors of DFU non healing.

Results: During this period diabetic foot clinic dealt with 3544 ulcers, data from only 2013 ulcers underwent Statistical Analysis. 1107 were males with mean age 57.37 ± 9.81 . Percentage of neuropathic, ischemic and neuroischemic ulcers was 95.4, 2.4, 2.2% respectively. Percentage distribution of ulcer site was 74.1%, 7.1%, 6.9%, and 7.8% in forefoot, midfoot, hindfoot and non-pressure site respectively. Ulcer healing rates was 73% with median time to heal 66(12-670) days. Percentage of recurrence was 9.6% and recurrence at other site was 22.5%. Granulating ulcer base had best healing (75.8%) and polypoid base was least (48.1%). Percentage of healing was correlated to ulcer site with best healing of toe ulcer (77.7%), ulcer surface area at presentation (median 1[0.01-72]cm²), grading of Texas classification (91.8, 2.9, 0.6% for Texas grade 1,2,3 respectively) number of follow up visits (median 3[1-29] visit) and type of offloading. Different offloading modalities were used; 26.9% casting sandal, forefoot wedge 24.7%, felted foam in 24.7% and removable cast walker in 16.6% with the rest healing wedge and total contact cast. Surprisingly the healing rate was 89.7 % among those who used felted foam. Kaplan Meier curve revealed that probability of healing decrease by time with best probable healing rate of 95.6% during first 15 days and reach only 52.6% by 60 days. multivariate revealed that difficult healing was mainly related to metatarsal head ulcer, polypoid base, larger size, grade3 Texas classification (OR 1.56,3.42,1.05,2.6 respectively) with over all prediction of 71.9%.

Conclusions: The overall healing rate of diabetic foot ulcer in this study was 73.4%. Different patients' parameters that lead to better healing are important to consider in prognostic evaluation and improving of clinic strategy.

P10.2-3

Even one foot ulcer occurring in people with diabetes predicts relatively early mortality especially in younger age at ulcer onset

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Background: Foot ulceration confers excess mortality in diabetes. However, the relative impact of even one foot ulcer episode on mortality remains unclear.

Aim: To evaluate mortality outcomes in people with diabetes-related foot ulceration (DRFU) across diabetes phenotypes: T1DM, T2DM, and age at foot ulceration.

Method: Retrospective analysis of a tertiary Diabetes Centre Database and High-Risk Foot Service with linkage to the National Death Index. Cox proportional hazard regression modelling was used to calculate adjusted hazard ratios for mortality.

Results: Overall, n=20,122 patients were studied from 1988 to 2015. There were n=18,557 without, and n=1,565 with, a DRFU history. By propensity data matching (age at first visit, ethnicity, gender, diabetes type), mortality was higher in those with a foot ulcer history, at 55.6% vs 41.2% with no ulcer history ($P<0.0001$). Adjusted hazard ratios for DRFU mortality were: 1.8 (95% CI 1.4-2.5) for T1DM, 1.9 (1.7-2.0), for T2DM, and 4.3 (3.2-5.7) for younger age of diabetes (<50yrs) (p for homogeneity <0.0001). Even for those with a single foot ulcer history, early, 5 year mortality in T1DM was 20.4%, and in T2DM was 28.6%, which were much higher than the 5 year mortality rates in those without a DRFU history at 3.7% for T1DM and 9.7% for T2DM, respectively (each $P<0.0001$). For those with a single DRFU episode compared to people with diabetes but no DRFU history in the same age category, adjusted hazard ratios (95%CI) for 5 year mortality were: 3.6 (2.6-5.0) for DRFU onset at age <50 years, 2.4 (1.8-3.0) for 50-59 years, 2.0 (1.6-2.4) for 60-69 years, 1.5 (1.2-1.8) for 70-79 years, and 2.3 (1.8-3.0) for 80 years and above (all $P<0.001$).

Conclusion: Even with one foot ulcer episode, DRFU associates with high relative excess mortality, especially at a younger age category of DRFU occurrence. Further exploration of factors linking foot ulceration in diabetes to mortality is needed.

P10.2-4

ECW/ICW ratio is a risk factor for mortality in diabetic foot patients.

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Background The scientific literature on the role of body water distribution measured by bioimpedance (BIA) is scarce. The extracellular water (ECW)/intracellular water (ICW) ratio in haemodialysis patients is associated with long-term mortality.

Aim To assess whether the EWC/ICW ratio is a risk factor for short-term mortality in patients admitted for diabetic foot and its possible relationship with inflammation and muscle function.

Seventy-six patients admitted for diabetic foot in the vascular surgery department were evaluated. Analyses were taken with a nutritional profile and haemogram; sarcopenia was assessed with bioimpedance and dynamometry. The CONUT and Prognostic Nutritional Index (PNI) tests were used to screen for malnutrition. Statistical analysis was performed with SAS software.

Results Mean age 70.5 years, 81.6 % male and 93.4 % type 2 diabetes. The most frequent macrovascular complication was myocardial infarction (21.1%) and the most frequent microvascular complication was diabetic retinopathy (61.6%). 36.8 % were at risk of moderate or severe malnutrition by CONUT, 45.3 % had a fat free mass index value compatible with sarcopenia. 73.7% of the patients had altered dynamometry. 38.2 % suffered minor amputation and 17.1 % major amputation.

In linear correlation analysis, ECW/ICW was significantly associated with CONUT ($p < 0.001$), neutrophil-lymphocyte ratio (NLR) ($p = 0.007$), platelet-lymphocyte ratio (PLR) ($p = 0.002$), and negatively associated with PNI ($p = 0.001$), dynamometry ($p < 0.001$) and glomerular filtration rate ($p = 0.003$).

In multivariate analysis, both NLR ($p = 0.0015$) and ECW/ICW ($p = 0.0331$) were risk factors for early mortality.

21.1% of patients died and the mean follow-up of patients was 291 days.

Conclusions The ECW/ICW ratio is a risk factor for short-term mortality in a DM population. This ratio seems to reflect the interrelationship between malnutrition, inflammation and atherosclerosis (MIA syndrome).

Figure caption

Extracellular water/intracellular water ratio correlation matrix

P10.2-5

External validity and predictive power of the DIAFORA-score for predicting lower-limb amputations in a Danish cohort

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Background: A foot ulcer in a person with diabetes (DFU) is a major risk-factor for a lower-limb amputation (LLA). To help clinicians predict the risk of LLA in this cohort, the DIAbetic FOot Risk Assessment (DIAFORA) was developed, but it is yet to be validated outside the original cohort.

Methods: All persons presenting with a newly occurred DFU were enrolled at the tertiary foot clinic at Steno Diabetes Center North Denmark, Aalborg University Hospital, Denmark, between November 2020 and March 2022. Participants had their DIAFORA-score calculated at baseline and were subsequently followed until LLA, death, or for at least 3 months. Participants were grouped into three groups based on their DIAFORA-score: low-risk (<15), medium-risk (15-25), and high-risk (>25). Logistic regression was used to derive Receiver Operating Characteristic (ROC)-curves for evaluation of sensitivity, specificity, likelihood-ratio and to estimate the Area Under the Curve (AUC).

Results: A total of 134 participants completed at least 3 months of follow-up for a median duration of 183 days. 12.2% underwent minor amputation, 3.4% major amputation, 9.8% died, and 81.5% healed during follow-up. People in the low- and medium-risk categories had 1.4% and 1.8% risk of major LLA and negative likelihood-ratios of major LLA of 0.1 and 0.37, respectively, while the people in the high-risk category had a 30.0% risk and positive likelihood-ratio of 11.1. People in the low-risk category had a 5.7% risk and a negative likelihood-ratio of 0.1 for minor LLA, while the people in the medium- and high-risk categories had 27.3% and 40.0% risk and positive likelihood-ratios of 4.1 and 4.9, respectively. Furthermore, a DIAFORA-score cutoff at 15 (medium and high risk versus low risk) had for major LLA a sensitivity of 70.0% and a specificity of 75.5% with a corresponding AUC of 0.83, and for minor LLA a sensitivity of 65.7% and a specificity of 79.3%, with a corresponding AUC of 0.80.

Conclusion: In our population, the DIAFORA-score was a useful tool for risk-stratification of people presenting with a newly occurred DFU. The DIAFORA-score may guide clinicians towards more individualized DFU treatment-regimens, but further validation is warranted.

P10.3-1

Recurrent diabetic foot ulcers; Results of a maximal multidisciplinary approach including reconstructive foot/ankle surgery.

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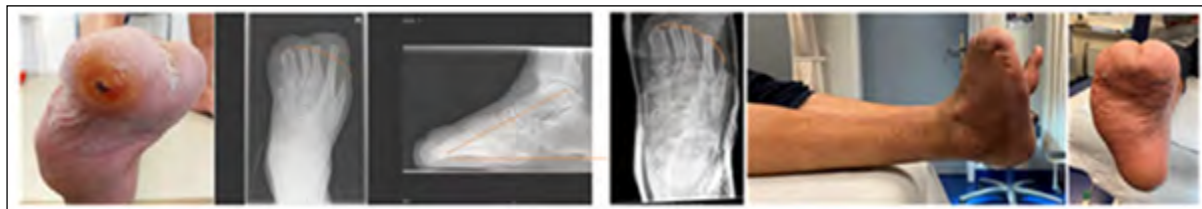
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Introduction: The diabetic foot ulcer (DFU) and Charcot Neuroarthropathy (CN) are serious complications of diabetes mellitus in which wound closure is complex to achieve. Treating recurrent DFU in patients with a combination of infection, ischemia and deformities is extremely challenging and this group of patients has a very poor outcome.

Methods: This case series describes the outcomes of patients with a recurrent DFU and CN, with a mean SINBAD score of 4 and of which 40% had a TCS of D3, using a multidisciplinary protocol that includes reconstructive foot and ankle surgery.

Results: In 24/35 (69%) of patients, wound closure was achieved after a mean of 75 days postoperatively. The mean ulcer free period was 358 days. The mean number of interventions was 6.7 (range 3-9). Post treatment 27/35 (77%) of patients were mobile, without additional amputation or ulcer recurrence (mean follow-up 374 days).

Conclusion: This study shows that wound closure and a long ulcer-free period can be achieved in patients with a DFU and CN and its multifactorial underlying diseases when treated in a multidisciplinary team, including reconstructive foot and ankle surgery.



An example of the course of the treatment, reconstructive foot surgery included.

P10.3-2

Tibiototalcalcaneal arthrodesis in the treatment of infected major deformity in Charcot-foot

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Background: Diabetes mellitus is frequently associated with Charcot neuroarthropathy characterized by peripheral neuropathy, bone destruction and joint subluxation. This osteoarticular deformity presents an increased risk of ulceration and foot infection. The approaches to transform an infected-deformed foot into an ulcer and infection free plantigrade foot are complex. A several step-approach is often used to control infection and allow the ulcer to heal long before surgical reconstruction and stabilization. However, this leads to prolonged overall treatment with extended periods of immobilization. No unanimous guidelines exist.

Methods: We present a clinical case of a diabetic patient with Charcot neuroarthropathy and a severe deformity with significant subtalar subluxation that underwent a tibiototalcalcaneal arthrodesis promptly after ulcer healing to highlight and discuss the role of surgical reconstruction and stabilization in a diabetic foot to achieve an infection-free and plantigrade foot.

Results: We present a case of a 50 year-old man, followed in the diabetic clinic for 10 years with multiple episodes of ulceration/infection that was easily treated with antibiotics and proper immobilizations. In 2020 a rapid progression of foot deformity was evident presenting a Charcot foot (Bdodsky 4) which motivated 6 months of immobilization. 7 months later, the patient developed a lateral ulcer of 5 cm with bone exposure, which lead to new non-weightbearing immobilization period and antibiotic treatment. 15 months later and 2 months after ulcer healing, the patient was submitted to a tibiototalcalcaneal arthrodesis with autologous bone graft and locally delivered antibiotics. Cast immobilization was used for 2 months and weight bearing was avoided for 2 more months. The patient is currently satisfied, able to bear weight and walk without any external support and has not had any complications such as ulcers or infection in 7 months of follow-up.

Conclusions: Charcot neuroarthropathy increases the risk of ulceration and infection leading to severe comorbidity in diabetic patients. Ankle arthrodesis is a viable approach to reconstruct and stabilize the foot. This case suggests that surgical treatment should be considered in a timely manner as an additional tool to help ulcer healing, infection control, weight bearing and therefore increasing the patient's quality of life.

P10.3-3

Outcomes of talus fracture open reduction and internal fixation in patients with Diabetes mellitus

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Background/Aim: In patients with diabetes mellitus (DM), little is known regarding outcomes of talus fracture treatment. This study aimed to compare post-operative outcomes and odds of complications after open reduction and internal fixation for talus fracture in patients with complicated DM, uncomplicated DM, and patients without DM.

Methods: The PearlDiver Database identified 30,916 patients who underwent ORIF of talus fractures from 2015 to 2021, who were followed for a minimum of one year [24,184 without DM (78%), 4,517 uncomplicated DM (15%), 2,215 with complicated DM (7%)]. Post-operative complications of nonunion and amputation were assessed at one year, as well as 30-day and 90-day rates of reoperation, acute kidney injury, cardiac arrest, dehiscence, cerebrovascular accident, deep vein thrombosis, myocardial infarction, pulmonary embolism, sepsis, pneumonia, surgical site infection, and wound disruption.

Results: Below knee amputation (OR 4.62, $p < 0.0001$), reoperation (OR 1.61, $p < 0.0001$), acute kidney injury (OR 27.36, $p < 0.0001$), deep vein thrombosis (OR 4.41, $p < 0.0001$), myocardial infarction (OR 15.98, $p < 0.0001$), pulmonary embolism (OR 4.64, $p < 0.0001$), sepsis (OR 12.56, $p < 0.0001$), surgical site infection (OR 3.72, $p < 0.0001$), and wound disruption (OR 4.18, $p < 0.0001$) were significantly higher in patients with complicated DM compared to patients without DM. See Table 1 for full results at one year.

Conclusions: Complicated DM is associated with significantly higher risk of multiple adverse events following talus fracture ORIF, notably these patients have nearly five times higher likelihood of amputation. Talus fractures in patients with complicated DM may serve as a useful comparison for hindfoot Charcot neuroarthropathy.

Table 1: Comparison of patient outcomes after talus fracture open reduction internal fixation at 1 Year

Adverse Event	No Diabetes (N, %)	Diabetes without Complications (N, %)	Diabetes with Complications (N, %)	OR, p-value
Non-Union	289 (1.20%)	44 (0.97%)	34 (1.53%)	a 0.81, 0.2039 b 1.29, 0.1647 c 1.58, 0.0451
Delayed Union	190 (0.79%)	38 (0.84%)	27 (1.22%)	a 1.07, 0.6991 b 1.56, 0.032 c 1.45, 0.1387
Reoperation	81 (0.33%)	91 (2.01%)	71 (3.21%)	a 6.12, <0.0001 b 9.85, <0.0001 c 1.61, 0.003
Acute Kidney Injury	255 (1.05%)	667 (14.77%)	500 (22.57%)	a 16.26, <0.0001 b 27.36, <0.0001 c 1.68, <0.0001
DVT	121 (0.50%)	66 (1.46%)	48 (2.17%)	a 2.95, <0.0001 b 4.41, <0.0001 c 1.49, <0.0001
Myocardial Infarction	180 (0.74%)	373 (8.26%)	237 (10.07%)	a 12.00, <0.0001 b 15.98, <0.0001 c 1.33, 0.0011
Pulmonary Embolism	81 (0.33%)	93 (2.06%)	34 (1.53%)	a 6.26, <0.0001 b 4.64, <0.0001 c 0.74, 0.1391
Sepsis	86 (0.36%)	101 (2.24%)	95 (4.29%)	a 6.41, <0.0001 b 12.56, <0.0001 c 1.96, <0.0001
Surgical Site Infection	104 (0.43%)	62 (1.37%)	35 (1.58%)	a 3.22, <0.0001 b 3.72, <0.0001 c 1.15, 0.5023
Wound Disruption	310 (1.28%)	149 (3.30%)	114 (5.15%)	a 2.63, <0.0001 b 4.18, <0.0001 c 1.59, 0.0003
Below Knee Amputation	50 (0.21%)	17 (0.38%)	21 (0.95%)	a 1.82, 0.0327 b 4.62, <0.0001 c 2.53, 0.0045

^aNo DM vs DM without complications

^bNo DM vs DM with complications

^cDM without complications vs DM with complications

P10.3-4

Plastic Closure of the Skin Defects on Feet Using NPWT Therapy

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Title. The method is based on treating diabetic foot ulcers by their closure with skin grafts followed by negative-pressure wound therapy.

Background. Diabetic foot is one of the most severe complications of diabetes mellitus that requires a step-by-step and minimum-load treatment, and NPWT proved its effect due to its angiogenesis stimulation and blood flow increase.

Methods. The study included patients with diabetes mellitus type 2 complicated with a neuro-ischemic form of diabetic foot syndrome. A total of 47 patients were distributed into a study group – 27 people, and a control group – 20 people. The wound area was different for each patient and ranged from 4.2 to 21 cm². The patients got primary wound cleaning with the use of local sorbents – a bandage with sorption-based antimicrobial composition of nanosized silica. The wound cleaning phase lasted 2-3 days and was a preparation for dermatoplasty. On the last cleaning day, the vacuum-assisted closure was applied to the wound with a standard negative pressure of 125 mm Hg for 4-8 days. At the dermatoplasty stage, the lower abdomen (suprapubic area) or the outer surface of the thigh was determined as the donor area for taking a skin autograft. The donor site was closed with primary sutures, and the skin graft was placed on the wound surface and attached to the edge with a surgical stapler. The atraumatic mesh cover was applied to the graft, and then closed with NPWT with a constant negative pressure of 110 mm Hg for 4 days.

Results. The 23 patients in the study group provided engraftment grafts. The full engraftment time and the time for healing of the wound defect in patients of the study group was 14±3 days, and the time for healing ulcers in the control group was – 52±10 days. The developed method of closing wound defects ensured the engraftment of 85.2% of the graft.

Conclusions. The method can be effectively used for wound pressure closure due to its quick and minimum traumatic effect and the specific benefits for neuro-ischemic diabetic foot patients.

P10.3-5

The use of infrared thermal imaging as a predictor of healing in trans-metatarsal amputation in diabetic foot patients

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Aim - To evaluate the efficacy of infrared thermal imaging (IRT) in predicting healing of diabetic foot (DF) trans-metatarsal amputation (TMA).

Methods - we prospectively studied all the consecutive DF patients admitted in our department May-June 2022 who had indication for TMA, didn't have a non-revascularizable critical ischemia and weren't smoker. We evaluated them with IRT (FLIR ET 500 infrared thermal camera) measuring skin temperature (ST) pre-operational (V0), one (V1) and two (V2) days after TMA, and at the desuture (V3) in three points of the plantar flap. Patients were then divided into two group: healed (G1) and not healed (G2) at three weeks.

Results - we enrolled 10 patients (6G1/4G2), [1/9 DM1/DM2, duration of diabetes 21.3±7.3 yrs, TcPO2 46.8±4.8 mmHg]. At V0 average ST did not differ between the groups (35.45±0.42°C in G1 vs 34.73±0.42°C in G2), at V1 [36.05±0.17°C vs 34.57±0.32°C (p<0.002)] and V2 [36.25±0.17°C vs 34.35±1.46°C (p<0.046)] ST was significantly higher in G1 than in G2, while at V3 no differences were found between the groups [34.65±0.33 in G1 vs 34.12±0.2 in G2 (p=0.095)].

Conclusions - Our preliminary data shows that ST measured with IRT in the days immediately after TMA in DF patients may predict healing of the surgical wound at 3 weeks.

P10.3-6

Role of Achilles Tendon Surgery in Diabetic Foot Ulceration Healing

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Background/Aim: All patients with complicated diabetic foot syndrome, i.e. with chronic diabetic foot ulceration (DFU) or development of equinus deformity in Charcot neuropathic osteoarthropathy terrain, are exposed to a great risk of subsequent lower limb amputation. For quite a long time it has been known that off-loading (conservative or surgical) of the foot in the Achilles tendon pathologic conditions is crucial for the healing. On the other hand, less well known is the importance and efficacy of Achilles tendon surgery itself.

Methods: This single-center retrospective (2012-2022) case-control study aims to compare and analyze the clinical outcomes in 37 diabetic patients with DFU who underwent Achilles tendon surgery with some type of foot off-loading followed-up. Majority of the patients were male (~70%) at an average age of 61 years at the time of surgery (min. age of 32 years, max. age of 86 years). In 64% the left lower limb was treated. Total contact casting (TCC) was applied in 22 cases. Surgical off-loading technique by the construction of biplanar external fixation (EF) was used in 15 cases.

Results: In our study group, 68% of patients gradually healed the DFU – 27% with TCC and 41% with EF applied ($p < 0.001$). Both methods of Achilles tendon surgery, i.e. lengthening (18 patients) or tenotomy (17 patients), were practically equally successful ($p = 0.3140$). A reasonable average healing time we observed in our study was 9 months (260 days - min. of 27 days vs. max. of 1733 days to complete DFU healing). Patients with TCC healed for a shorter time – average of 128 days vs. 347 days when EF applied. The main reason for non-healing was progression of limb ischaemia (66%), local persistent infection (8%), but also patient non-adherence (26%). In only 8.7% of patients (none from EF group) the major amputation was necessary.

Conclusions: The combination of Achilles tendon surgery with proper surgical off-loading (external fixation) can successfully heal diabetic foot ulceration and significantly reduce the risk of its recurrence in the future.

P10.4-1

Internet-based foot-ankle exercises program and its effects on gait biomechanics: a proof-of-concept study

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Background/Aim Previous studies have shown the efficacy of foot-ankle exercises for reducing diabetic peripheral neuropathy (DPN) signs and symptoms[1]. However, the quality of evidence is still low and the effects of an internet-based foot-ankle therapeutic exercise program - the Diabetic Foot Guidance System (SOPeD, www.soped.com.br)[2] - in people with diabetes and DPN have not yet been evaluated. Therefore, the aim of this study was to pursue initial evidence for potential benefits of an internet-based foot-ankle therapeutic exercise program on DPN-related outcomes in 12 weeks of intervention for people with DPN.

Methods We conducted a proof-of-concept study that is part of a full randomized controlled clinical trial—the FOot CAre (FOCA) trial, in which 30 adults with DPN were randomized to either the usual care (control group) or usual care plus an internet-based foot-ankle exercise program through SOPeD (intervention group) three times per week for 12 weeks. We assessed DPN-related outcomes at baseline, 12 and 24 weeks. Generalized Estimating Equations estimated between-group differences and 95% confidence intervals. At the beginning of the intervention protocol, the user had a face-to-face supervision by the physiotherapist on how to perform the exercises in the SOPeD. The other sessions were monitored remotely via software. The outcomes were: DPN symptoms extracted from the Brazilian version of the Michigan Neuropathy Screening Instrument[3], DPN severity given by the Decision Support System for Classification of Diabetic Polyneuropathy[4] and foot health and functionality from the Brazilian version of the Foot Health Status Questionnaire (FHSQ)[5].

Results Intervention group showed greater improvement in the FHSQ foot pain compared to the control group after 12 weeks (mean difference [MD]= 24.81; 95% confidence interval [CI]: 7.97, 41.84), and in FHSQ foot function domain after 24 weeks (MD= 20.75; 95%CI: 0.95, 40.55).

Conclusions This study found that an internet-based foot-ankle exercise program based on the SOPeD software has the potential to reduce foot pain and improve foot function in people with diabetes and DPN.

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P10.4-2

Objectively assessed long-term wearing patterns and predictors of wearing orthopaedic shoes in people with diabetes at risk of foot ulceration

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Background/Aim: Orthopaedic shoes can only be effective in preventing diabetic foot ulcers if worn by the patient. Robust data on long-term wearing time of orthopaedic shoes are not available, and needed to gain more insights into wearing patterns and associated factors in daily practice. The aim was to objectively assess long-term wearing patterns and identify factors associated with wearing orthopaedic shoes in people with diabetes at moderate-to-high risk of ulceration.

Methods: People diagnosed with diabetes mellitus with either loss of protective sensation or peripheral artery disease and prescribed with orthopaedic shoes were included and followed for 12 months. Wearing time was continuously measured using a temperature sensor inside the footwear. One-way analyses of variance tested for wearing time differences between (in)consistency subgroups, weekdays and weekend days. Factors potentially associated with wearing time were collected by questionnaires and medical files. Univariately associated factors were entered into a multivariate linear regression analysis.

Results: 61 participants were included, whereof 27 (44%) had International Working Group on the Diabetic Foot (IWGDF) risk 2 and 34 (56%) had IWGDF risk 3 (mean (SD) age: 68.0 (7.4) years; females: n=17; type 2 diabetes mellitus: n=54). Mean (SD) daily wearing time was 8.3 (6.1) hours/day. Participants with an inconsistent wearing pattern showed lower daily wearing times than participants with a consistent pattern ($P<0.001$). Wearing time was higher during weekdays compared to weekend days ($P\leq 0.01$). In the multivariate model ($R^2=0.28$), "satisfaction with my amount of orthopaedic shoes wear" was positively associated ($P<0.001$) with wearing time. Other investigated factors were not associated with wearing time.

Conclusions: Adherence to wearing orthopaedic shoes is suboptimal in most people with diabetes at moderate-to-high risk of foot ulceration. Changing wearing time to a more consistent pattern seems promising to improve long-term adherence to wearing orthopaedic shoes. Patients should be aware of the importance to wear orthopaedic shoes every day. Since investigated factors are not associated with wearing time, adherence to wearing orthopaedic shoes should be objectively measured on an individual level in daily practice.

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P10.4-3

Study Protocol For DEveloping a Core Outcome set for Diabetic nEuroopathy clinical trials (DECODE)

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Background and Aim: Diabetic neuropathy is the most common complication of diabetes, affecting more than 50% of people with diabetes [1]. It is characterised by peripheral nerve dysfunction, typically leading to sensorimotor symptoms such as unsteadiness, pain and/or numbness in the distal extremities. Diabetic neuropathy can lead to a reduced quality of life, and further complications include diabetic foot ulceration and Charcot neuropathic osteoarthropathy, which are associated with significant morbidity and mortality [2].

There have been several landmark diabetic neuropathy clinical trials, however, there has been heterogeneity in the outcomes measured leading to challenges in evidence synthesis. In addition, it has been proposed that promising novel therapies for diabetic neuropathy may have failed in clinical trials due to the outcomes measured. The aim of this study is to develop a core outcome set (COS) for diabetic neuropathy clinical trials.

Methods: The proposed methods will follow the Core Outcome Measures in Effectiveness Trials (COMET) Initiative Handbook. A systematic review of the literature will be conducted to identify and synthesise the outcomes measured in diabetic neuropathy clinical trials. Focus groups and semi-structured interviews with diabetic neuropathy patients, caregivers and patient support group representatives will be performed to identify which outcomes are most important to these stakeholders. A wide range of international stakeholders such as patients, healthcare professionals, researchers and charities will be surveyed to identify their most important outcomes. A multi-round Delphi process will be undertaken to develop a COS for diabetic neuropathy clinical trials.

Results: The process for diabetic neuropathy COS development is underway, with the purpose of improving the quality of diabetic neuropathy research and inform future clinical trials, clinical practice guidelines and systematic reviews. Registration of the project in the COMET database has been applied for.

Conclusions: The project is ongoing, so conclusions cannot be drawn yet.

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P10.4-4

Major differences in people with diabetic foot ulcers can be found based on clinical history and setting

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Background/aim: Foot ulcers in people with diabetes (DFU) are a universal issue related to severe outcomes. However, the outcomes might vary between different countries and groups of people. We aimed to examine differences in baseline characteristics and outcomes between people seen with their first ever (FE) or not first ever (NFE) DFU in two tertiary diabetic foot clinics.

Methods: A total of 530 consecutive individuals who presented with a DFU at either Steno Diabetes Center North Denmark (n=198) or at Pisa University Hospital (n=332) were included. Participants were sub-grouped based on them having their FE (n=249) or NFE (n=281) DFU. Baseline characteristics included demographics, ulcer characteristics, and information on previous treatments. Follow-up for assessment of death, DFU recurrence, amputation, and revascularization were conducted at 3, 6 and 12 months after the initial visit by physical examination or assessment of electronic records.

Results: No differences were found in baseline characteristics between people having their FE or NFE DFU in Denmark, while the NFE-group had longer diabetes duration (17 years vs 9 years, $p<0.01$) and more peripheral arterial disease (PAD) (89% vs 71%, $p<0.01$) in Italy. There was a significant difference in diabetes duration (20 vs 12 years, $p<0.01$), end-stage renal disease (8% vs 12%, $p<0.01$), PAD (43% vs 89%, $p<0.01$), foot deformity (36% vs 63%, $p<0.01$), previous lower limb amputation (22% vs 42%, $p<0.01$) and previous Charcot neuroarthropathy (4% vs 15%, $p<0.01$) between Denmark and Italy, respectively. After 12 months of follow-up, the NFE-group had higher recurrence-rates (31% vs 19% and 30% vs 15%), more revascularization procedures performed (15% vs 9% and 20% vs 9%), and higher mortality-rates (23% vs 14% and 20% vs 9%) than the FE-group in both Denmark and Italy, respectively.

Conclusions: Despite similar baseline characteristics, people with a NFE ulcer presented worse outcomes than people with a FE ulcer, confirming consistent prevention of ulcer recurrence must be given priority. Although with shorter diabetes duration, people in Italy presented higher prevalence of diabetes-related complications. This may represent differences in genetic and/or clinical pathway characteristics. The recurrence rate appears to be similar between countries despite the difference between populations.

P10.4-5

Construction of the prediction model of diabetic patients with high-risk foot based on the gait feature

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Aim: To investigate the walking ability, walking phase, support, swing and micro movement of diabetic patients and to build the model of predicting the risk of high-risk foot in diabetic patients.

Methods: 380 diabetic patients were selected from a tertiary hospital in Shanghai from August 2019 to December 2019. The patients with diabetes were investigated by high-risk diabetic foot evaluation questionnaire and real-time gait detection tools. The general data, assessment data related to the occurrence of diabetic high-risk foot (ankle brachial index, occurrence of foot deformity, protective sensory loss, history of heart disease and/or smoking, diabetes duration, history of diabetic nephropathy or retinopathy, previous foot ulceration or amputation); overall walking ability analysis (symmetry, stability and standard degree), step phase analysis (Landing phase, flatfoot phase, pedal extension phase and swing phase), micro motion analysis (cadence frequency, stride length, maximum swing speed, maximum swing width and height above the ground, foot axis angle) were collected. The enrolled diabetic patients were divided into a modeling cohort (70% of the total) and a validation cohort (30% of the total). Data from the modeling cohort were applied to construct a predictive model for diabetic high-risk feet. Through the method of single factor analysis, the risk factors that enter into the prediction model of high-risk foot of diabetes were screened out, and then through the logistic multiple regression analysis, the regression coefficient of each factor in the prediction model of high-risk foot of diabetes was established, according to which the mathematical formula of the prediction model of high-risk foot of diabetes patients was established.

Results: Diabetes High Risk Foot Risk Score = $22 \times \text{Age} - 16 \times \text{Gait Stability} - 31 \times \text{Gait Standardity} - 9 \times \text{Step} + 2 \times \text{Stride} - 5 \times \text{Ground clearance} - 13 \times \text{Swing Speed} - 2 \times \text{Flat Foot Phase} - 4 \times \text{Pedaling Phase} + 1 \times \text{Swing Phase}$.

Conclusions: The model has a certain prediction efficiency (the area under ROC curve reaches 0.7310), suggesting that the model can be applied to the population. When the best total risk cut point was -566.93, the sensitivity was 64.10%, the specificity was 79.26%, and the rough consistency was 74.81%. It has a certain predictive effect.

P10.4-6

The experience of a diabetic foot unit continuing face-to-face consults during the COVID-19 pandemic

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Background: During the COVID-19 pandemic, many centres reported an initial increase in lower limb amputation rates for diabetes-related foot complications. Amputation rates then decreased with lockdowns and healthcare disruption. In the studied city, the government implemented 263 days of lockdown.

Aims: To map trends in diabetes-related lower limb amputation and hospitalisation rates in a quaternary Australian hospital that prioritised face-to-face reviews throughout the pandemic.

Methods: We performed a retrospective cohort study of patients who underwent a lower limb amputation for a diabetes-related foot complication, from January 2018—December 2021, in our hospital. This was compared to hospitalisation rates. COVID-19 onset was defined as March 16, 2020, when a State of Emergency was declared.

Results: In contrast to previous studies, this study identified a stable decrease in amputation rates during the pandemic, a comparable trend to pre-COVID-19 (Figure 1). During the study period, 360 lower limb amputations for diabetes-related foot complications were performed. The median monthly number of amputations remained stable, with 8.0 amputations (IQR 6.5-11) prior to COVID-19, compared to 6.5 amputations (IQR 5.0-8.3) during COVID-19 ($p=0.23$). Hospitalisation with a diabetes-related foot complication significantly increased from a median monthly rate of 11 patients (IQR 9.0-14) prior to COVID-19, to 19 patients (IQR 14-22) during COVID-19 ($p<0.001$). The increased hospitalisations are likely due to withdrawal of many community wound services during lockdown.

Conclusion: Face-to-face care of diabetes-related foot wounds was prioritised here. This is likely to have stabilised the number of amputations performed during the pandemic, despite disrupted community wound care services.

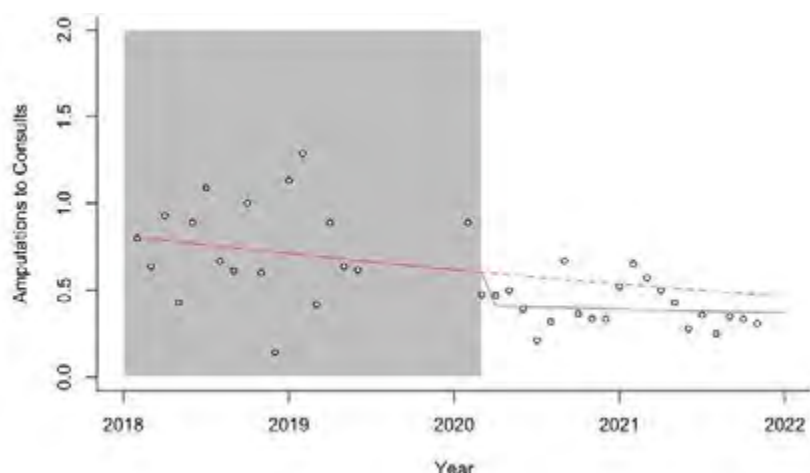


Figure 1. Interrupted time series analysis comparing rates of amputations to Diabetic Foot Unit caseload prior to and post COVID-19 pandemic onset. Time period includes January 2018 to October 2021, and excludes data from June to December 2019. The grey box represents January 2018 to the end of March 2020. The solid red line represents the actual rate of amputations to consults over time, while the dotted red line represents the counterfactual scenario. The step change ($p=0.18$) and interaction term for the slope change ($p=0.73$) were both not significant.

P10.6-1

Erythrocyte Sedimentation Rate is an Independent Predictor of Outcomes Following Diabetic Forefoot Amputations

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Background/ Aim: Inflammatory markers have been associated with detection of osteomyelitis in diabetic foot infections and can help determine the severity of infection, which may predict outcomes of treatment. Previous studies have shown inflammatory markers to be a valuable predictor of healing in diabetic foot ulcers. However, no identified studies have shown the value of erythrocyte sedimentation rate (ESR) or C reactive protein (CRP) as independent predictors of outcomes following amputations. The purpose of this study was to evaluate if laboratory values used to measure infection; ESR, CRP, and white blood cell count (WBC); can help predict outcomes following pedal amputations in patients with diabetes.

Methods: Retrospective chart review of patients with diabetes who underwent pedal amputations was performed. Inclusion criteria was defined as patients with diabetes, pedal amputation secondary to infection, recorded pre-operative ESR, CRP, and WBC value, and having follow-up within 1 year. 127 patients (152 amputations) were included. Logistic regression was used to evaluate ESR, CRP, and WBC values with amputation site healing at 1, 3, 6, 12 months postoperatively, as well as 5 years and 10 years when applicable. Logistic regression was additionally used to evaluate patients risk of proximal amputation, hospital readmission within 30 days, and further pedal amputations within 1 year.

Results: Low ESR values pre-operatively were associated with healed amputation sites at 1,3,6 months ($p<0.05$). Low ESR was additionally associated with decreased risk for proximal amputation ($p<0.05$), further pedal amputation within 1 year ($p<0.05$), and reduced hospital readmission rates ($p<0.1$). Low values of CRP and WBC showed some correlation with healing but was not as significant as ESR. All markers were significantly associated with proximal leg amputation ($p<0.5$).

Conclusions: ESR showed superiority in predicting outcomes when compared to other laboratory markers for infection. This study demonstrates the utility ESR can provide as risk stratification for healing and complications following at risk diabetic foot amputations. The predictability ESR can provide may help guide initial treatments and should be considered as a standard in the management for diabetic foot infections.

P10.6-2

Bedside Amputation Surgery for isolated toe(s) necrosis in a Diabetes Department: prognostic after 1-year follow-up

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For isolated toe(s) necrosis complicating diabetic foot ulcer (DFU), level of amputation is a frequent topic of disagreement between diabetologists and surgeons. Bedside Amputation Surgery (BAS) performed by a diabetologist might be an option to get rid of a major surgery (complete transmetatarsal amputation [TMA] or transtibial amputation [TTA]) usually and initially recommended by the surgeon in this case. Indications of this practice need to be specified.

This monocentric, retrospective, observational study assessed the outcome at 1 year of patients with diabetes mellitus (DM) after an accessible BAS performed by the diabetologist for isolated and delimited toe(s) necrosis consisting of transphalangeal amputation, metatarsophalangeal disarticulation or TMA of one axis. The primary endpoint is the one-year healing rate without secondary surgery performed by a surgeon in the operating room.

Out of 783 patients admitted for DFU (05/2016-10/2021), 66 underwent BAS (8.5%). One-year follow-up was achieved for 55 patients (5 deaths from other causes and 6 lost of follow-up): males 82%, type 2 DM 96%, DM median duration 18 years, median HbA1C 9%. One-year healing rate was 62% (34/55). Among 21/55 patients with no healing at 1 year, 19 received secondary surgery in the operating room (TTA 32% (6/19), complete TMA 37% (7/19) and revision surgery gesture 31% (6/19), median delay: 41 days). Failure was observed in patients with more severe leg arteriopathy (1 vs 2 arterial leg axes, $p=0.03$) with no significant difference in foot vascularization. Soft tissue infection at the time of BAS was significantly more present in the unhealed group (80% vs 47%, $p=0.02$) with a higher CRP level (84 vs 23mg/L, $p=0.001$).

BAS allows optimal care in about 2 out of 3 cases, avoiding the need to perform major surgeries. The number of arterial leg axes (<1) as well as degree of soft tissue infection need to be assessed before suggesting the indication.

P10.6-3

Charcot neuroarthropathy with osteomyelitis of the tarsus. Report of a new technique for surgical therapy without bone resection

Dr Armin Koller

¹Dr. Guth Hospital, Hamburg, Germany

Background: The combination of Charcot neuroarthropathy (CN) and concomitant osteomyelitis (OM) is a therapeutic challenge. Antiinfectious therapy alone is usually ineffective; surgical therapy is often associated with extensive bony resection. Two cases of active CN with infection of all tarsal bones with 18 and 36 months of follow-up are presented, in which a new surgical procedure was used without any bone resection. Patients had been scheduled beforehand for internal tarsal amputation and Chopart amputation, respectively.

Methods: Two type 2 diabetic patients with CN type 2-3 according to Sanders and histologically or microbiologically proven OM of all tarsal bones were treated with drilling multiple channels in the tarsus via a small incision, which were then filled with an osteoconductive bone substitute with gentamicin additive. For securing the fracture-prone foot stabilization was performed in an external fixator, which also served to calm infection as well as CN activity. The fixator was left in place for 6 weeks, followed by three months of follow-up treatment in an ankle foot orthosis.

Results: At latest follow-up, there was complete remission in both cases. Previously existing ulcerations healed, so far also without recurrence. The foot skeleton stabilized completely; there was no longer an increased risk of fracture or instability. The procedure left no significant foot deformity. Both patients were provided with bottine type orthopaedic shoes with stiffened rocker sole.

Conclusions: Various procedures for reaming or curettage of infected bone and filling with local antibiotic carrier have been published. No publications are yet available on the procedure described here in CN with OM. After detailed explanation, both patients gave their written consent to the application of a new surgical technique as further development of existing procedures. It was important that in case of failure the initial situation for the planned amputation was not worsened. In case of simultaneous involvement of the tarsus with CN and OM, the results obtained after 3 years maximum encourage further applications and long-term observations.

P10.6-4

Spiculectomy and orthonyxia for ingrown toenails in patients at risk; prospective observational cohort study

Ms Leonie Rosien¹, Dr. Peter van Dijk, Dr. Jacques Oskam, Dr. Klaas Groenier, Prof.Dr. Rijk Gans, Prof.Dr. Henk Bilo, Dr. Gijs Landman

¹InnoFeet And Isala, Heino, Nederland

Background Ingrown toenails (unguis incarnatus) are common in persons with diabetes mellitus (DM) and peripheral arterial disease (PAD). Gold standard for a stage 2,3 ingrown toenail is a surgical partial nail resection with fenolisation¹. For people with high risk for wound healing problems the advices are less strong due to lack of evidence.

Minimal invasive treatment of ingrown toenails with spiculectomy and/ or orthonyxia might be a promising treatment option.

Aim The aim of this study was to evaluate the efficacy and safety of minimal invasive treatment spiculectomy and orthonyxia

Design/Setting Prospective observational cohort study in an outpatient podiatric clinic in persons with high risk on wound healing problems (due to diabetes, peripheral arterial disease or immune suppression)

Method Eighty-eight patients with unguis incarnatus were included. Primary outcomes were post-procedural complication rate (infection and hemorrhage), and duration of pain. Patient satisfaction during and after treatment procedure was evaluated.

Results Healing was achieved in 80 / 88 (90.9%) persons; non-DM group 28 / 32 (87.5%) vs DM group 51 / 56 (91.1%); median healing time (21 [14,42] days) and median treatment time; (56 [30,86] days) were comparable between the non-DM and the DM groups. (Sixty-four patients (72.7%) had a significant pain reduction within 0-2 days. Median reduction of the VAS score after the first treatment was 2.0 points [0.0,6.0] (non-DM group 3.5[1.0,6.0]; DM group 2.0[0.0,5.0] (p=0.0117)). Forty-eight (94,4%) patients, 31(96.9%) non-DM group vs 53(94.6%) DM group (p=0.534)) had no limitations in daily activities by the affected toe after 14 days. There were no treatment-related complications like bleeding or infection.

Conclusion Spiculectomy and orthonyxia resulted in a high patient satisfaction. Five of 88 patients needed referral for a partial nail resection. This treatment seems to be very suitable for persons with a high risk for foot ulcerations and could probably be an alternative treatment option for surgical interventions.

PLEN1-1

The diabetic foot; four decades of progress

Prof. Andrew Boulton¹

¹University of Manchester, , United Kingdom

No abstract available

PLEN1-2

What progress did we make in management of PAD

Prof. Joseph Mills¹

¹Baylor College of Medicine, , United States

No abstract available

PLEN1-3

Diabetic foot infections; developments in diagnosis and treatment

Dr Edgar Peters¹

¹Amsterdam UMC, Location VUmc, , The Netherlands

No abstract available

PLEN2-1

What have I learned from performing 30 years clinical trials in diabetic foot ulceration

Dr William Jeffcoate¹

¹Nottingham University Hospitals Trust, , United Kingdom

One of the main aims of the IWGDF has been to collate the evidence to support claims of the effectiveness of different treatments used in the management of diabetes-related foot ulcers (DFUs). The evidence is now restricted to that available from randomised controlled trials (RCTs).

RCTs can be hard to conduct and hard to complete. Many are flawed by errors of trial design, low numbers, poor quality reporting and, sometimes, the possibility of bias on the part of some researchers. It follows that available RCT evidence needs to be carefully assessed before the use of any particular treatment is endorsed. This is now routine practice in the IWGDF.

But in addition to basing care only on treatments which have been shown to be effective in RCTs, clinicians need to adopt other criteria to ensure that the service they provide for all people with DFUs is of the best possible quality. To this end, it is essential that they evaluate their management by systematically reviewing the outcomes of the people that they care for. These outcomes may focus on ulcer factors (such as time to healing) and patient factors (including survival and progression of co-morbidities) and should then be used to compare performance with other centres.

It should become standard practice for clinical outcomes to be documented for each person at pre-defined intervals so that meaningful comparisons can be made between all participating centres. Observed differences between centres should then lead to adjustment of the processes of care such that the best possible results could ultimately be achieved by all. It is not enough for any carer to believe that they deliver best quality care: there should be evidence that they do.

Such a process requires careful planning to ensure that the burden of data collection and analysis is kept to a bare minimum while similar measures should, ideally, be collected by all.

A strong case could be made for such a process to be developed in time for a multicentre, multinational scheme to be launched at the time of the next IWGDF meeting in 2027.

PLEN2-2

These shoes are made for walking, but how, which, and where to?

Prof. Sicco Bus¹

¹Amsterdam UMC, location AMC, The Netherlands

Increased mechanical load on the foot during ambulation is an important risk factor for foot ulceration in people with diabetes who have loss of protective sensation. Therefore, reduction of these pressures is important both in the prevention and treatment of these chronic wounds. For ulcer prevention, special footwear (therapeutic, custom-made) is commonly prescribed to people with diabetes, in particular to those who are at moderate risk because of deformity present or high risk who have healed from a plantar foot ulcer. Such footwear aims to redistribute pressures on the foot and reduced pressure at locations that are at risk for ulceration (pressure points). International guidelines from the IWGDF report on the importance of appropriately fitting and pressure-relieving footwear and insoles to prevent occurrence and recurrence of foot ulcers. Innovations in footwear technology include the use of plantar pressure measurements to guide design and modifications to the footwear that optimize the pressure relieving properties of the shoe. The efficacy of this approach has been tested and shown in several trials. Other innovative methods are also available and may help to improve footwear design, and include the development of scientific-based protocols to help in clinical decision-making for the right type of footwear and for the right design at different levels of foot complications. The aim of such initiatives is eventually to design the most optimal shoe for a given patient at the right time, through a personalized state-of-the-art approach. However, the footwear can only be effective when worn and different solutions to improving footwear use are currently available, including the use of special footwear for indoors. All these topics on footwear are investigated at the Amsterdam UMC Center for Diabetes-related foot Complications (ACDC) and will be discussed during the lecture, and also where the gaps in our knowledge are and a research agenda will also be presented.

PLEN2-3

Charcot neuro-osteoarthropathy

Prof. Dane Wukich¹

¹UT Southwestern Medical Center, United States

No abstract available

PLEN3-1

New developments in diagnosis and treatment of (painful) diabetic neuropathy

Prof. Dan Ziegler¹

¹Leibniz Center for Diabetes Research at Heinrich Heine University Düsseldorf, Germany

No abstract available

PLEN3-2

How to optimise healing of a diabetic foot ulcer

Prof. Fran Game¹

¹University Hospitals of Derby and Burton Nhs Foundation Trust, United Kingdom

No abstract available

PLEN3-3

Diabetic (foot) care in wartime

Prof. Boris Mankovsky¹

¹Shupyk National Medical Academy Of Postgraduate Education, Ukraine

No abstract available

PLEN4-1

Presidential address: My lessons learned in a 30-year long journey from brain to toe (and back)

Prof. Nicolaas Schaper¹

¹Maastricht University Medical Center, The Netherlands

No abstract available

PLEN4-2

Using the knife to preserve the foot

Prof. Joon Pio Hong¹

¹University of Ulsan College of Medicine, South Korea

No abstract available

PLEN4-3

The potential for secondary prevention of diabetes-related foot disease

Prof. Jonathan Golledge^{1,2,3}

¹Queensland Research Centre for Peripheral Vascular Disease - James Cook University, Australia, ²Townsville University Hospital, Australia, ³The Australian Institute of Tropical Health and Medicine - James Cook University, Australia

Diabetes-related foot disease is one of the commonest causes of hospital admission. While an in-patient management focuses on treating infection and revascularization. People with diabetes-related foot disease are also at high risk of major adverse cardiovascular events, such as myocardial infarction, stroke and cardiovascular disease. Recurrent foot disease and hospital readmission is also very common. Secondary prevention of cardiovascular events and foot complications is thus of critical importance. This talk describes evidence from randomised controlled trials which guides our choice of medical management. Discussed is evidence for the benefit of control of modifiable risk factors such as lipids, blood pressure and diabetes. Much of the data draws on trials which have included or focused on people with peripheral artery disease, given its importance in diabetes-related foot disease. Also discussed is evidence supporting the value of offloading, foot temperature monitoring and education programs in the prevention of foot ulcers. The greatest burden of diabetes-related foot disease occurs in rural and remote and low-income populations. Also discussed are the challenges of implementing secondary prevention and research to develop a telehealth program to facilitate implementation of secondary prevention for people at risk of foot disease.

PLEN4-4

New technology that we can apply today (not tomorrow) to improve PROMs

Prof. David Armstrong¹

¹University of Southern California, , United States

Over the past generation, significant advances in care have led to incremental improvements in healing worldwide. However, it may be argued that the most potent advances in healing have been in organization of care. Technologies are now emerging that may allow further enhancements of organization and integration of care while also bringing in much needed bedside, chairside, and in-home diagnostics to identify key points in healing and potential early warning signs for recurrence for the patient in diabetic foot remission. This lecture reviews what are believed to be several key areas of change over the next generation. These include portability, durability, automation, intelligence, ubiquity, and affordability, all yielding specific advances in wound diagnostics. These technologies now blur the line between consumer electronics and medical devices whether stationed in the home, the clinic, and on (or in) the patient

MS01-1

Mechanisms of impaired tissue healing

Prof. Gian Paolo Fadini¹

¹University of Padova, , Italy

No abstract available

MS01-2

Update on research to develop new medical therapies for ischemia driven foot disease

Prof. Jonathan Golledge^{1,2,3}

⁰The Australian Institute of Tropical Health and Medicine - James Cook University, Australia, ¹James Cook University, Australia, ²Townsville University Hospital, Australia

Diabetes-related foot disease results from the interplay between limb ischemia, neuropathy, biomechanical dysfunction and infection. Depending on cohort between 1/3rd and 2/3rd of people admitted to hospital for treatment of diabetes-related foot disease have evidence of foot ischemia which is a major risk factor for major adverse events, particularly major amputation. This talk discusses current animal research and human clinical trials testing novel treatments for ischemic foot disease. This includes the pros and cons of current animal models of ischemic ulcers and interventions which have shown promise in these models. Also discussed are clinical trials testing cell therapies, growth factors, gene therapies and oxygen therapy. Challenges to designing studies of these types are also highlighted.

MS01-3

Surgical procedures to improve wound healing

Dr Klaus Kirketerp-Møller¹

¹Copenhagen Wound Healing Center, , Denmark

No abstract available

MS01-4

Topical antimicrobial treatment

Prof. Eric Senneville¹

¹Gustave Dron Hospital, France

Diabetes-related foot ulcers (DFUs) are chronic wounds with complex microbiology and a high frequency of biofilm involvement. The chronicity of the skin break is a major factor that explains about half of the DFUs are complicated by an infection. Systemic antimicrobial treatments especially antibiotics are indicated in case of infected DFUs. Their usefulness in non-infected DFUs has not yet been demonstrated

especially with the aim of accelerating ulcer healing. Topical antimicrobial agents have the theoretical advantage of reducing the extent of antimicrobials needed, achieving high concentrations in the infected sites, and limiting adverse effects. In addition, topical antimicrobial therapy is less likely to promote the selection of resistant bacteria in the gut in comparison to systemic antibiotics with a high digestive elimination. Potential disadvantages of topical antimicrobial use include local skin toxicity. Among antibiotics, aminoglycosides and vancomycin have both mainly used with mitigated results for the treatment of mild to moderate diabetes-related foot infections (DFIs). Many other interventions with the aim of reducing the bacterial load present in DFUs have been assessed in clinical settings. It is important to make clear whether or not DFUs are clinically infected, and whether the goal is to prevent or treat the infection. Over the last few years, the concept of DFUs with chronic biofilm infections has emerged which results in the appearance of a lot of new products with potential antimicrobial and antibiofilm effects on the market. Overall, only low certainty of the evidence suggests that any topical antimicrobials may increase the likelihood of healing of DFUs. Their role in the treatment or prevention of DFU infection has not yet been clearly established. The effect of topical antimicrobials versus systemic antibiotics on the resolution of infection in infected DFUs and the need for surgery is uncertain. The use of antimicrobial dressings seems to be associated with a higher probability of healing when compared to non-antimicrobial dressings. While very limited data suggest that topical antimicrobials could result in decreasing the use of systemic antimicrobials in mild DFIs, this has not yet been established in moderate-to-severe DFIs. This question needs urgent comparative clinical trials.

MS01-5

Wireless and telemedicine wound care

Prof. Neil Reeves¹

¹Manchester Metropolitan University, , United Kingdom

Management of diabetic foot ulcers (DFU) can be costly and time-consuming for both patients and health professionals, negatively affecting treatment efficacy. Low cost, accurate and user-friendly remote monitoring solutions could therefore offer major benefits for DFU monitoring. The multidisciplinary research group based in Manchester, UK has generated a body of research to develop 'FootSnap', an app for automated detection and monitoring of DFU operating on a mobile device. This app uses artificial intelligence (AI) to automatically detect the location and delineate the borders of the DFU and surrounding skin. This presentation will cover aspects of the ~8-year body of research that has contributed to the development of this remote monitoring technology, including a recent 'real-world' trial in the clinical setting using a cloud-based AI system. Predictions/decisions made by the cloud-based artificial intelligence system showed excellent sensitivity and high specificity against expert clinical judgement. This technology shows promise for effective remote monitoring of DFU in the hands of the patient and/or their spouse/carer.

Recent research with 'smart insole' systems measuring and feeding back foot pressure information have shown proof-of-concept efficacy for reducing the risk of re-ulceration in high-risk patients. These systems have primarily been focussed on DFU prevention, however, these remote monitoring solutions could also be applied for monitoring offloading for DFU healing. The presentation will also explore aspects of these 'smart insole' technologies and their potential for remote monitoring of patients with DFU.

MS02-1

Evolution of our surgical decision making in Charcot neuro-osteoarthropathy

Dr Katherine Raspovic¹

¹University of Texas Southwestern Medical Center, , United States

The goal of this presentation is discuss several important topics related to surgical intervention in patients with Charcot Neuro-osteoarthropathy of the foot and ankle. These topics will include indications for operating in the active phase, pre-operative patient optimization, pre-operative edema reduction and post-operative complications.

MS02-2

Towards personalized medicine for safe physical activity in people at risk of foot ulceration

Dr Jaap van Netten¹

¹Amsterdam UMC, location AMC, , The Netherlands

Prevention is better than treatment – a paradigm all healthcare professionals are aware of. Because the easiest foot ulcer to heal, is the ulcer that never develops. However, foot ulcer prevention is, and has been for decades, underexposed in both research and clinical practice.

In this lecture, I will describe and discuss the various strategies we employ at the Amsterdam UMC Center for Diabetes-related foot Complications (ACDC) to work towards our aim of improving the lives of people with diabetes at (high) risk of foot ulceration, by increasing the evidence-base on foot ulcer prevention and implementing effective interventions. I will discuss three research aims (the best shoe; safe physical activity; understanding ulceration), and the three impact priorities (implementing evidence; improving research capacity; communicating science) of ACDC.

In more detail, I will discuss how we aim to move from stratified healthcare for all people with diabetes, towards personalized medicine for safe physical activity in people at risk of foot ulceration. This shift firstly considers the importance of personalized medicine. This is a medical model characterized by providing the right treatment, to the right patient, at the right time. In order to deliver this in diabetes-related foot disease, better understanding of ulcer development is required, as well as better understanding of when to use which interventions. Secondly, this shift considers the relevance of changing our outcomes. From the negative focus on not getting a specific outcome (i.e. foot ulcer or lower-extremity amputation), towards the positive focus on increasing safe physical activity in people at risk of foot ulceration.

Finally, scientific evidence is meaningless when it fails to have an impact. To increase our impact, we undertake and investigate various implementation projects. In this lecture, I will describe these endeavors. Also, we aim to create impact by improving research capacity, in Amsterdam and beyond, and we explore new and more diverse ways of communicating science. Both will also be described during this lecture.

In all, with this lecture I hope to take you along in our journey to improve the lives of people with diabetes at risk of foot ulceration.

MS02-3

The evolution of patients with diabetic foot disease: a history of the last 20 years

Prof. Marco Meloni¹

¹University of Rome 'Tor Vergata', Italy

Approximately 20 years ago, the EURODIALE study defined a milestone on the epidemiology of diabetic foot disease. The project included 14 European diabetic foot services which included consecutive patients which referred for a new diabetic foot ulcer (DFU). Overall, more than 1000 patients were included and among those nearly 50% showed ischaemic/neuro-ischaemic ulcers and 50% neuropathic ulcers. Ischaemic DFUs were related to worse outcomes in terms of non-healing, and outcomes were impaired in the case of infection. Patients were characterized by several co-morbidities, but <10% reported end-stage-renal-disease (ESRD) and heart failure. In the same years, Jude et al reported as peripheral arterial disease (PAD) among diabetic subjects in comparison to not diabetic subjects showed a more distal localization involving more frequently the vessel below-the-knee (BTK). In addition, the involving of BTK arteries increased the risk of major amputation if compared to PAD above-the-knee.

During the last 20 years, it has been reported an evolution of diabetic foot disease with a specific increase of ESRD and heart failure in patients with DFU. ESRD and heart failure have been documented to be more likely associated to worse outcomes such as non-healing, major amputation and mortality influencing the management of these kind of patients. Concomitantly, it has been also reported an evolution on the characteristics of PAD, which seems to be more severe involving frequently the arteries below-the-ankle (BTA). BTA arterial disease resulted more difficult to be treated and it is closely associated to higher risk of non-healing, minor amputation and mortality in comparison to above-the-ankle arterial disease.

Finally, the not rare presence of diabetes and ESRD in patients with DFU defines a new pattern of diabetic foot disease, "the renal-diabetic foot" which is characterized by the most severe pattern of PAD and predisposes to a very complex condition to be managed in comparison to diabetic patients with preserved renal function.

The evolution of diabetic foot disease invites physicians to define day by day new strategies for managing these complex patients and improve their short and long-term outcomes.

MS02-4

1 foot or 2%? A journey to understanding the globe's diabetes footprint

Dr Peter Lazzarini¹

¹Queensland University of Technology, , Australia

No abstract available

MS03-1

Case presentation

Dr Edgar Peters¹, Dr Jeff van Baal²

¹Amsterdam UMC, The Netherlands, ²ZGT Almelo and Wender Hengelo, The Netherlands

No abstract available

MS03-2

Infectious diseases aspects

Prof. Ilker Uçkay¹

¹Balgrist University Hospital, Switzerland

No abstract available

MS03-3

Radiology aspects

Prof. Mario Maas¹

¹Amsterdam UMC, The Netherlands

No abstract available

MS03-4

Foot surgery / podiatry aspects

Prof. John Steinberg¹

¹Georgetown University School of Medicine, , United States

No abstract available

MS03-5

Vascular intervention aspects

Prof. Robert Fitridge¹

¹*The University of Adelaide, , Australia*

No abstract available

MS03-6

Geriatric and Internal medicine aspects

Prof. Frank Nobels¹

¹*OLV Ziekenhuis Aalst, Belgium*

No abstract available

MS04-1

Diabetic foot ulceration as a metaphor: the patient perspective

Mr Andy Lavender¹
¹NHS, United Kingdom

No abstract available

MS04-3

How can technology improve patient adherence

Prof. Bijan Najafi¹
¹Baylor College of Medicine

No abstract available

MS04-4

Which psychological interventions can improve adherence

Prof. Khalida Ismail¹
¹King's College London, United Kingdom

No abstract available

MS04-5

Psychological barriers that impair self-care

Prof. Francois Pouwer¹
¹University of Southern Denmark

No abstract available

MS05-1

Current treatment of type 1 and 2 diabetes in 2022

Prof. Max Nieuwdorp¹

¹*Amsterdam UMC, The Netherlands*

No abstract available

MS05-2

Glycemic control and other strategies to prevent lower extremity complications of diabetes

Prof. Ed Boyko¹

¹*University of Washington, United States*

The defining metabolic abnormality in diabetes mellitus is hyperglycemia and this abnormality gives rise to multiple complications of this metabolic disorder. I will review the evidence for the association between hyperglycemia and diabetes complications with a focus on foot complications in general and contributors to it such as neuropathy and peripheral artery disease. The evidence available includes many observational studies and meta-analyses based on this research. Some available research demonstrates an exponential relationship between glycemia and complication risk. For example, a 1% increment in HbA1c from 10% to 11% results in a greater increase in a complication risk than a 1% increment in HbA1c from 7% to 8%. These results argue that treatments to reduce glycemia will result in a decrease in diabetes complications. This has been confirmed in randomized controlled trials, most convincingly in the Diabetes Control and Complications Trial (DCCT) in patients with recent onset type 1 diabetes which demonstrated reductions in risk of retinopathy, nephropathy, and neuropathy progression with intensive versus conventional insulin treatment. The DCCT, however, did not designate foot complications as a trial outcome leading to challenges in assessing foot outcomes, in particular risk of diabetic foot ulcer. The results of a recent analyses of the DCCT and one other randomized controlled trial of glycemic control (Action to Control Cardiovascular Risk in Diabetes – ACCORD) that focus on foot outcomes will be reviewed. In addition, the results of these trials on factors affecting foot outcomes other than glycemic control will be discussed.

MS05-3

Advances in the prevention of modifiable risk-factors: a paradigm shift to foot-related exercises

Prof. Isabel Sacco¹

¹*University of São Paulo, Brazil*

Compiled data from Global Burden of Diseases (1990 and 2019), considering 25 health conditions that could benefit from rehabilitation, indicated that the top condition for almost 30 years has been musculoskeletal disorders; one in every three people worldwide would benefit from rehabilitation. Diabetes is pointed as the fourth-most common cause of disability globally, being considered as well as a chronic

musculoskeletal disorder, affecting approximately 131 million people with lower-extremity complications, including 105.6 million with diabetic peripheral neuropathy (DPN). Diabetes progression and DPN compromise musculoskeletal function, leading to limitations in everyday physical functioning; thus, there is a strong need for further research about rehabilitation strategies for musculoskeletal dysfunctions. Disease-modifying medications for improving glycemic control and therapeutic strategies for changing clinical outcomes are the first-line approach for reducing the incidence of DPN-related complications, since these strategies seem to be more pragmatic for clinical practice. However, multifactorial risk reduction strategies, including exercise rehabilitation and education, can be second-line approaches for preventing the development and progression of DPN-related musculoskeletal and sensorial deficits. Interventions that aim to prevent foot ulcers, such as with footwear and insoles, podiatric care and self-management, do not seek to reverse the foot dysfunctions that have led to the ulcer. These interventions help prevent foot ulcers, however, they do not work for mitigating the risk factors that caused these ulcers, such as loss of protective sensation, higher mechanical stress, reduced range of motion, foot strength and function. An intervention that does target these factors is a foot-ankle exercise program. Given the potential effects of foot-ankle exercise programs on ulcer risk factors, research in this field has been growing in the past decade, and the research findings provided the foundation for the International Working Group on Diabetic Foot rehabilitation strategy recommendations, such as foot- and mobility-targeted exercises, to mitigate risk factors for foot ulceration. This presentation summarizes the current knowledge about the musculoskeletal deficits and biomechanical alterations caused by DPN; shows the effects of different exercise therapy strategies, including foot-related exercises, balance training, and weightbearing and resistance exercises, on different DPN-related outcomes; discusses the main strategies and protocols of therapeutic exercises for foot-ankle deficits; and shows further efforts in exploiting the applicability of assistive technologies to improve the adherence to an exercise program.

MS05-4

Mind the foot: psychology of a recurrent ulcer

Dr Loretta Vileikyte¹

¹University of Manchester, United Kingdom

No abstract available

MS05-5

Screening for and diagnosing polyneuropathy in daily practice

Prof. Nikolaos Papanas¹

¹Democritus University of Thrace, Greece

No abstract available

MS06-1

Why & how to set up a nationwide registry: lessons learned?

Prof. Graham Leese¹

¹Ninewells Hospital and Medical School, United Kingdom

No abstract available

MS06-2

How can I get my colleagues doing what they say they are already doing?

Prof. Ralf Lobmann¹

¹Klinikum Stuttgart, Germany

No abstract available

MS06-3

How to manage difficult leadership, toxic settings and turf wars

Prof. Mark Kramer¹

¹Amsterdam UMC, The Netherlands

No abstract available

MS06-4

What can we learn from observational research and what not

Prof. Coen Stehouwer¹

¹Maastricht UMC+, The Netherlands

No abstract available

MS06-5

Who makes a diabetic foot team successful: forty years of experience

Prof. Michael Edmonds¹

¹King's College Hospital, , United Kingdom

No single discipline can successfully look after the person with diabetic foot problems and thus no discipline alone makes a diabetic foot team successful. Effective management needs the expertise of a multidisciplinary team which provides integrated care focused in a diabetic foot clinic. Members of the team comprise podiatrist, physician, nurse, orthotist, radiologist, and surgeon, including vascular surgeon, orthopaedic surgeon, plastic and podiatric surgeon. Other important members are the vascular scientist, microbiologist, pharmacist, physiotherapist, occupational therapist, dermatologist, and psychologist. The patient is an important member of the team and can provide useful feedback information as a service user.

The diabetic foot team should work closely together, within the focus of the diabetic foot clinic, but also in inpatient areas including wards, operating theatres, and angiography suites. It also meets regularly for ward rounds and X-ray conferences. Everyone needs to be clear on their own role and be sure about the role of other team members. Specific personnel will vary according to the health care system and country. However, principles of care are universal and should be upheld by the particular personnel in different health care systems.

In the UK, podiatrists are the gatekeepers of the clinic, making initial assessments on both emergency patients and those with planned appointments, before ensuring that appropriate members of the multidisciplinary team jointly assess and treat the patient.

The multidisciplinary team works optimally under a good leader who must be passionate about the care of the diabetic foot and be able to motivate and encourage patients and health care professionals, acting as 'local champion' for diabetic foot care. The leader must be able to co-ordinate interlinking pathways of care and drive the work of the team. Different disciplines may be best positioned to take on leadership roles but enthusiasm and belief in the importance of diabetic foot care is the overriding prerequisite to lead the diabetic foot team.

The diabetic foot and its progression may seem difficult and complex but it is not an impossible condition, and with abundant energy, skill, patience, enthusiasm, and coordination of expert multidisciplinary treatment, surprisingly good results can be achieved.

MS07-1

Oxygen to the wound

Prof. Magnus Lundahl¹

¹Skane University Hospital, Sweden

No abstract available

MS07-2

Comments & Discussion

Prof. Fran Game¹

¹University Hospitals of Derby and Burton Nhs Foundation Trust, United Kingdom

No abstract available

MS07-3

Medial artery calcification: an innocent bystander?

Dr Roberto Ferraresi¹

¹San Carlo Clinic, Italy

Medial artery calcification (MAC) is characterized by the presence of diffuse calcium deposits along the medial layer of the arteries resulting in a typical “railroad-track” appearance on plain X-ray imaging [1].

In the last decades, it has been extensively shown that MAC is strongly associated with cardiovascular events, death, chronic limb threatening ischemia (CLTI), and can be considered a potential risk factor for lower limb amputations [2]. We found a strong association between MAC and small artery disease (SAD), a condition defined by the occlusion of small below-the-ankle arteries and leading to CLTI [3].

SAD and MAC are two sides of the same coin, a single non-atherosclerotic disease spreading to the entire arterial tree and jeopardizing the fate of the limb and of the patient.

Medicine has spent the last 50 years fighting big artery disease (BAD) and considering SAD-MAC an occasional and unfortunate “no-option” condition. BAD is considered an atherosclerotic, plaque-based disease, developing from an initial lipid deposition in the intima, and treatable with many powerful weapons: statins, antiplatelets, angioplasty, bypass etc. Today, fueled by age, diabetes and hemodialysis, we are facing an epidemic of predominantly SAD-MAC-CLTI patients for whom revascularization is not possible or with limited results, and the role of drugs is unclear. It is time to consider SAD-MAC the new target of our efforts and develop new more appropriate weapons.

References

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MS07-4

Comments & Discussion

Prof. Robert Hinchliffe¹

¹University of Bristol, United Kingdom

No abstract available

MS07-5

Foot temperature monitoring and plantar pressure measurements

Dr Jaap van Netten¹

¹Amsterdam UMC, location AMC, The Netherlands

Two key interventions in diabetes-related foot ulcer prevention are foot temperature monitoring and plantar pressure measurements to guide treatment. For both interventions, positive results have been shown in randomized controlled trials. However, interpretation of these trials is not as straightforward as it might look. Every reason to take a closer look at them during this “Critical Reviews” mini-symposium.

To start, I will discuss mechanisms that are associated with diabetes-related foot ulceration. If either foot temperature monitoring or plantar pressure measurements is to help prevent foot ulcers, the outcomes measured with these systems should be associated with mechanisms that cause foot ulcers. For both, however, this can be questioned.

For the trials on foot temperature specifically, I will further reflect on both the multiple systems available and their differences, and the unintended outcomes associated with daily monitoring. What's the price patients and clinicians are willing to pay to prevent foot ulcers?

For the trials on plantar pressure measurements, I will critically review the evidence and their sometimes overly optimistic interpretations, and the relevance of adherence – and what this means for daily clinical practice.

Finally, implications for both clinical practice today, and future research tomorrow will be discussed.

MS07-6

Comments & Discussion

Prof. Lawrence Lavery¹

¹The University of Texas, United States

No abstract available

MS07-7

Topical antimicrobial treatment and prevention of infection

Prof. Ilker Uçkay¹

¹Balgrist University Hospital, Switzerland

No abstract available

MS07-8

Comments & Discussion

Prof. Eric Senneville¹

¹Gustave Dron Hospital, France

No abstract available

MS08-1

Diabetic foot complications: a key role for surgery

Dr Robert Frykberg¹

¹Diabetic Foot Consultants, United States

Surgery for acute and chronic diabetic foot problems has long been an integral component of care. While partial foot amputations remain as important diabetic limb-salvaging operations, foot-sparing reconstructive procedures have become equally important strategies to preserve the functional anatomy of the foot while addressing infection, chronic deformities, and ulcerations. A classification of types of diabetic foot surgery is discussed in accordance with the soft tissue status and acuity of the presenting foot problem. This brief overview from the International Association for Diabetic Foot Surgeons (IADFS) describes common conditions best treated by surgical interventions, as well as specific indications. While techniques and indications continue to evolve, effective surgical management of the diabetic foot remains an integral component of care as well as for the prevention of recurrent ulceration.

MS08-2

Diabetic foot infections: surgery is not adjunctive!

Dr Giacomo Clerici¹

¹Ospedale San Carlo, Italy

No abstract available

MS08-3

Diabetic foot osteomyelitis - When surgery is necessary

Dr Arun Bal¹

¹SL Raheja Hospital, India

No abstract available

MS08-4

Critical limb threatening ischemia - best approaches for management 2023

Dr Luuk Smeets¹

¹Rijnstate Ziekenhuis Arnhem, The Netherlands

According to the guidelines and recent publications insight will be given on the treatment of limb threatening ischemia, and thus amputation prevention.

Both endovascular and “classic” open and hence hybrid procedures will be addressed; indications, techniques, limitations and pit falls.

The listener will be able to understand the different techniques and know how to treat or to whom to refer his/her patient with limb threatening ischemia.

MS08-5

Diabetic Charcot foot and surgical management principles

Prof. Venu Madhav Kavarthapu¹

¹King's College Hospital, United Kingdom

No abstract available

MS09-1

What can be done to overcome the unsustainability of DF education programmes in developing countries?

Dr Hermelinda Pedrosa^{1,2}

¹Endocrinology Unit / Research Centre – Taguatinga Hospital, Secretariat of Health, Brasilia, Brazil, ²D-FOOT International, Brazilian Diabetes Society, International Diabetes Federation

The major differences between low and high resource countries are investment in research, financial availability for preventative programmes, organization of health systems, priority to train and educate health care professionals – all of them lacking in different levels in low and middle resources countries. Non-communicable diseases (NCDs) play a role in morbidity and mortality through the coexistence with infectious diseases what makes it difficult to balance investment in screening and prevention of diabetic foot and its complications.

Advances in both scenarios have been achieved though not available into daily clinical practice, even in the European scenario as it has been shown by the Eurodiab study.

The pioneer Project to train HCP and doctors implemented in Brazil in the nineties until the mid-2000s was a success while the Ministry of Health support lasted: over 70 outpatient clinics were set up there. The Step by Step, inspired in the Brazilian action and introduced in Tanzania, changed the reality in India, China including developed countries from 2003 onwards. Successful educational and training examples have been reported in developing countries such as Argentina, Brazil, Chile, Colombia, India, Peru, Romania, Senegal among others.

A joint action implemented by IWGDF and IDF, the Train the Foot Trainers (TtFT), whose 1st edition was held in Brasilia (2012) and the last 7th edition in Chennai (2023), rescued the training programme after the COVID motivating HCP from IDF SEA region.

And, what about sustainability?

Sadly, in developing countries public policies are not of state policy but of government. This leads to high turnover of actions, HCP and physician involvement which prevent links of primary, secondary and more complex care and proper protocol insertion and maintenance. The result is unsustainability.

How to circumvent it?

Turning into real practice the policies of WHO linked to IDF towards DFU and amputations which have been endorsed by D-FOOT. For that a Call to Action could be a strategy to be emerged in the Hague so that Olympic Games of Diabetic Foot would reach more players – policy makers mainly - and ensure committed support to reduce the devastating diabetic foot impact.

MS09-2

Updates on initiatives from the Asia Pacific region

Prof. Harikrishna Nair¹

¹Kuala Lumpur Hospital, Malaysia

Diabetes is a pandemic in the Asia Pacific region which is the home to 4.7 billion people. Malaysia records 25% of the population having Diabetes Mellitus (Zanariah et al 2020). Diabetic foot complications are a major complication.

Various programmes have been launched and will be highlighted such as prevention initiatives and early diagnosis to enable early treatment or intervention to save lives and limbs. The save lives and

save limbs initiative was stressed upon and involves initiatives such as courses, publicity to the public, campaigns, medical camps, wound fiesta, publications and others. Patients also spoke about their experiences and we put it up in the websites in different languages.

Meanwhile, for early detection of diabetic peripheral neuropathy we started a pilot project in 50 health clinics and GP setups with a proper referral pathway and the diagnostic foot assessment kits and charts to support the physicians and nurses. It was a huge success whereby we manage to screen many patients who were then referred to us for advance management.

MS09-3

Learning from each other to generate effective solutions

Ms Mariam Botros¹

¹Wounds Canada, Canada

No abstract available

MS09-4

Tackling the diabetic foot burden in low income countries

Dr Zulfiqarali Abbas¹

¹Muhimbili University of Health and Allied Sciences, Tanzania, United Republic of

Diabetes mellitus is one of the most common non-communicable diseases globally. In Africa, rates of diabetes are increasing, so there is a parallel increase in foot complications. Peripheral neuropathy is the main risk factor for foot ulceration in people with diabetes in developing nations, but the peripheral arterial disease is also increasing in number owing to the change in lifestyle and increasing urbanization. Ulcerations arising from peripheral neuropathy, peripheral arterial disease, and trauma are highly susceptible to secondary infection and gangrene and are hence associated with increased morbidity and mortality.

Government funding is very limited in many developing countries, and diabetes and its complications impose a heavy burden on health services. In particular, the outcomes of foot complications are often poor, and this is the result of various factors, including a lack of awareness of the need for foot care among patients, relatives, and health care providers; relatively few professionals with an interest in the diabetic foot and with the training to provide specialist treatment; non-existent podiatry services; long distances for patients to travel to the clinic; delays among patients in seeking medical care, or the late referral of patients for specialist opinion; and lack of awareness of the importance of a team approach to care, and the lack of training programs for health care professionals. Many of these can, however, potentially be tackled without exorbitant spending of financial resources.

In conclusion, cost-effective educational efforts should be targeted at both healthcare workers and patients. These include the implementation of sustainable training programs for healthcare professionals with a special interest in foot care and focusing to disseminate foot care information, on the prevention and management of diabetic foot, to other healthcare professionals and to patients. An interdisciplinary team or multidisciplinary approach is needed for the management of diabetic foot. Patients presenting early at a less severe stage will definitely lead to a reduction in morbidity and death rates.

MS09-5

Prevention of diabetes related amputations in India

Prof. Vijay Viswanathan^{1,2}

¹M.V. Hospital for Diabetes, India , ²President of Prof.M.Viswanathan Diabetes Research Centre, India

India has a high burden of people with diabetes and diabetic foot complications, which often leads to amputation. There are several factors causing foot ulcer in people with diabetes in addition to neuropathy and peripheral vascular disease. A considerable differences exist between patients in Western countries and those in developing countries in risk factors and clinical presentation of foot problems. Diabetes related foot problems in India can be attributed to neuropathy and progressive infection while it is neuro - ischemic vascular in origin in the developed nations. One of the socio-cultural factors is the barefoot walking /Improper footwear that remains as an important reason for the development of foot ulcer in India. Evidence suggests that appropriate foot wear and foot care education plays an important role in preventing diabetic foot problems. There is a huge economic burden and also productivity loss in the society due to diabetes related complications. Early identification of risk factors associated with foot ulcer may prevent amputation. Networking and training healthcare professionals and mass screening for high risk feet helps in identifying people with high risk foot and prevent diabetic foot ulcer and amputation. A recent survey conducted as part of the “Save the Feet and Keep Walking Campaign” by the Research Society for the Study of Diabetes in India (RSSDI, the larger scientific network for diabetes in India) has showed that nearly one-fourth of people with diabetes in India had high risk feet. A framework for early screening and multi-factorial interventional strategies are required to control the progression of the condition, increasing life expectancy, and economic burden. Building and promotion of multi-disciplinary team and bringing in all the facilities under one umbrella and a referral system in place have played a major role in limb salvage in India.

MS10-1

Global disability burdens of diabetes-related lower extremity complications

Dr Peter Lazzarini¹

¹School of Public Health and Social Work - Queensland University of Technology, , Australia

No abstract available

MS10-2

Topical Wound Oxygen: The TWO2 Study

Dr Robert Frykberg¹

¹Diabetic Foot Consultants, United States

OBJECTIVE

Topical oxygen has been used for the treatment of chronic wounds for more than 50 years. Its effectiveness had remained disputed due to the limited number of robust high-quality investigations. The aim of this study was to assess the efficacy of multimodality cyclical pressure Topical Wound Oxygen (TWO2) home care therapy in healing refractory diabetic foot ulcers (DFUs) that had failed to heal with standard of care (SOC) alone.

RESEARCH DESIGN AND METHODS

Patients with diabetes and chronic DFUs were randomized (double-blind) to either active TWO2 therapy or sham control therapy - both in addition to optimal SOC. The primary outcome was the percentage of ulcers in each group achieving 100% healing at 12 weeks. A group sequential design was used for the study with three predetermined analyses and hard stopping rules once 73, 146, and ultimately 220 patients completed the 12-week treatment phase.

RESULTS

At the first analysis point, the active TWO2 arm was found to be superior to the sham arm, with a closure rate of 41.7% compared with 13.5%. This difference in outcome produced an odds ratio (OR) of 4.57 (97.8% CI 1.19, 17.57), $P = 0.010$. After adjustment for University of Texas Classification (UTC) ulcer grade, the OR increased to 6.00 (97.8% CI 1.44, 24.93), $P = 0.004$. Cox proportional hazards modeling, also after adjustment for UTC grade, demonstrated >4.5 times the likelihood to heal DFUs over 12 weeks compared with the sham arm with a hazard ratio of 4.66 (97.8% CI 1.36, 15.98), $P = 0.004$. At 12 months post enrollment, 56% of active arm ulcers were closed compared with 27% of the sham arm ulcers ($P = 0.013$).

CONCLUSIONS

This sham-controlled, double-blind randomized controlled trial demonstrates that, at both 12 weeks and 12 months, adjunctive cyclical pressurized TWO2 therapy was superior in healing chronic DFUs compared with optimal SOC alone.

MS10-3

Geospatial mapping and data linkage uncovers variability in outcomes of foot disease

Prof. Jim Woodburn¹

¹*School of Health and Life Sciences - Glasgow Caledonian University, United Kingdom*

No abstract available

MS10-4

Flexor tendon tenotomy of the diabetic foot

Mr Jonas Askø Andersen¹

¹*Steno Diabetes Center Copenhagen (Region Hovedstaden), Denmark*

Objective: The aim of the studies was to evaluate effects of needle flexor tendon tenotomy treatment of the diabetic hammertoe deformity.

Research Design and Methods A multicenter randomized controlled trial of individuals with diabetes, and ulcers or impending ulcers associated with hammertoes, performed between 1st of November 2019 and 31st of March 2021. Participants were stratified on the presence of ulcer, into individuals with ulcers and individuals with impending ulcers. Participants were randomized to tenotomy and standard non-surgical treatment or standard non-surgical treatment alone. Primary outcomes were time to ulcer healing and progression from impending ulcer to active ulcer.

A sub study was performed to assess the effects of tenotomy treatment on standing balance and plantar pressure of treated individuals. A sub-group of the randomized individuals were invited to examination of standing balance and barefoot plantar pressure measurement before and three months after tenotomy.

Results: Of 224 screened individuals, 95 (59.0% male) were included. The mean follow-up was 291 (± 70) days, 28 (29.5%) had type 1 diabetes, mean diabetes duration was 20 (13-26) years and mean age was 67.7 (± 9.8) years. Of the included participants 16 had ulcers, of whom eight were randomized to intervention. Of the remaining 79 individuals with impending ulcers, 39 were randomized to intervention.

For participants with ulcers, healing rates favored tenotomy (100% vs 37.5%, $p=0.026$) as did time to ulcer healing ($p=0.04$). For individuals with impending ulcers, incidence of progression to an active ulcer was lower (1 vs 7, $p=0.028$) and number of ulcer-free days were higher ($p=0.043$) in the tenotomy group. No serious adverse events were recorded.

Of the 95 included participants 48 participants were included in the sub-study. The standing balance examination showed no effects of tenotomy on the standing balance. The plantar pressure examination showed significantly reduced plantar pressure in the toe regions from before (205.6 kPa (152.0 – 289.1)) compared to three months after tenotomy treatment (61.3 kPa (39.1 – 100.5)) ($p>0.001$).

Conclusion: This randomized study showed that the simple procedure of needle flexor tendon tenotomies was effective and safe when treating and preventing ulcers associated with the diabetic hammertoe deformity.

MS11-1

Choosing the right study design

Prof. Ed Boyko¹

¹University of Washington, United States

Multiple study designs exist. This symposium will provide guidance on how to best select a study design to successfully conduct your research. The focus will be on clinical and epidemiologic research, but the principles discussed will apply to some types of non-human research. Research in general can be divided into two categories, experimental (e.g., randomized controlled trial) and observational. Experimental research will provide the strongest evidence regarding causation since the investigator can design a comparison between treated and untreated groups that differ only by whether the treatment is received. A randomized controlled trial, for example, assigns treatment based on a random process, such that known and unknown factors associated with the outcome are likely to be distributed equally between treated and untreated groups by chance. The use of a control group also permits assessment of treatment effect compared to the background rate of recovery (or harm) occurring without treatment. Since experimental designs provide the strongest causal evidence, this is the preferred design to use when evaluating new treatments and is often the design required by regulators for new treatment approval. Experimental designs can be used not only for new treatments but also for assessment of diagnostic and screening strategies. Experimental research presents multiple challenges such as high costs and recruitment challenges. Also, it cannot be used to assess exposures potentially linked to poor health outcomes (e.g., tobacco use or radiation), and may not be feasible when assessing important but infrequent outcomes such as mortality or amputation due to the large sample size required. Observational research can be used in these instances but provides weaker support for causation due to the potential for residual confounding by unmeasured factors. However, statistical adjustment can be performed for measured factors thereby reducing bias due to their influence on the estimate of exposure effect. Multiple types of observational study designs will be discussed along with their merits including cohort, case-control, case-cohort, and emulated clinical trial. Participants will gain an understanding of the spectrum of study designs and how to select the design most likely to achieve their research objectives.

MS11-2

What makes a wound healing study successful

Prof. Fran Game¹

¹University Hospitals of Derby and Burton Nhs Foundation Trust, United Kingdom

No abstract available

MS11-3

Application of artificial intelligence (AI) and machine-visioning to wound care

Dr Sheila Wang¹
¹McGill University, Canada

Diabetic foot ulcers occur in 16% of patients with diabetes in North America and Europe; these wounds are difficult to treat and cause significant disability for those afflicted.

We present the clinical applications of an AI-powered, digital wound care platform technology that empowers both clinicians and patients with easy-to-capture, automatic and accurate wound measurements, tissue classification and tracking of wound healing anywhere on the body. The software application provides autonomous measurements with an accuracy of 95-98% and an inter-rater reliability of over 99% between expert and novice users. Real-world outcomes include 14% reduction in re-hospitalization rate, 69% reduction in the cost of advanced wound care supplies per patient and 77% reduction in pressure injury prevalence.

Our imaging technology, captured in a pocket-sized, multispectral diagnostic imaging device, has been adopted by over 4000 healthcare organizations in all 50 states across the USA and 7 Canadian provinces.

MS11-4

Brilliant failures: the road to innovative research

Prof. Paul Iske¹
¹Maastricht University School of Business and Economic, The Netherlands

No abstract available

MS11-5

What are relevant outcomes and how should they be measured

Prof. Robert Hinchliffe¹
¹University of Bristol, United Kingdom

No abstract available

MS12-1

Introduction on behalf of World Federation of Vascular Surgeons

Prof. Philippe Kolh¹
¹CHU de Liège, Belgium

No abstract available

MS12-2

Distal bypass Olympics in Japan- virtual training in 2022

Prof. Nobuyoshi Azuma¹
¹Asahikawa Medical University, Japan

No abstract available

MS12-3

Relevant outcomes in PAD

Prof. Robert Hinchliffe

No abstract available

MS12-4

Techniques and challenges in management of vascular and foot disease in patients with diabetes

Prof. Palma Shaw¹
¹Upstate Medical University, United States

No abstract available

MS12-5

Managing peripheral artery disease and diabetic foot ulceration in indigenous people

Prof. Viv Chuter¹

¹Western Sydney University, Australia

No abstract available

MS12-6

How to manage no-option patients with chronic limb threatening ischemia and diabetic foot ulceration

Dr Roberto Ferraresi¹

¹Peripheral Interventional Unit - San Carlo Clinic, Italy

About 20% of patients with chronic limb threatening ischemia (CLTI) are considered not suitable for any type of traditional revascularization due to severe unreconstructable arterial disease [1]. Outcomes of these patients are poor, with high rates of major amputation, low quality of life and higher death rates relative to other patients with CLTI [1]. Thus, the need for alternative treatment strategies in “no-option” CLTI patients is pressing.

Lumbar sympathectomy, stem-cell therapy, prostanoid infusion and spinal cord stimulation have been proposed, but several reviews confirmed absent or poor benefit of these therapeutic approaches.

Many studies demonstrated that in no-option CLTI patients foot vein arterialization has good results in terms of limb salvage and wound healing [2]. In the last years, a totally percutaneous approach has been demonstrated to be safe, reproducible and effective for limb salvage in these no-option patients and new prospective multicenter studies are ongoing [3 4 5].

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3. Kum, S. et al. Midterm Outcomes From a Pilot Study of Percutaneous Deep Vein Arterialization for the Treatment of No-Option Critical Limb Ischemia. *J. Endovasc. Ther. Off. J. Int. Soc. Endovasc. Spec.* 24, 619–626 (2017).
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WS01: Workshop Management of edema

Dr Miriam Loots¹

¹ Lootskliniek, The Netherlands

No abstract available

WS02: Workshop Complex diabetic foot infections cases (in collaboration with IADFS)

Dr Giacomo Clerici¹, Prof. Venu Madhav Kavarthapu², Prof. Eric Senneville³

¹ Policlinico di Abano e Terme (Padua) and Policlinico di Sassari (Sassari), Italy, ² Health Care - NHS, United Kingdom, ³ Gustave Dron Hospital, France

Complex diabetic foot infection presentations, including diabetic foot attacks, require expert multidisciplinary care that often includes a combination of medical, infection control, surgical and offloading components. This workshop includes presentations from a group of diabetic foot experts and covers various clinical case scenarios of complex diabetic foot infections. The delegates will have an opportunity to identify the spectrum of infection presentations, identify the spectrum of infection presentations, receive an update on current antimicrobial therapy, understand the well-established as well as emerging surgical treatment methods, and analyse the current treatment outcomes.

WS03: Workshop Shoes: from science to art

Dr Gustav Jarl¹, Mr Rob Verwaard²

¹ Region Örebro / Örebro University, Sverige, ² Wittepoel, Netherlands

For a long time prescription of footwear for people with diabetes was more of an art than a science. During the last decades, the evidence base for therapeutic footwear has expanded. However, research results from groups of patients can be challenging to transfer to single patients with unique needs. In this workshop, we will discuss how to implement research findings on footwear in clinical practice.

WS04: Workshop Radiology: pearls and pitfalls

Prof. Mario Maas¹

¹ Amsterdam UMC, Amsterdam, The Netherlands

Acute Charcot disease? Osteomyelitis? Fracture? Response on therapy? These are the questions we frequently encounter when reading radiology images of diabetic feet. In order to aid the treating clinician we choose the appropriate technique to solve the problem. During a case-based open and friendly approach the role of frequently used imaging techniques will be illustrated in identifying various pathologies that can occur in patients with diabetic foot complications. The audience will learn about the strengths of various techniques, are taught in assessing conventional radiology and MRI is made easy...well almost!

WS05: Workshop Podiatry: a live diabetic foot clinic

Ms Ingrid Ruys¹, Ms Lian Stoeldraaijers²

¹ Maxima Medisch Centrum, The Netherlands, ² Dutch Association of Diabetes Podiatrists, The Netherlands

No abstract available

WS06: Workshop Workshop Diabetic foot disease in end-stage renal disease

Prof. Joseph Mills¹, Dr Jeff van Baal²

¹ Baylor College of Medicine, US, ² ZGT, The Netherlands

No abstract available

WS07: Workshop Prevention and education

Prof. Khalida Ismail¹, Mr Andy Lavender², Ms Anne Rasmussen³

¹ King's College London, United Kingdom, ² NHS, United Kingdom, ³ Steno Diabetes Centre Copenhagen, Denmark

No abstract available

WS08: Workshop Casting techniques: an instructional course

Prof. David Armstrong¹, Mr Ron Slegers²

¹ Southwestern Academic Limb Salvage Alliance, Keck School of Medicine of USC, United States,

² Maastricht University Medical Center, Netherlands

"It's not what you put on, but what you take off."

Strategies for focused offloading in the diabetic foot

The basic etiology of neuropathic diabetic foot wounds involves pressure times cycles of repetitive stress leading to failure of skin and soft tissue. The central tenet of any treatment plan addressing neuropathic diabetic foot wounds is appropriate debridement of non-viable tissue coupled with adequate pressure relief (offloading). While numerous advances have been made in the treatment of diabetic foot wounds, none will succeed without addressing effective offloading of damaging stresses. This workshop will, in a highly interactive manner, discuss a practical, hands-on approach toward pressure offloading using a variety of removable and irremovable techniques.

WS09: Workshop Prevention and education

Prof. Lawrence Lavery¹, Ms Ellie Lenselink²

¹The University of Texas Southwestern Medical Center, United States, ²Haaglanden Medical Centre, The Netherlands

The workshop NPWT will start with an overview of the literature and the evidence of the treatment (discussed by Professor Lawrence Lavery).

When that has been done, a presentation will be held on how to apply NPWT with tips and pitfalls. The most important part of the workshop is live practice by the participants with different devices of NPWT.

WS10: Workshop Translating guidelines into real world care (in collaboration with WFVS)

Dr Roberto Ferraresi¹, Prof. Robert Fitridge²

¹San Carlo Clinic, Italy, ²The University of Adelaide, Australia

According to the Global Vascular Guidelines, every treatment of patients with chronic limb threatening ischemia (CLTI) should be done according to the PLAN concept of evidence-based revascularization (EBR) that stresses a structured management approach based on Patient risk, Limb severity and Anatomic pattern of disease, in that order of priority. The authors believe that adequate stratification along these three independent axes is clinically relevant and of fundamental importance to improve evidence quality and to achieve EBR for patients with CLTI.

WS11: Workshop Bone biopsy: an instructional course

Dr Edgar Peters¹

¹Amsterdam UMC, The Netherlands

In this workshop, we will discuss the pro's and con's of and indications for a percutaneous bone biopsy for diabetic foot osteomyelitis. You will get an opportunity to perform a bone biopsy on animal cadaver specimens (swine). You will see that a percutaneous bone biopsy does not require advanced surgical skills.

WS12: Workshop Functional anatomy and biomechanics of the foot

Dr Robert Frykberg¹, Mr Wilbert van Laar²

¹Diabetic Foot Education, LLC, United States, ²Alrijne Ziekenhuis, The Netherlands

This workshop will focus on Foot Deformities that place the High Risk Foot in danger of ulceration or amputation. Understanding the role for deformities in this regard, their identification, and their consequences will allow the attendee to better address patients' needs. Whether focusing on Prevention Protocols or Treatment Protocols for active ulcers, we address strategies for ameliorating the high plantar foot pressures that predispose the neuropathic patient to these potentially limb-threatening complications.

WS13: Workshop Treatment of acute Charcot neuro-osteoarthropathy

Prof. Michael Edmonds¹, Dr Katherine Raspovic², Prof. Dane Wukich³

¹ King's College Hospital, United Kingdom, ² University of Texas Southwestern Medical Center, United States, ³ UT Southwestern Medical Center, United States

In this workshop, the pathophysiology and diagnosis of acute Charcot foot, non-operative treatment of acute Charcot and surgical treatment of acute Charcot will be discussed. The early presentation of the acute Charcot foot will be considered and diagnostic investigations (Xray, MRI and SPECT- CT) will be described. Patients with suspected acute Charcot foot should be promptly offloaded with a below knee cast. Surgery may be necessary for severe deformity in the acute stage.

WS14: Workshop When and how to choose dressings, advanced wound healing interventions and maggots

Prof. John Steinberg¹, Dr Gwendolyn Cazander²

¹ Georgetown University School of Medicine, United States, ² Ikazia Hospital, Rotterdam, Nederland

When and how to choose dressings and advanced wound healing interventions can be a very challenging dilemma. This session will discuss the wound environment and how we can interact with it to yield wound improvement and even wound closure.

Maggot therapy is successfully used to treat complex, infected wounds, including diabetic ulcers. Mechanisms of action will be discussed, such as biofilm reduction and immunologic inhibition. Moreover, there will be a demonstration of the application of live larvae on wounds. No abstract available

WS15: Workshop Treating the whole geriatric patient and not the hole in the patient

Prof. Ralf Lobmann¹, Prof. Frank Nobels²

¹Klinikum Stuttgart, Germany, ²BVBA Dr F. Nobels, Belgium

In older and geriatric patients the treatment of DFU poses extra challenges. And our DFU population gets older and older!

Co-morbidities, polymedication, wishing to stay independent, dementia, ... present extra challenges. Offloading, revascularization, wound care, pharmacological treatment, ... are more individual and specific. In this course the broad spectrum of typical problems of older people with DFU will be presented and cases will be discussed (own experiences are welcome to discuss).

Out-of-the box thinking to provide patient centered care will be put central.

WS16: Workshop How local factors can impact management of the ischemic diabetic foot in 2023 (in collaboration with WFVS)

Prof. Nobuyoshi Azuma¹, Prof. Viv Chuter², Prof. Palma Shaw³

¹Asahikawa Medical University, Japan, ²Western Sydney University, Australia,

³Upstate Medical University, United States

Management of the ischemic diabetic foot can vary across disciplines as well as the globe. Local factors impact healing and ultimately limb loss in this vulnerable population. Decision making regarding the assessment, decision making, and treatment modalities will be discussed not only in the context of the established guidelines but also considering special socioeconomic or cultural circumstances in which the standard algorithms cannot be applied. Case based presentations and interactive discussion will illustrate challenges and solutions to address this problem.

WS17: Workshop Footwear and offloading when resources are limited (in collaboration with D-Foot International)

Prof. Klaas Postema¹, Prof. Vijay Viswanathan²

¹University Medical Center Groningen, The Netherlands, ²M V Hospital for Diabetes, India

After the presentations there will be questions for an interactive discussion about the materials used in difficult possibilities, what kind of shoe adaptations, how to promote adherence and how to deal with the problem of patients who cannot wear footwear inside. The goal is to learn from each other creative solutions.

WS18: Workshop Foot infections in hot and humid environments (in collaboration with D-Foot International)

Dr Zulfikarali Abbas¹, Prof. Ilker Uçkay²

¹MUHAS / AMC, Tanzania, ²Balgrist University Hospital, Zürich, Switzerland

Diabetic Foot Ulcers in developing countries frequently become infected, but the health systems are not equipped to conduct the culture and the sensitivity tests required for prescribing appropriate antibiotic treatment for every infection (DFI). Antibiotic stewardship programs for DFIs, at every level of health care, are necessary, but must be adapted to the financial and practical realities of the regions; and the epidemiology of the causative pathogens. The application of the point-of-care Gram-stain in choosing suitable empirical antibiotics for the management of DFI is efficient, rapid, and can be applied everywhere. In this workshop, we discuss efficient approaches to the management of DFI in resource-poor settings, ranging from epidemiology to diagnosis; from bed-side tests to combined therapy of these infections and associated problems.

WS19: Workshop Minor amputations (in collaboration with IADFS)

Dr Robert Frykberg¹, Prof. Venu Madhav Kavarthapu²

¹Diabetic Foot Education, LLC, United States, ²Health Care - NHS, United Kingdom

This brief symposium will be an overview of several diabetic foot amputations commonly used to address chronic or necrotizing infections, gangrene, and deformities.

Using literature reviews, personal experience, and case studies, the faculty will discuss indications, techniques, and post-operative care to be considered for these potentially limb-salvaging procedures as well as potential quality of life improving major amputations.

We will allow for ample time to address audience questions prior to the conclusion of the symposium.

WS20: Workshop Diagnosis and management of skin and nail disorders of the foot

Dr Annemie Galimont¹

¹Bravis Ziekenhuis, The Netherlands

People with diabetes have a higher risk of skin rashes and nail changes. 50% of diabetics sooner or later have skin problems, the most common are Infections, xerosis cutis and Inflammatory skin disorders. Skin and nail abnormalities can be alarm signals, they can be the first symptom of diabetes or a symptom of poorly controlled diabetes!

I will guide you through the world of the skin and nails and help you to understand the influence of diabetes on their function.

WS21: Workshop How to present my research data (for young investigators)

Prof. Bijan Najafi¹, Dr Jaap van Netten²

¹Baylor College of Medicine, United States, ²Amsterdam UMC, The Netherlands

In today's world of research, the ability to effectively present research data is essential. Well-crafted presented data not only showcases your research findings but also engages and informs your audience. In this interactive workshop, we will alternate between theory and practice. We will provide tips and techniques for presenting research data in a compelling and meaningful way. Bring your own laptop, as you will have to get active yourself!

Starting with some theory, we will introduce the workshop and discuss the importance of organizing and structuring your data. Step 2 is visualizing your data, which we will do individually using the same dataset, followed by collective discussions on do's and don'ts.

Now that we have data visualized, it's time to move to the story. Using storytelling techniques can help you communicate your research findings in a way that resonates with your audience. We will provide tips for tailoring your presentation to different audiences, from laypeople to subject matter experts, and handling questions from your audience, including how to manage difficult or unexpected questions. Based on the visualized graphs, you will then have to try and create your own little story.

If time allows, we end with discussions on creating open access datasets. This is becoming the norm, and also a great tool to support future directions and how to identify opportunities for collaboration or partnerships.

By the end of this workshop, you will have a toolkit of best practices and techniques that will help you present your research data effectively and with confidence.

And again: don't forget to bring your own laptop.

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