8th internation symposium on diabetic foot

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Oral Sessions

O1.1

Remote Temperature Monitoring with a Telemedicine Smart Mat: from Research to Practice

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Aim: Despite compelling clinical evidence and inclusion in multiple practice guidelines, data and experience from non-research practice of once-daily remote temperature monitoring (RTM) for the early detection and prevention of diabetic foot ulcers (DFU) is lacking. Translational "real-world" evidence may improve adoption of RTM, which has the potential to substantially reduce DFU-related morbidity, mortality, and resource utilization.
Methods: We therefore present data from recent uncontrolled use of a RTM smart mat. This mat was previously found to detect 97% of nonacute DFU approximately 5 weeks before identification by providers [1]. In this effort, a total of 630 patients from the US Department of Veterans Affairs (n=600) and a large US integrated health delivery system (n=30) were evaluated for adoption and outcomes.
Results: Within the US Veterans Health Administration (cohort 1), RTM with the mat has been prescribed for more than 600 veterans and nearly 1000 patient-years have been collected. Observed alerts/patient-year (1.6) was substantially lower than in the research setting (3.1), potentially due to successful interventions resolving inflammation and reducing the false positive rate reported in a non-interventional trial [1]. In the most recent six months, 68% of all alerts resolved via offloading; in those cases that required exam, 76% of patients reported a clinically-meaningful action during exam prompted by the mat. The 30 patients followed in cohort 2 (non-veteran integrated health delivery system) completed 28 patient-years of participation. Consistent with research, 78% of participants remained engaged in regular mat usage after one year. Dramatically, use of the mat eliminated all DFU-related emergency department visits, hospitalizations, and proximal amputations in this high-risk cohort. Only 1.4 alerts/patient-year were observed, suggesting a low burden to the clinician.
Conclusions: Studies examining both long-term patient engagement as well as impact on resource utilization are critical for furthering the role of RTM in practice, which may improve patient outcomes and reduce costs.

[1] Frykberg et al. Diabetes Care. 2017 Apr 29:dc162294.

O1.2

Thermography Shows That a Temperature Difference ≥ 2.2°C between Corresponding Sites of the Feet Does Not Always Lead to a Foot Ulcer

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Background and aims: Diabetic foot ulcer (DFU) is often associated with a rise in foot skin temperature (≥2.2°C) compared with the corresponding contralateral side. We analysed plantar thermal images of feet in high-risk diabetic foot patients who remained ulcer-free over a 12 month follow-up.
Method: Fifteen patents with past history of DFU and neuropathy underwent monthly blinded thermography with a novel imaging device after a barefoot rest for 10 minutes on a podiatry chair. At each visit, patients received standard podiatric treatment and offloading with insoles and therapeutic footwear. At the end of the study, thermal images were unblinded. Temperatures at 12 plantar regions of interest (ROIs) including 1st to 5th toes, 1st to 5th metatarsal heads, 5th metatarsal base and centre of the heel were recorded. The mean temperature difference (ΔT) for all ROIs was calculated for each visit. The percentage of ROIs with ΔT ≥2.2°C was calculated.
Results: The percentage of ROIs with ΔT≥2.2°C varied between visits and ranged from 6.3% to 30.8% (average 19.7±8.1%). No particular pattern in the between-visit variability was noted.
Conclusion: Thermography revealed that on average 20% of all plantar ROIs have a temperature difference ≥2.2°C. None of these areas progressed to DFU at the subsequent visit. A temperature difference ≥2.2°C between corresponding sites on foot thermograms should be interpreted in the context of clinical presentation and does not always lead to DFU.

Funded by the National Institute for Health Research

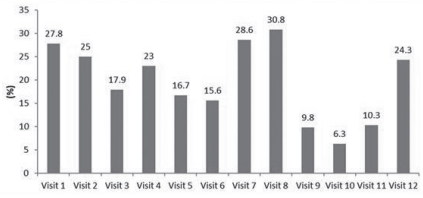

Figure 1 Percentage of plantar ROIs with ΔT≥2.2°C at 12 follow up visits

O1.3

Angiosomal Interpretation of Preulcerative Inflammation Identified by Remote Temperature Monitoring

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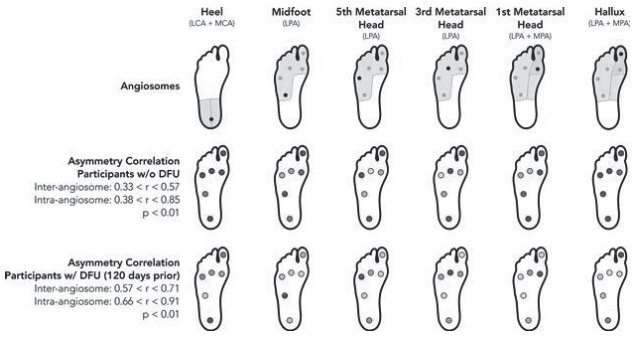
Aim: Remote temperature monitoring (RTM) is an effective and recommended practice for identifying inflammation preceding diabetic foot ulcers (DFU). RTM uses temperature asymmetries between contralaterally-matched locations ("keypoints") on the feet. After inflammation is identified, preventative treatment, such as offloading and debridement of pre-ulcerative lesions is initiated. Improved understanding of how inflammation manifests may inform tailored preventive therapies and guide foot exams. Although previous studies have investigated how inflammation manifests spatially in the foot, these were qualitative and limited in scope. We hypothesize that inflammation manifests consistent with the angiosome concept, which segments the foot into regions with common arterial supply. We therefore assessed the association between angiosomes and the spatial distribution of inflammation.
Methods: We used secondary data from a 129 participant, 34-week, multicenter study (NCT02647346) of the accuracy of a RTM mat and computed the correlation matrices of the keypoint asymmetries stratified by patient outcome, duration to outcome for those with DFU, and location of DFU. We then compared the intra- and inter-angisomal keypoint correlations for significance at alpha=0.05 level using the Student's t-test.
Results: The figure shows the correlation matrices superimposed over the foot's keypoints. The correlation among intra-angiosome keypoint asymmetry is significantly higher than the correlation among inter-angiosome keypoint asymmetry for participants both with and without DFU.
Conclusions: The results of this study suggest that inflammation preceding DFU manifests in a manner that is spatially consistent with the overlying angiosome. Improved understanding of the data provided by RTM may inform preventive therapies, resulting in better patient outcomes and lower resource utilization.



Correlation of RTM inflammation segmented by plantar angiosome

O1.4

Development of MyFootCare: a Smartphone Application to Actively Engage People in their Diabetic Foot Ulcer Self-Care

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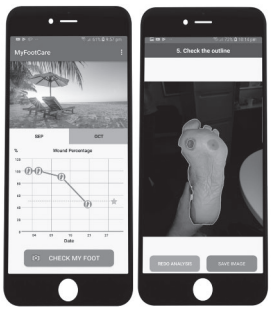
Aim: New strategies are needed to improve diabetic foot ulcer (DFU) self-care. We aimed to develop a smartphone application to engage people with DFUs in self-care.
Methods: User-centred design process. A functional application prototype was qualitatively evaluated with 11 DFU patients, and during three workshops with total 16 clinicians.
Results: We developed "MyFootCare", a smartphone application to engage patients through goal-setting, progress monitoring, and reminders. Key feature is the novel visual analytics to extract and monitor DFU size from mobile phone photos (Figure 1).
Key themes identified based on user experiences: (1) Already using mobile phone photos to monitor DFU progress, but (2) limited experience with smartphone applications. (3) Desiring objective DFU size data. (4) Ambivalence about goal setting and diary features. (5) Desiring to share their data with clinicians.
Clinicians indicated: (1) Patients benefit from meaningful and quantifiable goals; (2) Application needs to be easy to use to fit with a patient's routine; (3) It should monitor both feet, rather than focus on a single DFU only.
Conclusions: MyFootCare is a smartphone application to engage patients through goal-setting, progress monitoring and reminders. It shows promising features to engage people in DFU self-care. Most notably, ulcer size data is useful to monitor progress and engage people. These findings open the door for further work to develop an application that is easy to use and functions in daily life. We are currently prospectively enrolling participants to investigate usability of MyFootCare during 12 weeks in people with DFUs.



Screenshots of MyFootCare.
Left: the goal image (top) and ulcer tracking graph to monitor healing progress (bottom);
Right: visual analytics for automatic ulcer size calculation and tracking.

O1.5

The Molecular Mechanism of HBOT in the Treatment of Chronic Diabetic Foot Ulcers: Critical Regulation of Angiogenesis by Nrf2 Signaling

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Aim: To investigate the cytoprotective effects of Nrf2 along with its downstream targets (NQO1, Catalase, HO-1), angiogenic markers (HIF-1α, VEGF, SDF-1α), pro & anti-inflammatory cytokines (both Th1 &Th2) in ulcer tissue biopsies obtained from patients exposed to HBO therapy.
Methods: Wound biopsies were collected from patients attending the inpatient department at Hycare for wounds, Chennai, India. Study subjects were divided into two groups, Group-1 the initial day or (Day 0) before starting HBO therapy and Group-2 were the follow up of the same patients on the 20th day (Day 20) of HBO therapy. The study protocol was approved by Hycare institutional Ethics Committee (Project No: 009/HYC/IEC/2017). The gene and protein expression was carried out using qPCR and immunoblotting respectively. Profiling of Th1 & Th2 cytokines,were analyzed using a multiplex bead-based assay.
Results: Immunoblotting analysis in the tissue biopsies of HBOT treated patients showed an increased expression for Nrf2, when compared with non-treated wounds. Further, we found that the mRNA expression from the tissue biopsy of HBOT treated subjects had increased levels of NQO1 ($p<0.0001$), Catalase ($p<0.0001$), Heme-oxygenase-1 ($p<0.001$). On the other hand, we also found an increased expression of these selected angiogenesis markers in the tissue biopsies of HBOT treated subjects [HIF-1α (4.14-fold, $p<0.0001$), VEGF (2.74-fold, $p<0.004$), SDF-1α (4.24-fold, $p<0.0001$) respectively] when compared with non-treated wound biopsies.Our data also showed that the levels of pro-inflammatory Th1 cytokines like IL-12 ($p=0.005$), TNF-α ($p=0.0007$) and IFN-γ ($p=0.001$) were significantly decreased and the levels of anti-inflammatory Th2 cytokines like (IL-4, IL-10 and IL-13) were significantly increased after HBO treatment. Interestingly, tissue Nrf2 expression showed a positive correlation with HIF-1α ($r=0.60$; $p=0.02$), VEGF ($r=0.52$; $p=0.01$) and SDF-1α ($r=0.57$; $p=0.001$).
Conclusion: The present study evidenced that elevated Nrf2 transiently regulates angiogenic gene expression in wound biopsies thereby enhance wound healing process during HBOT.

O2.1

Diabetic Foot Surgery Performed by Diabetologists in a Third Level Centre: Results of 15 Years of Activity

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Aim: to evaluate surgical outcomes of a third-level centre managed by diabetologists in the last 15 years.
Method: we retrospectively evaluated 1.857 consecutive DF patients (Age 67.1±12.3 yrs, diabetes duration (DD) 19.2±9.8 yrs, HbA1c 8.1±2.0%) surgically treated in our Department between 2000 and 2014, divided in 3 groups: Group 1, patients treated 2000-2004 (397 pts), group 2, 2005-2009 (728 pts) and Group 3, 2010-2014 (732 pts). Main clinical outcomes [peripheral revascularization rate (PR), healing rate (HR), healing time (HT), major amputation (MA) and death (D) rates] were compared between the groups.
Results: no difference was observed at baseline between the Groups, except for age, significantly ($p<0.05$) higher in Group 3 (70.6±14.7 yrs) than in Group 1 (64.4±11.6 yrs) and 2 (65.1±11.2 yrs). Total HR was 81.6% (HT 143.3±53.8 days); total MA rate was 4.9% and D rate was 27.9% during the follow up period. No difference emerged comparing HR and MA between the groups; HT was significantly ($p<0.05$) shorter in group 3 (104±44 days) than in Group 2 (169±72 days) ad 1 (235±67 days). D rate was higher ($p<0.05$) in Group 1 (41.7%) than in Group 2 (20.7%) and 3 (24.2%). PR rate was 19.4% in Group 1, 28.1% in Group 2 and 53.8% in Group 3 ($p<0.05$).
Conclusions: despite the increasing age and complexity of patients our data show improvement of outcomes alongside 15 years of activity, probably due to better surgical techniques, more aggressive medical therapy and a more effective treatment of critical limb ischemia.

O2.2

Medial Plantar Artery Flaps for Reconstruction of Diabetic Foot and Ankle Wounds: a Systematic Review

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Aim: Medial plantar artery (MPA) flaps have been well-described for use in traumatic and diabetic foot wounds, and more recently reported in combination with complex reconstruction for osseous deformities. The aims of this systematic review were to review the MPA flaps in soft tissue reconstruction of diabetic foot and ankle wounds, and to analyze the difference in outcomes between isolated MPA flaps versus in combination with osseous deformity correction.

Methods: Systematic review was conducted by 3 independent reviewers through several electronic databases using search terms: medial plantar artery flap, foot, ankle, wound, ulceration, pedicle, diabetic foot, diabetes mellitus, peripheral neuropathy, Charcot neuroarthropathy, trauma, neurovascular flap, fasciocutaneous flap, reconstruction, external fixation, instep flap, non-microsurgical flap. Inclusion criteria were English language studies published within the last 20 years, diabetic patients who underwent reconstruction using MPA flap for foot or ankle wounds, documented post-operative follow-up of at least 6 months, surgical outcomes including healing rates, complications, and need for revisional surgery. Isolated literature reviews and descriptions of surgical technique and/or cadaveric studies were excluded.
Results: The initial search identified 60 eligible studies, but 52 studies were excluded based on inclusion/exclusion criteria. Remaining 8 studies used for data extraction had 47 MPA flaps performed for diabetic foot and/or ankle wounds. Analysis identified 42 patients that underwent isolated MPA flap, while 5 had concomitant MPA flap plus osseous reconstruction. Success defined as healing without occurrence of complication during the follow-up period was found in 74.5%, and the overall complication rate was 25.5%. Major complications (transmetatarsal or below knee amputation) comprised 14.9%, while minor complications (dehiscence and re-ulceration) affected 10.6%.
Conclusion: The MPA flap was successful in the majority of diabetic foot and/or ankle wounds; however, the results should be interpreted with caution due to lack of high-quality evidence and heterogeneity among the studies. Promising preliminary results were found in the small number of cases that had MPA flap combined with osseous reconstruction, therefore larger studies are necessary to determine whether osseous reconstruction of underlying diabetic foot and/or ankle deformities may improve long-term outcomes of MPA flaps.

O2.3

Charcot Foot Reconstruction – How Does Major Hardware Breakage and Non-union Affect the Clinical Outcomes?

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Aim: Surgical reconstruction of severe Charcot foot deformities using internal fixation is a commonly used option. However, there has been a concern that this carries a higher risk of major hardware failure (nail, plate or beam breakage). The aim of our study was to look at the demographics of hardware failure and non-union in Charcot midfoot and hindfoot reconstructions, the radiological and clinical outcomes in those with and without hardware failure.
Methods: We retrospectively reviewed our prospectively collected database on 82 patients that have undergone reconstruction of Charcot deformity affecting the midfoot, hindfoot or both, between October 2007 and December 2017, with a minimal follow up of 12 months. This included 3 patients with bilateral procedures. Two patients died within 12 months post-operatively, therefore they were excluded. The patients' demographics were collected for analysis. The post-operative clinical outcomes included ambulatory and footwear status. The radiological outcomes included bone union and major hardware failure.
Results: 85 feet were reconstructed in 82 patients and about one 3rd of these were recommended below knee amputation by the referring centre. There were 19 (22%) major hardware failure out of 85. This includes 4 hindfoot nails (out of 54, 7%), 18 plates (out of 68, 26%) and 1 beam (out of 27, 4%).
7/19 (37%) feet showed radiological evidence of full bone fusion despite hardware failure and 11/19 (58%) achieved full weight-bear in shoes; in comparison to 54/66 (82%) and 53/66 (82%) in the non-hardware failure patients respectively.
The hardware failure is highest among the combined hindfoot and midfoot reconstructions (14 out of 26, 54%), in comparison to isolated hindfoot (2/31, 6%), midfoot (3/28, 11%) procedures. 8 (42%) of the hardware failure cases required further surgery, which included revision of hardware in 2. There was no loss of limb among all reconstructed patients.
Conclusion and Discussion: The hardware breakage is common following Charcot hindfoot and midfoot deformity corrections, highest among combined reconstructions (image). However, the clinical and radiological outcomes are still satisfactory following such complex procedures. Dedicated durable hardware designed for Charcot foot reconstructions will potentially reduce this complication and improve the patient outcomes further.

Weight-bearing lateral radiograph of Charcot reconstruction with hindfoot nail and midfoot plate at post-operative follow up with full fusion and no hardware failure.

O2.4

Partial Calcanectomy for Heel Ulcers Revisited – a Possible Solution to a Difficult Problem

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Aim: Diabetic heel ulcers are a major problem, often leading to amputations. Partial or total calcanectomy has been described as a possible salvage procedure, by allowing soft tissue coverage after debridement of necrotic and infected tissue, and possibly allowing walking. We report on our experience with this technique which is not commonly used
Methods: Fourteen patients, who presented with diabetic heel ulcers between 2010-15, and who were BKA candidates, underwent debridement and partial calcanectomy. Average age was 67.8 ±12.7 years, M:F ratio was 6:1 Extent of procedures, need for additional procedures and complications were noted. Outcome assessment included wound closure and walking status. No patients were lost to follow up.
Results: Nine patients underwent partial calcanectomy as the initial procedure while others underwent prior debridement. Calcanectomies were subtotal (1), wedge (5) or partial (8). Primary

closure was mostly achieved (11), the remainder requiring local skin graft (2) or myocutaneous flap (1).
Ten patients underwent re-vascularization prior to calcanectomy, either angiographic (8) or bypass (2).
Most calcanectomies (9/14) healed successfully, while five subsequently required amputations. Most failures were noticed within 24 days, with similar prevalence in wedge and partial calcanectomies. One patient had wound complications requiring BKA.
At one year, the nine patients had full wound closure and could bear weight. Five patients regained full ambulatory status wearing specially modified shoes with custom fillers.
Conclusions: Partial calcanectomy is a little-known procedure, that is a viable alternative to BKA. We present our positive experience with this procedure, which in a majority of cases not only prevented BKA, but also allowed weight bearing. Poor vascular supply is not necessarily a contraindication, as re-vascularization prior to calcanectomy is a viable option.

O2.5

To Value Safe, Effectiveness of "Modified" Masquelet Technique (MT) in Treatment of Midfoot and Active Osteomyelitis in Ulcerated Charcot Foot

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Aim: To value safe, effectiveness and outcome of "modified" Masquelet Technique (MT) in treatment of midfoot and active osteomyelitis in ulcerated charcot foot.
Method: from October 2015 to June 2017 10 pts were treated by "modified" MT, defined as "biological membrane technique" described in 1986 for nonunion or bone loss treatment consisted in two surgical steps First step consisted of bone resection and placement of antibiotic spacer while the second step removal of antibiotic spacer replaced by bone graft. Foot stabilization was obtained by external fixation. 10 diabetic patients (mean age 52±10, PVD in 3 patients submitted to PTA, active ulcer with bone exposure and osteomyelitis in 10 pts, 5 pts affected by midfoot and 5 pts by ankle charcot foot. All patients were treated with the technique previously described. Osteomyelitis was treated with antibiotic therapy according to cultural swab for 60 days. 60 days have passed between first and second and second and third steps (external fixation removal). Total treatment period was of 130 days
Results / Discussion: NO infectious episodes were observed during treatment. 9 patients presented a stable arthrodesis while in 1 patient stable nonunion. Back to walk with protective custom made shoes was observed after 60 days. During a follow up of 661±161 days no infectious recurrence or ulcer were observed
Conclusion: Our study, the first as far as we know, demonstrated that "modified" Masquelet Technique is safe and effective surgical strategy in ulcerated Charcot foot with active osteomyelitis with high rate of limb salvage

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O3.1

Benefit of Footwear Intervention to Reduce Likelihood of Falls in Older Adults

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Background: People with diabetic foot have high fear of falling (FoF) [1]. In our previous study [2], we have demonstrated that daily use of Ankle-foot orthoses (AFOs) is effective to reduce FoF among older adults.
Objective: This randomized controlled trial examined effectiveness of footwear intervention (custom-made AFO vs. walking shoes only) on reducing likelihood of falls and determined the role of plantar-sensation.
Study Design: Forty-four ambulatory older adults (age=74.7±6.4 years, BMI: 28.5±5.6 kg/m2, 70% female, 64% history of fall) were randomly allocated (ratio=1:1) to receive either AFO intervention plus fitted walking shoes (AFO-G), or fitted walking shoes only (Shoe-G). Self-reported fall history of 12-month duration were compared at baseline and 12-month follow-up to determine fall-incident-rate (FIR). Plantar sensation was quantified using vibratation-perception-threshold (VPT).
Results: Overall, FIR was reduced from 2.02 at baseline to 0.90 at 12-month follow-up (p = 0.032) irrespective of group assignment. Reduction of FIR was however only achieved statistical significant level in AFO-G (65%, p=0.032) higher than Shoe-G (44%, p=0.293). Those with reduced FIR in response to footwear intervention had higher VPT than those without reduction in FIR (31.6V. v. 16.7V, p=0.002).
Conclusion: Results suggest that footwear intervention and in particular AFO is effective to reduce likelihood of falls in particular with those with severer loss of plantar-sensation. The fall prevention effects of AFOs could be explained by improvements in balance and fear of falling reported in our previous study [2]. Considering people with diabetic foot are among those with the highest concerns for falls [1] and poorer plantar sensation, we antricipate the AFO may be an effective startegy to reduce falls and fear of falling in those with diabetic foot.

References:
[1] Kelly et al (2013). Fear of Falling Is Prevalent in Older adults with diabetes Mellitus But Is Unrelated to Level of Neuropathy. JAPMA.
[2] Wang et al (2018). Effectiveness of Daily Use of Bilateral Custom-Made Ankle-Foot Orthoses on Balance, Fear of Falling, and Physical Activity in Older Adults: A Randomized Controlled Trial. Gerontology.

O3.2

Cost-Effectiveness of Offloading-Improved Custom-Made Footwear to Prevent Plantar Foot Ulcer Recurrence in High-Risk Patients with Diabetes

Dr. Sicco Bus[1], Nora Mejaiti[1], Prof Marcel Dijkgraaf[1]
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Aim: Offloading-improved custom-made footwear can prevent plantar foot ulcer recurrence in patients with diabetes when footwear is worn, but cost-effectiveness of these shoes and approach is not known.
Method: Data from the DIAFOS trial was used in which 171 neuropathic diabetic patients with a recently healed plantar foot ulcer were randomly assigned to 1) custom-made footwear which was evaluated, optimized and monitored at 3-monthly visits based on in-shoe plantar pressure analysis or 2) custom-made footwear, which was evaluated according to usual care. Primary clinical outcome was plantar foot ulcer recurrence in 18 months. Healthcare costs included the costs of the intervention (input) and treatment costs of a recurrent plantar diabetic foot ulcer (output). Intervention costs included the time investment of the footwear technician to modify the footwear and measure pressure, footwear materials costs, and write-off costs for equipment. The average total for direct treatment costs were derived from existing Dutch reference data (Rinkel et al., 2017)
Results: On the basis of intention-to-treat, 33 of 85 patients in the intervention group and 38 of 86 patients in the usual care group had a recurrent ulcer (relative risk -11%, P=0.48). A total of 1183 footwear modifications were made in 18 months in the intervention group; 33 footwear modifications were made in the usual care group. The total expenditures for the intervention were € 38.507 for the intervention group and €206 for the usual care group. Average costs for treatment of a foot ulcer are €9.472 Offloading-improved custom-made footwear led to lower costs since its effectiveness offsets the added costs of the intervention and was cost-saving by €9.059. In secondary analysis, for those 79 patients who were found to be adherent to wearing their custom-made footwear, the intervention was cost-saving by €98.014, based on 9 of 35 patients in the intervention group and 21 of 44 patients in the usual care group that had a foot ulcer recurrence.

Conclusion: Based on exact data for the intervention costs and reference data for ulcer treatment costs, offloading-improved custom-made footwear seems cost-effective compared with custom-made footwear that does not undergo such improvement.

O3.3

Custom-made Footwear for Indoor Use Increases Adherence in People at High-Risk for Ulceration

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Aim: Footwear adherence is a problem in people with diabetes at high-risk of ulceration. Adherence is lowest indoors, while patients are most active inside their house. The aim of this study was to investigate changes in adherence following provision of custom-made indoor footwear.
Methods: In patients with a previous foot ulcer and 'regular' custom-made orthopaedic footwear, baseline adherence was measured with the @monitor and a Stepwatch. Percentage steps while adherent to wearing the footwear was calculated. Patients were classified as non-adherent when <80% of their steps were made in their prescribed footwear. All patients were then provided with a pair of custom-made indoor footwear. Plantar pressure was measured with Pedar-X (Novel, Germany) in both the regular and the indoor custom-made footwear. Adherence was again measured with the @monitor and a Stepwatch after provision of the indoor footwear.
Results: 35 patients participated (mean age 70 (SD:10) years; n=15 female; n=26 type 2 diabetes). Of the 32 patients who completed the first adherence measurements, 23 were classified as non-adherent and 9 as adherent. Complete follow-up was available for 19 non-adherent patients. Peak plantar pressure in the forefoot regions was similar between regular and indoor custom-made orthopaedic footwear (hallux: 121 vs. 115 kPa respectively, p=0.319; first metatarsal head: 153 vs. 139 kPa respectively, p=0.636; all other regions also p>0.05). Total adherence increased significantly after provision of the indoor footwear: before 59%, after 71%; p=0.003. This was the result of a significant increase of indoor adherence (before: 42%; after: 64%; p<0.001), while outdoor adherence increased non-significantly (before: 87%; after: 91%; p=0.213).

Conclusion: Custom-made indoor footwear that is provided in addition to existing custom-made footwear significantly increases adherence in patients at high-risk of diabetic foot ulceration who are non-adherent to wearing their footwear. The indoor footwear has similar offloading quality (peak plantar pressure reduction) compared to the regular footwear, and is therefore safe to use. The combination of both forms of custom-made footwear might prevent foot ulceration.

O3.4

An Innovative Sealed Therapeutic Shoe to Offload and Heal Diabetic Forefoot Ulcers

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Aim: Non-removable knee-high offloading devices are gold standard to treat neuropathic forefoot ulcers, but they immobilize the ankle, impairing joint functioning and daily activities. The aim was to investigate the feasibility of using a therapeutic shoe, rendered irremovable, to treat forefoot ulcers.
Methods: Seven men with diabetes type 2, sensory neuropathy and long-lasting metatarsal head ulcers (median 1.0 year, range 0.3-4.7) were prescribed therapeutic roller shoes and custom-made insoles (Fig. 1). Ulcers had Wagner grade 1 (n=4) or 2 (n=3) and a median size of 0.5 cm2 (range 0.2-2.0). Offloading was assessed with a pressure measurement system.* The shoe was sealed with a plastic band and worn day and night like a cast.
Results: All ulcers healed; median time to healing was 8 weeks (range 1-23). The median peak pressure on the ulcer was 116

kPa (range 62-192). Five of seven participants respected the seal. Complications were secondary ulcer (n=1) and plantar hematoma (n=1). The most common complaint was difficulty to dress (n=5).
Conclusions: It seems feasible to seal a therapeutic shoe to offload and heal forefoot ulcers. Sealed therapeutic shoes are an interesting avenue for future research; they may include advantages of non-removable knee-high devices (effective offloading and high adherence) and overcome their disadvantages (mobility restrictions and high costs). A randomized controlled trial is underway in which sealed shoes are to be compared to total contact casting.
Reference: Jarl G. Diabetic Foot & Ankle. 2017;8:1348178.
Acknowledgements: Promobilia Foundation and Region Örebro County, Sweden, funded the study.

*F-scan, Tekscan, USA.

Figure 1. Left: Insole (2-layer EVA with 3 mm microcellular urethane) grinded from the underside to offload the ulcer. Right: Therapeutic shoe sealed with Brace-lok plastic band (DJO Nordic, Sweden).

O3.5

Patient Specific Optimisation of the Stiffness of 3D Printed Orthoses for People with Diabetic Foot Syndrome

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Aim: The stiffness of cushioning materials used in therapeutic footwear/orthoses play an important role for effective protection against tissue overloading and injury[1]. 3D-printing offers new capabilities for adapting the design and the stiffness of footwear/orthoses to the specific needs of individual patients. The importance of subject-specific optimisation of material stiffness for maximising pressure reduction has already been demonstrated in people with no diabetes[2,3]. The purpose of this study was to assess the importance of patient-specific stiffness selection in 3D-printed orthoses for maximum plantar pressure reduction in people with diabetes and peripheral neuropathy.
Methods: Seven people with diabetes (Type-2) and peripheral neuropathy were recruited for this study (4 male/3 female, age: 63y±6y, body mass: 89kgr±15kgr). Plantar pressure distribution was measured during walking using in-shoe sensors (F-Scan, Tek-Scan, USA) for six flat, 3D-printed insoles with varying stiffness. The condition of no orthosis was also tested as reference. The stiffness of the orthoses was gradually increased by increasing the infill density of the printing pattern from 10% and 20% (increments of 2%). The capacity of the orthoses to reduce overall peak plantar pressure relative to reference was assessed (averaged over 10 steps). Patient-specific optimum orthosis was identified for each participant as the one achieving maximum pressure reduction.
Results: On average, the patient specific optimum orthoses achieved 46%±11% reduction in peak plantar pressure. Pressure reduction was significantly higher for the optimum orthoses compared to the next softer or next stiffer ones (paired samples t-test, $p<0.05$). The pressure reduction achieved by the next softer or next stiffer orthosis (i.e. ±2% change in infill density) was 10%±7% or 22%±13% respectively.
Conclusions: Correct selection of stiffness can significantly improve the offloading capacity of therapeutic footwear/ orthoses. Patient-specific optimisation of stiffness is particularly important in the case of 3D-printed foot-beds/ orthoses where small changes in infill density can significantly affect their cushioning properties.
Acknowledgements: Support from CadScan Ltd. on the 3D printing of the bespoke orthoses is kindly acknowledged.
References:
[1] Shurr et al. Prosthetics Orthot.,Prentice Hall; 1990, p.17–29.
[2] Chatzistergos et al. Ann Biomed Eng 2017;45:1929–40.
[3] Chatzistergos et al. Med Eng Phys 2015;37:531–8.

O4.1

Non-Invasive Measurements of Tissue Perfusion in Diabetic Patients with Critical Limb Ischemia

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Aim: to perform the results of non-invasive measurements of tissue perfusion in diabetic patients with critical limb ischemia (CLI) including ankle-brachial index (ABI), transcutaneous oxygen tension (TcpO2) and indocyanine green fluorescence angiography (ICGFA) before and after percutaneous transluminal angioplasty (PTA).
Methods: From October 2017 to November 2018, 41 patients with diabetes mellitus (DM) and CLI in 41 limbs were treated. The average age of patients was 62.7 ± 9.8 years. The duration of DM 15.9 [8; 25.8] years. ABI, TcpO2 and ICGFA were performed during 1 week before and after endovascular treatment in all the cases. The equipment for ICGFA was conducted by BioSpec (Russia). To evaluate the soft tissue perfusion of the foot via ICGFA the following parameters have been used: Tstart - time to reach maximum for fluorescence intensity after intravenous administration of ICG; Tmax- time of onset of maximum fluorescence intensity after its appearance in the area of interest; Tmax-start – time difference between Tmax and Tstart. The region of interest for TcpO2 and ICGFA was dorsal surface in the forefoot.
Results: ABI measurement in 36,6% patients with CLI was not possible; in 49 % ABI was ≤ 0,5; in 14,4% < 0,9. Median of TcpO2 before PTA was 12 [5;23] mm Hg and after PTA - 39 [28;47,5] mm Hg, (p=0,001). Tstart before PTA was 21 [15;34] and after PTA 15 [10;23]sec, (p=0,001); Tmax before PTA was 71 [45;99] and after PTA - 41 [28;48], (p=0,001); Tmax-start before PTA was 41 [24; 68] sec and after PTA - 22 [18;31] sec, (p=0,001). A ROC – analysis showed a value 44 sec of Tmax as a cut-off point determing CLI and need for revascularization with an area under the curve 0,879 (95%CI 70,3 - 92,7).
Conclusions: There are some limitations in the use of routine di-

agnostic methods for determining CLI.
Real-time visualization of foot perfusion via ICGFA and time parameters seems to be additional tool for diagnosing CLI in diabetic patients. Upon completion of follow up period evaluation of the prognostic value of ICGFA could be possible to predict wound healing.

O4.2

Bone Histology of Percutaneous Bone Biopsy Specimens Identifies Five Distinct Subtypes and Provides Complementary Information in Diabetic Foot Osteomyelitis.

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Aim: To evaluate the role of histopathological assessment in the evaluation of percutaneous bone biopsy (PBB) specimens in suspected or treated diabetic foot osteomyelitis (DFO).
Methods: Histopathological and microbiological evaluation of 54 PBB specimens. All subjects (100%) had clinico-radiological evidence suggestive of DFO. The sampling protocol consisted of clinical assessment and review of radiological imaging to guide the percutaneous access site location and biopsy angle. Antibiotic therapy was stopped 7 days pre-procedure except in those presenting with acute osteomyelitis.
Results: The median age was 57.2±10.7 years, CRP 36.6±49.8 mg/L and WBC 8.4±2.5 × 109/L. We identified 5 histopathology patterns: A- Acute Osteomyelitis (n=3, 5.5%), B Chronic Osteomyelitis (n=2, 3.5%) C bone necrosis past or new (n=13, 24%), D. New bone formation/reparative changes (n=22, 41%) and E Normal/ No active inflammation (n=14, 26%). Bone microbiology was considered positive in the following: A:100%, B: 0%, C: 38%, D: 50%, E: 21%.
A subset, 24% (n=13) underwent surgical bone debridement immediately post PBB procedure. The corresponding PBB histopathology pattern was: A (n=3), B (n=1), C (n=3), D (n=2) and E (n=4). Intraoperative bone microbiology was positive in 11/13. In the two with negative microbiology, the preceding bone histology was pattern C (n=1) and pattern (D). The typical organisms identified in the histopathology pattern A were Staphylococcus aureus and Streptococcus beta-haemolitycus and those in pattern E were Staphylococcus simulans, S. epidermidis and S. capitis.
Conclusions: In DFO, histological evaluation PBB specimens allows the identification of a distinct sequence of osseous injury and repair. This provides the clinician with information complementary to that received from microbiological assessment and may allow recognition of the precise temporal overview of bone health. A larger evaluation with detailed clinical scrutiny is required, and if confirmed, the histopathologist should be considered a welcome new addition to the diabetic foot multidisciplinary team.

O4.3

Erythrocyte Sedimentation Rate Combining Probe to Bone Test to Diagnose Diabetic Foot Osteomyelitis in Early Stage

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Aim: The erythrocyte sedimentation rate has proven to be useful in diagnosing diabetic foot osteomyelitis (DFO). In IWGDF guidance, a highly elevated (usually defined as >70 mm/h) level will increase the likelihood of osteomyelitis underlying a diabetic foot wound. But in our clinical practice, ESR of patients with DFO (all definite diagnosis by histological) all less than 70mm/h. So the purpose of this study was to find the ESR cut-off point of diabetic foot osteomyelitis (DFO) for Chinese patients. X-ray may show 'normal' and may miss diagnosis for DFO in early stage (first two weeks). MRI dose not suit for every patient with DFO, especially in developing countries. Probe to bone (PTB) is a simple and useful test. So we try to evaluate DFO by ESR alone or ESR combined with PTB in early stage in developing countries.
Method: We collected 206 diabetic foot patients with different infection sites and different degree of infection from June 1st 2016 to December 30th 2017. Detection of white blood cell (WBC), neutrophil% (N%), C reactive protein (CRP), ESR were performed at admission within 24 hours. All 111 patients with diabetic foot osteomyelitis were confirmed by bone biopsy, while the other 95 patients showed no diabetic foot osteomyelitis. Although WBC, N%, CRP, and ESR had differences between the two groups, AUC of ESR was 0.832, with the value as a diagnostic indicator. The best-fit cut point of ESR>43mm/h, sensitivity was 82.9%, specificity was 70.5%, positive predictive value (+PV) was 0.78, negative predictive value (-PV) was 0.77, positive likelihood ratio(+LR) was 2.8, negative likelihood ratio(-LR) was 0.24.ESR combined with PTB test, the sensitivity was 63.56%, specificity was 98%, +PV was 0.97, -PV was 0.67, +LR was 31.75, -LR was 0.37.
Conclusion: ESR>43mm/h is more suitable for Chinese patients with DFO. ESR combination PTB is simple and easy to widely use in developing countries, and can diagnosis of DFO in the early.

O4.4

Hallux Gripping Force as an Indicator of Foot and Ankle Muscle Strength in People with Diabetes and Peripheral Neuropathy

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Aim: People with diabetes are very vulnerable to injury from falling. Assessment of muscle weakening in clinics could significantly enhance preventative care for falls but no established protocol currently exists. The purpose of this study was to investigate whether a measurement of hallux gripping force can be used to assess the strength of the muscles of the foot/ankle complex.
Methods: The correlation between hallux gripping strength and the isometric strength of the muscles of the foot/ankle complex was assessed in 69 people with diabetes (Type-2) and peripheral neuropathy (average age, BMI of 58(± 8) y, 28(±5) kg.m-2 respectively). Hallux gripping force was assessed by performing the paper grip test [1] on a pressure mat. The maximum net force under the hallux was recorded for each foot while performing the paper grip test. Isometric muscle strength of all muscle groups of the foot and ankle was assessed using a hand-held dynamometer according to an established method [2].
Results: Spearman's rank-order correlation analysis revealed significant associations ($p>0.05$) between hallux grip force and the isometric strength of all muscle groups of the foot and ankle complex. In all cases higher hallux grip force was associated with higher muscle strength. More specifically, moderate positive correlations were found between hallux grip force and the strength of the hallux plantar-flexor ($rs(54)=0.544$, $p<0.001$), hallux dorsi-flexor ($rs(54)=0.574$, $p<0.001$), lesser toe plantar-flexor ($rs(54)=0.505$, $p<0.001$), lesser toe dorsi-flexor ($rs(54)=0.574$, $p<0.001$), ankle evertor ($rs(54)=0.562$, $p<0.001$), ankle invertor ($rs(54)=0.549$, $p<0.001$), ankle plantar-flexor ($rs(54)=0.456$, $p<0.001$) and ankle dorsi-flexor ($rs(54)=0.440$, $p=0.001$) muscles.
Conclusions: The significant correlations between hallux grip force and the dynamometry-based isometric strength of all muscle groups of the foot/ankle complex indicate that hallux grip force could offer a measurement of overall foot/ankle strength. This simple measurement could be used to identify people with diabetes that need access to preventative care for falls including strengthening exercise programs.
References:
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[2] Spink et al. Gerontology. 2010;56:525–32.
Acknowledgements: This work was supported by the European Commission (FP7-PEOPLE-2011- IAPP) – Development of a new generation of DiaBetic footwear using an integrated approach and Smart materials (DiaBSmart).

O4.5

Neurovascular Response to Pressure in Patients with Diabetic Foot Ulcer

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Aims: Diabetic foot ulcer (DFU) is an increasing problem worldwide and prevention is crucial. We hypothesized that the inability of the skin to respond against pressure is involved in DFU genesis and could be an important predictive factor to take into account.
Method: We included 29 patients with DFU and 30 patients with type 2 diabetes without DFU. Neuropathy was assessed as well as skin blood flow (SKBF) at rest, in response to acethylcholine (ACh), sodium nitroprusside (SNP), local heating at 42°C and to non-noxious locally applied pressure. All measurement were realised on distal part of the same tibia. Vasodilatory responses were expressed as the maximal percent increase in SKBF from the baseline. Data were compared to ten healthy age-matched control subjects extracted from a previously studied population.
Results: Basal SKBF, the late plateau response to ACh, the initial peak response to heat and response to pressure were significantly impaired in both diabetic groups compared to healthy subjects but no the response to SNP stimulation. The vasodilator capacity to pressure was significantly more altered in patients with DFU compared to those without DFU and lidocaine did not further decrease the vasodilation capacity to pressure in DFU group whereas it was reduced in patients without DFU. There is no difference between the two groups with diabetes in term of age, NSS, warm perception threshold, cutaneous pressure perception threshold, basal SKBF, SKBF responses to ACh, SNP and heat. Patients with DFU have a significant higher NDS score than those without DFU.
Conclusion: This pronounced alteration of neurovascular response to pressure in patients with DFU seems to be a good marker of skin vulnerability and could be used to better predict individuals at risk.

O5.1

Diabetes Mellitus and Charcot Neuro-Osteoarthropathy (CNA): Retrospective Analysis and Identification of Predictive Factors

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Aim: We retrospectively analysed the cohort of CNA patients followed in our clinic and the correlations between clinical and demographic characteristics and the evolution of the disease to identify predictive factors of severity and clinical outcomes.
Methods: We retrospectively searched in our databases for all patients with a diagnosis of CNA between 2000 and 2017. We analysed both inpatient and outpatient clinic records and we traced all patients which were submitted to a structured telephone interview. The items were limb salvage with or without minor or major amputation, number of surgical procedures performed and mortality.
Results: The diagnosis of CNA was hypothesized in 567 and confirmed in 436 pts [male/female % 64/37; mean age 48.6±11.9 yrs; type of diabetes (1-2) 25/75, BMI (Kg/m2) 29.7 ± 7.3]. All patients showed high prevalences of comorbidities, in particular ischemic cardiopathy (24.7%), diabetic retinopathy (31.5%) and peripheral artery disease (62.2%). One out of three had bilateral CNA. The onset modality was pain in 64%, oedema in 72% and the occurrence of a lesion in 47% of them. During the follow up of 89.1±76.4

months (7-188) 43% of patients underwent to a minor amputation and 4.7% of them to a metatarsal stabilization. In the same period 8.7% of patients required a major amputation and 14.8% of them died. Multivariate Cox regression was performed both in terms of major amputation and death. Amputation was predicted by peripheral artery disease(p<0.01), smoke habits (p<0.001) and acute onset modalities (p=0.02) while mortality was predicted by male sex (p=0.02), renal failure (p=0.02), peripheral artery disease (p<0.01) and acute onset modalities(p<0.001).
Conclusions: Despite its high prevalence CNA is underestimated and often misdiagnosed. Its impact on limb salvage and survival is important and its association with the other comorbidities conditions it clinical evolution.

O5.2

Comparison of Anatomic Diabetic Charcot Neuroarthropathy Classifications with Multi-Reader Analysis and Evaluation of Activity in Foot and Ankle Radiographs

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The purpose of this project was to assess the intra-reader and inter-reader reliability of the two CN classifications (Sanders/Frykberg and Brodsky/Trepman) and Eichenholtz staging. We hypothesized the inter reader reliability with respect to these three classification systems is moderate at best.
Digital radiographic images were assembled in a PowerPoint presentation. No clinical information was provided to reviewers. Prior to interpreting the study radiographs, all five reviewers underwent a teaching session by the PI, reviewing five cases of CN. None of the teaching cases were included the study group. Fifty-five cases of CN and five normal cases were distributed to each of the five physicians electronically, who in turn independently rated all of the 60 cases according to the three classification systems (table 3).
The 95% confidence interval of the ICC estimate for Sanders/Frykberg was 0.9601 to 0.9833 at week 0 and 0.9579 to 0.9814 at week 8, which can be regarded as “excellent” reliability. For Trepman/Brodsky, the 95% confidence interval of the ICC estimate was 0.8463 to 0.9327 at week 0 and 0.8129 to 0.9226 at week 8, which can be regarded as “good” to “excellent” reliability. The Eichenholtz, the 95% confidence interval of the ICC estimate was 0.6841 to 0.8640 and 0.6931 to 0.8730 at weeks 0 and 8, respectively, which can be regarded as “moderate” to “good” reliability.
Based upon the results at our institution, we found that the Sanders/Frykberg classification had the highest ICC suggesting excellent reliability. The Trepman/Brodsky classification had good to excellent reliability as well.

Intraclass correlation coefficients of Charcot neuroarthropathy classification systems

Table 3. Intraclass Correlation Coefficients Among the 5 Raters of the 60 Radiographs for the Classifications of Charcot Arthropathy

	Time Period of Charcot Radiographic Image Ratings					
	Week 0		Week 8		Test-Retest Reliability[c]	
Classification System[a]	ICC[b]	95% CI	ICC[b]	95% CI	ICC[b]	95% CI
Sanders-Frykberg	0.97	(0.96, 0.98)	0.97	(0.96, 0.98)	0.99	(0.98, 0.99)
Trepman Modification	0.90	(0.85, 0.93)	0.88	(0.81, 0.92)	0.94	(0.92, 0.96)
Eichenholtz	0.79	(0.68, 0.86)	0.80	(0.69, 0.87)	0.89	(0.84, 0.93)

ICC = Intraclass Correlation Coefficients; 95% CI = 95% Confidence Interval
[a]Charcot arthropathy classification
[b]ICC was estimated using the two-way random effects model among the 5 raters of the 60 images at week 0 and at week 8.
[c]In order to measure test-retest reliability, the same rater evaluated each of the same 60 radiographs (in random order) on two separate occasions (week 0 and week 8) and the two-way mixed effects model was used to estimate the ICC.

O5.3

Volumetric Assessment of Bone Marrow Edema in Patients with Charcot Neuroarthropathy: Feasibility of Three-Dimensional Segmentation in the Diabetic Foot

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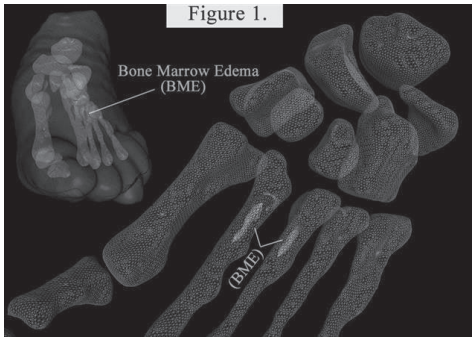
Objective: Magnetic resonance imaging (MRI) can detect subtle changes in Charcot neuroarthropathy (CN) including bone marrow edema (BME), However, no accepted method to objectively quantify BMI exists. The aim of this study was to examine the utility of 3D segmentation of BME in CN and to generate a protocol for quantitatively assessing these findings.
Materials and Methods: Ten lower-extremity MRIs from 8 patients with CN were examined using the image processing program 3D Slicer (Fig. 1). BME was identified and segmented using predefined intensity thresholds within selected regions of interest (ROI). Following BME segmentation, the total volume of identified BME was calculated in each dataset. Volumetric analysis was performed using 3D Slicer’s onboard segment statistics module.
Results: ROI threshold analysis allowed for semi-automated segmentation of BME in all 5 patients with radiologist confirmed BME. Threshold analysis did not return significant values for the remaining 3 CN patients who presented without noted edema. Four patients with radiologist confirmed BME presented with Sanders-Frykberg Class 2 CN and were found to have a median BME volume of 275 mm3 (range 63-313). The remaining patient presented with bilateral Class 2, 3, 4 CN, and segmentation analysis yielded volumes of 1322 and 2922 mm3 in the right and left foot, respectively.
Conclusion: The presented methods and results demonstrate feasibility of quantifying BME in patients with CN and indicate a potential use for objectively assessing disease progression, notably in the early stages of CN when radiologic findings may be of particular importance in diagnosing the disease.



Example of 3D rendering of bone marrow edema

O5.4

Calcaneal Quantitative Ultrasound in Type 2 Diabetes: a Prelude to Use in Monitoring Acute Charcot Neuropathic Osteoarthropathy

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Aim: To determine the reliability of calcaneal quantitative ultrasound (QUS), its utility in type 2 diabetes (T2D), and the influence of peripheral neuropathy on interpretation.
Methods: First, a reliability study was performed with healthy volunteers. Two observers each performed calcaneal QUS three times per foot with repositioning between measurements. Intraclass Correlation Coefficients (ICCs) were calculated.
Second, we analysed associations between QUS and bone mineral density (BMD) with prospective radiologically-proven fractures in the Dubbo Osteoporosis and Epidemiology Study (DOES) cohort. Atraumatic fracture risk prediction for bone parameters was assessed with Cox-regression and receiver operating curves (ROC).
Third, QUS was compared in T2D clinic attendees with and without peripheral neuropathy. Groups were matched for age, sex and body mass index (BMI).
Results: Twenty participants were recruited to the reliability study with mean age 48.9±12.1 years, half male, mean BMI 25.2±4.3 kg/m2 and 90% right foot dominant. Intra- and interobserver ICCs were high for Stiffness Index (SI) (0.96-0.98), Speed of Sound (0.97-0.98) and Broadband Ultrasound Attenuation (BUA) (0.80-0.88).
DOES participants with T2D (n = 96) had higher BMI than those without diabetes (n = 809) (28.4 vs 25.6 kg/m2, p<0.001). Demographic and lifestyle characteristics were similar. Atraumatic fracture incidence did not differ between groups. In T2D, hazard ratio for fracture was 1.62 (95% CI 0.95-2.77) per SD decrease in BUA and 2.24 (1.19-4.20) for femoral neck BMD. Corresponding figures for the non-diabetic group were 1.51 (1.30-1.75) and 1.48 (1.25-1.75). Area under ROCs in T2D for BUA and femoral neck BMD were 0.69 and 0.73 respectively.
Interim analysis included 12 participants without and 10 with peripheral neuropathy. Those with peripheral neuropathy tended to have lower SI (median 90.0 (IQR 70.5-92.0) vs 100.9 (88.4-113.8), p=0.08).
Conclusions: Calcaneal QUS is reliable and provides fracture risk assessment in T2D approximating BMD. In T2D, peripheral neuropathy tends to be associated with lower SI. Future studies will examine other metabolic influences on QUS parameters, and use QUS to monitor response in a randomised controlled trial of denosumab in acute Charcot neuropathic osteoarthropathy.
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O5.5

Outcomes Comparing Peripheral Arterial Disease Diagnosed via Angiography versus Clinical Examination in Charcot Neuroarthropathy Patients Who Underwent Osseous Reconstruction

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Aim: The primary aim was to compare post reconstructive outcomes in diabetic Charcot neuroarthropathy patients with peripheral arterial disease diagnosed by angiography versus those diagnosed clinically. Post reconstruction outcomes included wound healing, delayed healing, surgical site infection, pin tract infection, osteomyelitis, dehiscence, transfer ulcer, new site of Charcot collapse, contralateral Charcot event, malunion/nonunion, major lower extremity amputation, and return to ambulation.
Methods: A retrospective review of patients with diabetic Charcot neuroarthropathy requiring reconstruction secondary to ulceration or acute infection. Descriptive analysis compared outcomes between those diagnosed with peripheral arterial disease via angiography versus those diagnosed clinically. Bivariate analysis was performed for post reconstruction outcomes included wound healing, delayed healing, surgical site infection, pin tract infection, osteomyelitis, dehiscence, transfer ulcer, new site of Charcot collapse, contralateral Charcot event, malunion/nonunion, major lower extremity amputation, and return to ambulation.
Results: Of the 284 patients in the Charcot neuroarthropathy osseous reconstruction cohort after accounting for exclusion criteria, 19 patients were included in the angiography diagnosed peripheral arterial disease cohort, and 40 patients were included in the clinically diagnosed peripheral arterial disease cohort. Bivariate analysis found return to ambulation post reconstruction (p=0.0054) to be the only statistically significant factor; all other factors were not statistically significant.
Conclusions: Peripheral arterial disease diagnosed by angiography had a statistically significant higher rate of return to ambulation than peripheral arterial disease diagnosed clinically (p=0.0054). The clinical diagnostic modalities for PAD were affective in identifying the high-risk patients and therefore they were treated with aggressive medical and surgical intervention. With the aggressive treatment in both of the high-risk patient cohort, there were similar outcomes except for return to ambulation. Return to ambulation indicates improved functional outcomes. With this high-risk patient population, functionality is the most important marker of success. The main goal of limb salvage should not be focused on sparing the foot but on functional outcomes.

O6.1

Efficacy of Sucrose-Octasulfate Dressing in Neuro-Ischaemic Dfu Considering Factors Influencing Wound Closure Rate; a Post-Hoc Analysis of the Explorer RCT

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Aim: According to most recent guidelines, no treatment added to optimal Standard of Care (SOC) including efficient off-loading, has shown any clear benefit in the management of diabetic foot ulcer (DFU). Efficacy of a sucrose octa-sulfate wound dressing (TLC-NOSF dressing) versus a neutral dressing (TLC) in addition to the same standard of care, in patients presenting with a neuro-ischaemic DFU, was then assessed in neuro-ischaemic DFU, through a European RCT.
Methods: A double-blind RCT was conducted in 43 centres in patients presenting with a non-infected DFU (grade IC/ IIC, Texas Classification), and a surface area > 1cm². The primary outcome was the wound closure rate by week 20 in the ITT population (binary logistic analysis). Secondary outcomes included time to closure and adverse events occurrence (infection, notably).
Results: A total of 240 patients were randomised and received either the treatment dressing (n=124) or the control dressing (n=114). At Week 20, wound closure occurred in 34 patients (30%) in the control group and in 60 patients (48%) in the treatment group (adjusted odds ratio 2.60 [95% CI 1.43 to 4.73], p=0.002).
Post-hoc analysis were undertaken, considering parameters that may influence the tissue repair process (wound duration, wound location, patients' characteristics…), always showing favourable outcomes for the sucrose-octasulfate dressing, whatever the considered sub-group of patients.
Conclusions: Sucrose octasulfate dressing and good standard of care is significantly more effective than neutral dressing, in the management of neuro-ischaemic DFUs, and specifically when treatment is initiated early in the wound evolution.

O6.2

Healing Chronic Diabetic-Foot-Ulcers with Cyclical Pressurized Topical Wound Oxygen therapy: Results of the TWO2 Multi-National, Multi-Center, Randomized, Double-Blinded, Placebo-Controlled Trial

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Aim: Non-healing DFUs lead to increased mortality and morbidity. Our rigorous multinational RCT protocol was designed to explore the efficacy of a cyclical pressurized Topical Wound Oxygen (TWO2) modality in healing refractory DFUs.
Method: A Group-Sequential-Design was utilized with 2 interim analyses requiring a p<0.022. All subjects meeting enrollment criteria entered a 2 week run-in with optimal standard of care. Only DFUs achieving <30% wound area reduction were randomized (double blind) to either active, or sham, TWO2 device treatment arms. The primary endpoint of the study was 100% ulcer healing at 12 weeks. All analyses were exclusively of the Intent-to-Treat population. Secondary endpoints included ulcer re-occurrence at 12 months.
Results: At the first interim analysis point of 73 subjects, the active TWO2 arm was shown to be significantly superior to the sham arm (Pearson Chi2=7.2707, P=0.007). The active TWO2 arm showed nearly 4 times the likelihood to heal DFU in 12 weeks [HR 3.88 (95% CI 1.40 to 10.71), p=0.009]. Multivariate analysis showed that no covariates other than treatment achieved significance (See Table 1.). Larger active TWO2 arm wounds that had not fully healed at 12 weeks showed a mean reduction in size of 64% compared to sham treated ulcers that had a mean increase in size of 2% (P = 0.0052). 34 DFUs (23%) failed the run-in with ≥30% wound-area-reduction in 2 weeks.
Conclusion: This robustly designed double blinded RCT clearly demonstrates cyclical pressurized TWO2 therapy to be significantly superior in healing recalcitrant DFUs than gold standard care alone.

Table 1. Results by randomized group using ITT Analysis			
	Placebo	TWO2	Total
N	37	36	73
Gender			
Female	6 (16.2%)	4 (11.1%)	10 (13.7%)
Male	31 (83.8%)	32 (88.9%)	63 (86.3%)
UT Scale			
1A	29 (78.4%)	25 (69.4%)	54 (74.0%)
1B	2 (5.4%)	2 (5.6%)	4 (5.5%)
1C	1 (2.7%)	0 (0)	1 (1.4%)
2A	5 (13.5%)	8 (22.2%)	13 (17.8%)
2B	0 (0)	1 (2.8%)	1 (1.4%)
Neuropathic			
Yes	29 (78.4%)	28 (77.8%)	57 (78.1%)
No	8 (21.6%)	8 (22.2%)	16 (21.9%)
Infection			
Yes	3 (8.1%)	1 (2.8%)	4 (5.5%)
No	34 (91.9%)	35 (97.2%)	69 (94.5%)
Age (years)			
mean	61.9	64.6	63.3
sd	9.5	10.3	9.9
Wound area (cm^2)			
mean	3.22	3.02	3.13
sd	2.54	2.66	2.59
Duration (days)			
mean	174.6	157.9	166.4
sd	94	96.3	94.8
Hgba1c			
mean	8.07	8.43	8.25
sd	1.5	1.75	1.64
Ulcers Healed at 12 weeks	5 (13.5%)	15 (41.7%)	20 (27.4%)

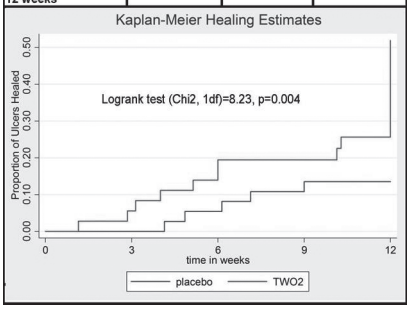

Table 1. Results by randomized group using ITT Analysis

O6.3

Recombinant Type 1 Human Collagen from Tobacco Plants Promotes Wound Repair in Diabetic Foot (DF) Post-Sugical Lesions.

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Aim: We aimed to evaluate the safety and efficacy of recombinant type 1 human collagen (T1HC) produced by transfected tobacco plants* in the management of DF post-surgical ulcers left to heal for secondary intent.
Methods: We tested T1HC in a group of patients surgically treated in our Department for DF between March and May 2017 after extensive debridement. Polyurethane film was adopted as secondary dressing. After discharge patients were followed weekly in our DF clinic until re-epitelizathion. We analysed healing rate and time to healing. The follow up was 75±18 days.
Results: We enrolled 24 diabetic patients (male/female 17/7; age 66.2±2.4 yrs; duration of diabetes 9.7±4.2 yrs, HbA1c 7.3±1.5), who underwent to surgical procedures and were left open to heal for secondary intent. Patients were randomized to receive T1HC on top of standard treatment (Group A, 12 pts) vs standard of care only (Group B, 12 pts). Healing rate was higher in Group A vs Group B (83.3% vs 58.3%, $\chi 2$ 13.6, $p<0.001$) and healing time was shorter (64±4 vs 90±11 days, $\chi 2$ 11.1, $p<0.02$). Multivariate Cox regression confirmed the positive effect on healing of collagen treatment. No patients presented adverse events or recurrences, neither required further antibiotic treatment or surgical procedures. Conclusion. Recombinant T1HC in wide diabetic foot post-surgical lesions allows to increase healing rate and to achieve complete healing in a shorter time. It can be therefore considered as a safe and effective modality to help secondary closure.
*Vergenix FG (Collplant, Ness-Ziona, Israel).

O6.4

Iron, Anaemia and Diabetic Foot Ulcers: Should We Care?

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Aim: To assess the prevalence of anaemia and functional iron deficiency (FID, low iron indices but normal haemoglobin) in patients attending a tertiary diabetic foot clinic, and to determine whether they are predictive of a poor DFU outcome.
Methods: A prospective cross-sectional study was undertaken between November 2017 and February 2018. Patients were stratified into how they were assessed on visitation, into New (DFU-N, n=48) or Follow up (DFU- FU, n=31) groups. They were then subsequently classified into an anaemia, FID or normal subgroups. The DFU-N cohort was followed up for a period of 24 weeks, and prognosis classified as favourable or unfavourable.
Results: Prevalence of anaemia and FID in the DFU-N group was 40% and 40% respectively; in the DFU-FU it was 55% and 32% respectively. For the whole cohort, haemoglobin value correlated with eGFR (0.282, p=0.01) and serum albumin (0.393, p<0.0001). Serum iron correlated with CRP (-0.591, p<0.0001), White cell count (WCC) (-0.359, p=0.001), albumin (0.233, p=0.02). In the follow up cohort, presence of anaemia and FID were both predictors of an unfavourable ulcer prognosis at 6, 12 and 24 weeks. Even at 6 weeks, 82% of those with anaemia and 67% of FID had an unfavourable outcome, compared to only 14% in those with normal haematinics (p<0.05). At 24 weeks post initial assessment, 81% of patients with anaemia and 73% of patients with FID had an unfavourable outcome, compared to only 14% in those with normal haematinics (p=0.007). Patients without FID or anaemia had a greater percentage of ulcers which healed without the need for amputation (p=0.007), over the full 24 week follow up.
Conclusions: A very high prevalence of Anaemia and FID was noted in patients with a DFU, and to our surprise, there was little difference between DFU-N and DFU-FU groups. This was associated with a poor DFU outcome, even at 6 weeks, and as late as 6 months. Taken together, along with the association with CRP, WCC and albumin, our findings suggest that inflammation of any degree may initiate the pathway to anaemia development which negatively impacts the rate of DFU healing.

O6.5

The Influence of Weight-Bearing Activity on Plantar-Wound Healing - Toward Personalization of Safe Physical Activities in People With Diabetic Foot-Ulcers

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Aim: The influence of weight-bearing activity on plantar wound healing is still debated. Some argue that regular engagement in weight-bearing activity even while wearing protected offloading may delay healing. Others suggest that stable and appropriately dosed protected weight-bearing exercise is beneficial to accelerate healing. This study performed a secondary analysis of data collected from a previous study [1] to determine the safety of dosed weight-bearing activity for people with active plantar-ulcers.
Methods: Forty-nine people with diabetic-foot ulcers were randomized to wear either a removable-cast walker (RCW) or an irremovable contact-cast (iTCC). Daily weight-bearing activities (walking and standing) were monitored using a validated wearable sensor. Rate of healing was defined by the change in wound area between baseline and week-two follow up. The regression analysis was performed to determine the association between weight-bearing activities and rate of healing.
Results: Regardless of offloading type, a significant negative correlation was observed between daily number of steps and rate of healing ($r=-0.45$, $p<0.050$). Results also suggest that every 1000 daily steps lead to 5% reduction in healing rate in iTCC group and 5.4% reduction in RCW group. Inter-subject comparison indicates that the negative association between daily steps and rate of healing is diminished for those with less than 3000 steps per day. No association between standing and speed of wound healing was observed in iTCC group. However, a significant negative correlation between healing rate and standing ($r=-0.64$, $p<0.050$) was observed in RCW, with every 30 minutes standing correlating to a 7% reduction in rate of healing.
Conclusions: Results suggest that while iTCC offloading is effective to protect a plantar wound during standing, it may not provide such protection when walking.. Between-subjects comparison suggests that walking up to 3000 steps per day will have minimum impact on wound healing and could be encouraged. The negative association observed between standing and rate of healing only in the RCW group suggests that RCW group may neglect wearing their offloading during standing.
Acknowledgements: This work was funded by Qatar National Research Foundation (NPRP 7-1595-3-405).
References: [1] Najafi et al., J. Diabetes Science and Tech, 2017 (11) 657-667.

O7.1

Assessment of Systemic Vasculogenesis After Autologous Cell Therapy of Ischemic Diabetic Foot

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Aim: Autologous cell therapy (ACT) injected into the lower limbs of patients with critical limb ischemia (CLI) is a new treatment method that induces local vasculogenesis. The evidence of possible systemic vasculogenesis after ACT (tumour growth, aggravation of diabetic retinopathy or distal revascularization potential) is lacking. The aim of study was to assess local vasculogenesis and the risk of systemic vasculogenesis after ACT in patients with CLI and diabetic foot.
Methods: Twenty-seven patients with CLI not eligible for standard revascularization who underwent ACT in our foot centre over 7 years were included into the study. Local vasculogenesis was assessed by transcutaneous oxygen pressure measurement (TcPO2) on the treated foot; systemic vasculogenesis was evaluated by TcPO2 on the contralateral foot, eye fundus examination and by myocardial scintigraphic parameters - ejection fraction (EF) and summed rest score (SRS). Difference in the levels of tumour markers and proangiogenic cytokines (vascular endothelial growth factor [VEGF], platelet derived growth factor AA and BB [PDGF-AA, PDGF-BB] and basic-fibroblast growth factor [b-FGF]) were compared in a subgroup of 12 patients. All parameters were assessed before and 6 months after ACT.
Results: Local vasculogenesis was proven by a significant increase of TcPO2 (from 19.1 to 42.8 mm Hg, $p<0.001$) after ACT on the treated foot in contrast with no change on the contralateral foot ($p=0.14$). Scintigraphic parameters did not significantly change after ACT (EF 55.9 vs. 56.2 % and SRS 5.6 vs. 4.5). No significant difference in tumour markers after 24 ± 6.5 months and no worsening of eye fundus were observed after ACT injection; in one case the eye fundus finding was improved. Plasmatic levels of VEGF, b-FGF, PDGF-AA did not change, we observed a trend for decrease in PDGF-BB levels ($p=0.076$).
Conclusion: Our study showed no systemic effect after intramuscular injection of ACT in patients with CLI, whereas the local vasculogenesis on the treated limb has been proven by significant increase of TcPO2. Despite of these results, all patients indicated for ACT should undertake complete oncological screening before the ACT injection.
Supported by Ministry of Health of the Czech Republic, grant no. 16-27262A and 00023001.

O7.2

Impact of Severe Diabetic Kidney Disease on the Effect of Autologous Cell Therapy in Diabetic Patients with Chronic Limb-Threatening Ischemia

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Aim: Diabetic patients with chronic limb-threatening ischemia (CLTI) not eligible for standard revascularization could obtain a therapeutic benefit from autologous cell therapy (ACT) using bone marrow-derived mononuclear cells. Severe diabetic kidney disease (sDKD) is a key factor influencing the prognosis and amputation rates. The aim of our study was to assess the impact of sDKD on the outcomes of ACT in patients with diabetes and CLTI.
Methods: Seventy patients with diabetes and CLTI persisting after standard revascularization treated by ACT in our foot clinic over 10 years, were divided into sDKD (n=22) and non-sDKD (n=48) groups. Controls were patients with the same inclusion criteria treated conservatively in the same period – sDKD (n=26) and non-sDKD (n=30). sDKD was defined as chronic kidney disease stages 4-5 (glomerular filtration rate<30ml/min/1.73m2). Death, amputation-free survival (AFS) and changes in transcutaneous oxygen pressure (TcPO2) were assessed during 24-month follow-up. Overall survival and AFS were evaluated using Kaplan-Meier estimation.
Results: TcPO2 increased significantly in both ACT groups (non-sDKD and sDKD) compared with baseline values (both p<0.001); no significant changes in both control groups were observed. Patients treated by ACT had significantly lower amputation rates regardless the presence of sDKD (p=0.0006). AFS was significantly longer in both sDKD (HR 0.35 CI 0.14-0.87) and non-sDKD (HR 0.46 CI 0.23-0.92) patients treated by ACT compared with controls. Overall survival of sDKD patients without regard to ACT was significantly lower compared with non-sDKD patients (p=0.002); we also observed a trend in lower mortality after ACT compared with controls regardless of sDKD (p=0.068).
Conclusions: Our study showed that patients with CLTI treated by ACT had significantly longer AFS and a significant increase in TcPO2 even when diagnosed by sDKD. On the other hand, overall survival was strongly influenced by the presence of sDKD in patients treated by ACT or conservatively.
Supported by the Ministry of Health of the Czech Republic, grants no. 16-27262A and 00023001.

O7.3

Adherence to Guideline-Recommended Medical Therapies in Type 2 Diabetic Patients with Chronic Critical Limb Ischemia (CCLI).

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Aim: The aim of this study was to evaluate the adherence to guideline-recommended medical therapies in type 2 diabetic patients managed by a third-level Center for chronic critical limb ischemia from January 2011 to December 2015.
Methods. We analyzed the database of 603 type 2 diabetic patients with CCLI (M/F: 430/173; age: 72±9 yrs; diabetes duration: 20±12 yrs; BMI: 27.6±4.9 Kg/m2; HbA1c 7.9±1.6%), focusing on the use of statin, anti-hypertensive and antiplatelet drugs, and smoke habits at the admission.
Results: In total, 63.7% of patients were on statin therapy; 82.6 % on anti-hypertensive treatment and 70.7% on antiplatelet drugs. Concerning smoke habits, 19% of patients were no-smokers; 41% former smokers and 40% active smokers. Among all patients, 32% were prescribed all the four guideline-recommended therapies. We observed no differences in total (138.8±42.2 vs 138.2±42.5 p=NS) and LDL cholesterol levels (75.0±35.4 vs 76.6±28.7 p=NS) in patients on statin therapy when compared with patients without hypolipidemic drugs. In patients treated with anti-hypertensive drugs we observed higher levels of systolic pressure (138.0±29.5 vs 107.7±36.6 p<0.02) while no differences were observed in diastolic pressure levels.
Conclusions: In conclusion, in diabetic patients with a severe limb and life threatening clinical condition, we observed a lower than expected application of international guideline-recommended medical therapies. In fact, only one out of three patients were following all the recommended therapies, but also these patients did not reach the standard targets requested to prevent cardiovascular disease.

O7.4

The Influence of Peripheral Arterial Disease on Muscle Activity in the Diabetic Foot

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Aim: The aim of this study was to evaluate whether there are any significant differences in muscle activity between individuals living with type II diabetes mellitus (T2DM) and individuals living with T2DM and peripheral arterial disease (PAD), during gait, at a self-selected speed and at various gait transition speeds.
Method: Ninety participants were divided into three groups of 30 participants each, namely Group A (T2DM), Group B(i) (T2DM and mild PAD) and Group B(ii) (T2DM and severe PAD). Surface elec-

trodes were placed on six lower limb muscles of both limbs, namely, rectus femoris, biceps femoris, tibialis anterior, gastrocnemius medius, peroneus longus and extensor hallucis longus. Muscle activity was recorded using a wireless electromyography system as participants walked at a self-selected speed. This procedure was repeated at 5% and 10% above the step frequency. Averaged Burst RMS was used to analyse the amplitude (mV) and the duration of muscle activation (s) of each signal.
Results: There was a significant increase in muscle amplitude and duration of activation in the presence of lower limb ischaemia during gait at a self-selected speed and at 5% and 10% above the baseline step frequency. The largest significant difference ($p = < 0.05$) in EMG amplitude and duration of activation was found between participants living with Type II DM [Group A] and participants living with Type II DM and severe PAD [Group B(ii)]. No significant difference was found between baseline step frequency, 5% above the baseline step frequency (Speed 2) and 10% above the baseline step frequency (Speed 3) in the mean EMG muscle amplitude and duration of activation in all six muscles tested.
Conclusion: That there was an increase in muscle EMG amplitude and duration of activation in individuals living with PAD during gait, indicating musculoskeletal and biomechanical changes in the lower limb musculature with increasing severity of PAD. Higher muscle exertion demands are required during gait to produce the desired action which may result in earlier fatigue. Electromyographic tests in the clinical setting would be beneficial for detecting muscle dysfunction objectively and non-invasively

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O7.5

Combining Diabetic Foot and Eye Screening - a Pilot Study

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Aims: This study aimed to explore the efficacy of combining foot and eye screening within one appointment. It also aimed to evidence the prevalence of asymptomatic Peripheral Arterial Disease (PAD), uptake of the additional screening and whether the patient experience welcomed a combined service in the future.
Methods: Potential participants were recruited whilst attending their retinopathy screening appointments 1 day a week over an 8-week period. Those consenting had a lower limb arterial assessment using an automated device (*Dopplex Ability, Huntleigh) measuring ankle brachial index (ABI) and pulse volume negating the need to rest the patient, plantar light touch sensation checked, and wave forms scrutinized for irregular heartbeat during the waiting time required for pupil dilation to occur prior to retinal screening.
Results: 360 participants were invited to take part. 89% (n=321) accepted the PAD screening and met the inclusion criteria. 24.6% (n=79) to have asymptomatic PAD not previously detected, 12% (n=38) were found to have neuropathy and 1% to have irregular heartbeat with a 100% positive patient experience. Binary Logistical regression was used to explore the data allowing for the potential risk factors for PAD investigated herein. Of the variables investigated in this study, the following predictors were found to be significantly associated with the presence PAD.
Conclusions: This novel combined screening model would not only identify asymptomatic PAD individuals and potentially unknown atrial fibrillation cases but would create an opportunity to increase patient knowledge and awareness of PAD and other life threatening cardiovascular risk factors associated with diabetes. This study was well-received and prevalence of undetected asymptomatic PAD in this study would indicate that opportunistic targeted screening could allow earlier identification and intervention of this potentially treatable limb and life-threatening disease.
Acknowledgements: Thanks goes to Cardiff Metropolitan University for funding this project through their Research, Enterprise and Innovation Fund (REIF). Thanks also goes to the Podiatry staff in both Cardiff & Vale and Cwm Taf UHB's and to the Diabetic Retinopathy Screening Service Wales for helping to facilitate this study.

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O8.1

The Effect of Daily Use of a Wearable Foot Compression Device on Pathophysiology and Motor Symptoms in Individuals With Diabetes

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Aim: Individuals with diabetic peripheral neuropathy (DPN) have impaired motor performance [1,2]. The aim of this study is to examine therapeutic effectiveness of mechanical stimulation through a wearable foot compression device equipped in a shoe insole on pathophysiology and motor performance in individuals with DPN.
Methods: Using a single-arm 4-week intervention study design, we examined effectiveness of daily use of shoes equipped with the foot compression device (FootBeat™, AVEX LLC, Colorado, United States) on improving plantar sensation (vibration perception threshold (VPTmax)), peripheral vascular status (skin perfusion pressure (SPP), ankle brachial index (ABI)), lower extremities edema (circumferences in the calf and ankle), and motor performances (postural sway with eyes open (EO) and eyes closed (EC) conditions, and gait performance during normal walking, dual-task walking and fast walking tasks). Thirty type 2 diabetic individuals with confirmed DPN (11 men; 68.1 ± 9.7 years; 33.4 ± 6.1 kg/m2) participated in this study.
Results: VPTmax decreased significantly post-treatment (27.4 ± 12.6 volts for pre-treatment and 23.3 ± 11.9 volts for post-treatment; $p = 0.007$). Center-of-mass sway in the medio-lateral direction decreased significantly for both EO and EC conditions post-treatment (0.94 ± 0.43 cm for pre-treatment and 0.76 ± 0.32 cm for post-treatment, $p = 0.020$; 1.10 ± 0.45 cm for pre-treatment and 0.83 ± 0.37 cm for post-treatment, $p = 0.033$, respectively). Stride velocity increased significantly for normal walking, dual-task walking and fast walking tasks post-treatment (0.87 ± 0.21 m/s for pre-treatment and 0.96 ± 0.23 m/s for post-treatment, $p = 0.017$; 0.75 ± 0.18 m/s for pre-treatment and 0.91 ± 0.23 m/s for post-treatment, $p = 0.001$; 1.10 ± 0.33 m/s for pre-treatment and 1.20 ± 0.27 m/s for post-treatment, $p = 0.043$, respectively). There was no significant changes in SPP, ABI and circumferences in the calf and ankle.
Conclusions: Our findings suggest the wearable foot compression device may be effective for treating neuropathic symptoms

and motor performances in individuals with DPN.
Acknowledgements: This work was funded by AVEX LLC.
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O8.2

Cardiometabolic Risk Factors as Determinants of Nerve Function – The Maastricht Study

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Aim: Neuropathy can already be present in the pre-diabetic stage, it is still debatable if this impairment is related to elevated glucose levels or other cardiovascular risk factors. Therefore, we examined associations of cardiometabolic risk factors and (pre-)diabetes with sensory and motor peripheral nerve function. Data were obtained in the Maastricht Study, a large population-based cohort study, characterized by an unique extensive phenotyping approach.
Research design and Methods: in 2401 adults (40-75 years) we determined fasting glucose, triglycerides (TG), HDL- and LDL-cholesterol, inflammation (sum score of 6 circulating markers), waist circumference, blood pressure and smoking. Diabetes status was derived from OGTT. Nerve conduction tests measured compound muscle action potential (CMAP) and sensory nerve action potential (SNAP) amplitudes, and nerve conduction velocities (NCV) of the peroneal, tibial and sural nerve. We assessed cross-sectional associations (standardized regression coefficients (β) and 95% confidence intervals) between cardiometabolic risk factors and nerve function. Associations were adjusted for potential confounders and for all other risk factors.
Results: Older age was associated with worse nerve function. Higher fasting glucose was associated with lower nerve function, with associations of strongest magnitude for motor peroneal and tibial NCV, β= -0.17 SD (-0.21;-0.13) and β= -0.18 SD (-0.23;-0.14), respectively. Larger waist circumference was associated with worse sural SNAP (β= -0.08 SD (-0.13;-0.03)) and tibial CMAP amplitude (β= -0.14 SD (-0.19;-0.09)). Smoking and inflammation were associated with lower peroneal NCV: β= -0.22 (-0.33;-0.11) and β= -0.08 SD (-0.14;-0.03), respectively. TG, HDL- and LDL-cholesterol, and blood pressure were not associated with worse nerve function; however, use of antihypertensive medication was associated with worse peroneal CMAP amplitude and NCV. Further, type 2 diabetes (n=25%) and prediabetes were associated with worse nerve function (p for trend <0.01 for all outcomes).
Conclusions: Older age, higher glucose, larger waist, inflammation, and smoking as well as pre-diabetes were independently associated with early-stage sensorimotor nerve damage. These data suggest that several cardiovascular risk factors have detrimental effects on nerve function, this decline already starts with mildly elevated glucose levels, within the 'normal range', and that lifestyle interventions might have beneficial effects on the course of neuropathy.

O8.3

The Natural History of Tarsal Tunnel Syndrome in Diabetic Patients

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Aim: Nerve entrapments like carpal tunnel syndrome are more prevalent in patients with diabetes, especially in those with diabetic sensorimotor polyneuropathy1. Recently the prevalence of tibial nerve entrapment at the tarsal tunnel was reported in a diabetic population of 416 subjects and a control group of 196 volunteers2. The neuropathic symptoms and higher sensory thresholds in (compressed) tibial nerve innervated areas were significantly more prevalent in diabetic patients. This provides evidence for the role of super-imposed entrapment neuropathy in diabetes related neuropathy, which is thought to relate to risk of ulceration3. The aim of the current study was to assess the risk for diabetic foot ulceration in patients with tarsal tunnel syndrome (TTS), compared to diabetic subjects without signs of tibial nerve entrapment.
Methods: Patients with TTS and patients without tibial nerve entrapment at baseline participating in the prospective Rotterdam Diabetic Foot Study were followed prospectively. Status of diabetic foot ulceration was assessed annually. Ulceration rates at three-year follow-up were estimated with Kaplan-Meier survival analysis. Events were diagnosed as the occurrence of an ulcer and time to event was time to diagnosis of ulcer.
Results: In the 416 patients studied, a left-sided unilateral TTS was observed in 8.5% (CI: 5.1-11.9%) of patients, a right-sided TTS in 8.3% (CI: 4.9-11.7%) and 17.7% (CI:13.9-21.5%) had a bilateral TTS. The mean follow-up was 1142 days (CI: 1110-1173), including patients who died during follow-up. Three-year ulceration rates were significantly higher for the group with right and bilateral TTS compared to subjects without signs of tibial nerve entrapment (right: 4.9% vs. 11.1%, p = .016, bilateral: 8.4% vs. 17.4%, p = .036). The group with left sided TTS showed the same trend (6.2% vs. 7.6%, p = .601).
Conclusions: TTS results in a higher risk for diabetic foot ulcers, compared to diabetic subjects without tibial nerve entrapment, at three-years of follow-up. This study provides evidence for the deterioration of nerve function as a result of nerve entrapment on top of diabetic neuropathy. Since treatment options for the entrapment component of neuropathy are available, a surgical release might lower the risk for incident diabetic foot ulceration.

O8.4

Continuous Temperature Monitoring Shows Plantar Foot Temperatures Change Throughout the Day for Persons with Diabetes and Neuropathy

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Aim: Over 425 people worldwide have diabetes, and upwards of 25% will have a foot ulcer (DFU) in their lifetime. DFUs are a severe complication of diabetes and may become infected, gangrene, and result in other complications such as lower limb amputations. DFU rates can be reduced by screening patients with diabetes to enable risk-based interventions. Skin temperature assessment has been clinically proven to reduce the risk of DFU. We introduce wireless sensor-embedded socks designed for daily wear, which perform continuous temperature monitoring of the feet of persons with diabetes. Combined with a mobile app, this wearable device informs the wearer about temperature increases in one foot relative to the other, to facilitate early detection of ulcers and timely intervention. The aim of this study was to observe the temperature pattern of the plantar surface of the foot in persons with diabetes and neuropathy, assess the accuracy of the sensors used, and obtain user feedback on the comfortability of the socks.
Methods: Temperature accuracy of the sensors was assessed prior to incorporation in the socks as well as in the completed sock design. A total of 35 patients with diabetic peripheral neuropathy (DPN), 18 years and older, were enrolled in a single-site study. The patients were instructed to wear the socks continuously for 6 hours after which the socks could be removed, and returned to the clinic.
Results: The temperatures measured by the standalone sensors were within 0.2°C of the reference standard. For all patients enrolled, continuous temperature monitoring shows that the plantar foot temperatures of patients with DPN change throughout the day. We found consistently that temperature measurements changed due to activity, inactivity, injury, and other situations. Furthermore, we found that temperature differences observed between the feet were consistent with clinical observations.
Conclusions: We report the first use of continuous temperature monitoring in the home environment for daily home use in patients with DPN. The temperature studies conducted show that the sensors used in the socks are reliable and accurate at detecting temperature, and the findings matched clinical observations.

This study was funded by Siren Care Inc.

O8.5

Therapeutic Effects of Mechanical Noise on Plantar Sensation in Diabetic Peripheral Neuropathy

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Aim: Noise applied to the skin is thought to enhance tactile sensation through a mechanism called stochastic resonance. In the past, real time effects of the application of mechanical noise to the plantar side of the feet (random vibration) on vibration perception threshold (VPT) (Zwaferink, 2018) and balance (Hijmans, 2008) were shown in people with diabetes mellitus (DM) and sensory peripheral neuropathy (SPN). So far no therapeutic effects of mechanical noise were shown. The aim of this study was to determine if mechanical noise, applied to the plantar side of the feet for 30 consecutive days, can improve VPT in SPN.
Methods: Seven adults (5 female, 2 male) with DM and SPN, aged 60 years on average (SD 11) participated in this preliminary study. Mechanical noise was applied to the plantar side of the feet, 30 minutes per day for 30 consecutive days, while the participant was seated. VPT was measured using a biothesiometer at baseline and post intervention by the same person. Seven points on the foot namely tip of the first toe, base of the first toe, second toe, third toe, fourth toe, fifth toe, and the medial instep of the foot were taken into account.
Results: Wilcoxon signed rank tests (non-parametric) revealed a significant decrease in VPT from 34.5V (SD12.8) to 25.1V (SD 12.0) on average (range -1V - 22V) for both the left and the right foot.
Conclusion: The use mechanical noise as a therapeutic intervention can improve protective sensation. As for each 1V increase in VPT the risk for foot ulceration increases with 5.6%, decreases found in this study of more than 9V have large potential in reduction of the risk for ulceration and lower limb amputation in patients with DM and SPN. The therapeutic effects found in this study are larger compared to the immediate effects found in previous research (Khaodhiar, 2003; Zwaferink, 2018).
Acknowledgements: This study was financially supported by Phoenix Medical Technologies

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O9.1

The Increasing Global Disability Burden Caused by Diabetes-related Lower-extremity Complications, 1990-2016

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Aims: Diabetes-related lower-extremity complications (DRLECs) are a leading cause of hospitalisations, amputations and disability. Yet, to our knowledge, no study has presented formal estimates

of the global disability burden caused by DRLECs over time. We therefore investigated the global prevalence and years lived with disability (YLDs) caused by DRLECs from 1990-to-2016.
Methods: We performed a secondary analysis of DRLEC-related prevalence and YLD data from the Global Burden of Disease Study (GBD) provided by the Institute for Health Metrics and Evaluation. We defined DRLECs as the GBD defined diabetes sequelae of diabetic neuropathy, foot ulcer and amputation. For each sequela in GBD studies, prevalence is estimated using a Bayesian meta-regression model based on systematic reviews of epidemiological literature, and disability weights using population-based surveys. YLDs are estimated by combining prevalence and disability weights. We investigated the changes in global prevalence and YLDs for DRLECs from 1990-to-2016, and compared the estimated YLDs for DRLECS against all other causes.
Results: The prevalence of the global population affected by DRLECs increased by 52.7%: from 1.15% (61.2 million) in 1990 to 1.75% (131.0 million) in 2016. The increases in subgroups were 50.3% for neuropathy (0.94%-to-1.41%), 63.8% foot ulcers (0.15%-to-0.25%) and 65.5% amputations (0.055%- to-0.091%) (all p<0.01).
The global YLD from DRLECs increased by 114.9% from 1990-to-2016 (7.84million-to-16.84million). The increases in subgroups were 110.4% for neuropathy (6.12million-to-12.88million), 129.7% foot ulcers (1.02million-to-2.51million), 133.3% amputation (0.62million-to-1.44million). After adjusting for age and population changes, DRLEC YLDs increased by 16.7%; 14.9% for neuropathy, 20.6% foot ulcers and 26.9% amputations. In 2016, 16.84million YLDs (2.10% of all global YLDs) would rank DRLECs as the 11th leading cause of global YLDs, compared with 7.84million YLDs (1.50%) in 1990 that ranked DRLECs as 18th.
Conclusions: We estimated that in 2016 DRLECs ranked 11th among the leading causes of global disability. Over the past three decades, the prevalence and disability burden of DRLECs have increased at a significantly greater rate than global population increases. This study provides the first formal estimates of the burden of DRLECs over time, and contains potentially important new information for organisations seeking to address the burden of disability.

O9.2

Recurrence of Diabetic Foot Ulcers: a Meta-Analysis

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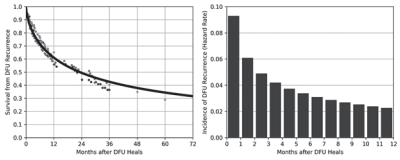
Aim: Despite decades of research on diabetic foot ulcer (DFU) recidivism, the authors are aware of no systematic attempt to synthesize epidemiological data in a statistically-rigorous manner. Therefore, we evaluated DFU recurrence for patients in remission.

Methods: We selected studies from a total of 390 results from a PubMed search on December 22, 2018 on the terms “diabetes,” “ulcer,” and “recurrence.” Where available, survival data in Kaplan-Meier curves were digitized; otherwise data reported at discrete times were used. We performed a parametric survival analysis on the available data using a maximum-likelihood formulation. We included a degree-of-freedom for each study that did not enroll patients upon healing to account for censoring informative right censoring of the left endpoint.
Results: There was high correlation (r^2=0.94; p < 0.001) between the log-logistic survival model and the raw survival data. The median recurrence duration was 22 months. The aggregate ulcer-free survival in the first year was 61%. Importantly, the recurrence decreased steeply over time, with 9.3% of patients suffering recurrence in the first month of remission, and 3.4% in month six. The studies considered have high heterogeneity across care environment, year undertaken, and patient demographics. Despite this, survival is characterized well by a fixed-effects parametric model.
Conclusions: The data suggest that advances in preventive practice over the last generation have not substantially improved outcomes for the diabetic foot in remission. Thus, renewed and additional focus on prevention is warranted for these patients. Additionally, that timing of these efforts should begin immediately following healing.



Parametric ulcer-free survival (left) and hazard function (right) for the diabetic foot in remission.

O9.3

Data Linkage and Geospatial Mapping Exposes Inequalities in Outcomes for Diabetic Foot Disease in Glasgow

PhD student Joanne Hurst[1], Dr Lesley Gibson[2], Mr David wylie[3], Dr Brian Kennon[3], Dr Ruth Barn[1], Dr Sicco Bus[4], Professor James Woodburn[1]
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Aim: The aim of this study was to identify trends and inequalities in outcomes for diabetic foot disease in the geographical boundary of a large Scottish health board using data linkage and geospatial mapping.

Methods: 112,231 people with diabetes were extracted from the Scottish Care Information – Diabetes Collaboration (SCI-diabetes) and anonymously linked to the National Records Scotland and the Scottish Morbidity record to identify death, amputation and ulceration outcome events between 2002-2016. Geospatial mapping software (ArcGIS Desktop 10.4) was used to map these outcomes across NHS Greater Glasgow and Clyde using the Scottish Index of Multiple Deprivation (SIMD) 2016 map. Hot spot analysis was used to spatially identify statistically significant zones for each outcome map. The relationship between SIMD quintiles and the fre-

quency of observed outcome was investigated using chi-squared analysis.
Results: Foot ulceration was observed in 6935 registry patients. Lower extremity amputations (LEA) were identified in 1507 patients. 3804 deaths were recorded in patients with a past history of foot ulceration or LEA. Statistically significant clusters formed across all outcomes across the health board (Figure 1). Significant hot spot clusters were associated with higher levels of deprivation, whilst cold spots were found in lower levels of deprivation for each outcome.
Conclusion: The use of routinely collected health data, its linkage and visualization over a large geographical area identified inequalities in outcomes for diabetic foot disease in Glasgow. Social deprivation is strongly associated with poor outcomes. These results have important implications for the diabetic foot services in the city.

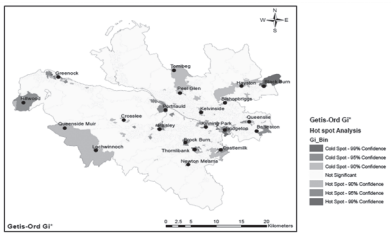

Figure 1: Hot Spot analysis illustrating spatial distribution of registry prevalence of LEA in individuals with diabetes within boundary of NHS Greater Glasgow and Clyde between the years 2002-2016.

O9.4

Development of Case-Mix Adjusted Models to Study Variation in Clinical Outcome of Diabetic Foot Ulcers

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Aim: Case-mix adjustment may be needed when comparing the effectiveness of DFU services. We used the 38,480 ulcer episodes registered with the National Diabetes Foot Care Audit (NDFA) of England and Wales from 2014-2018 to develop risk-adjustment models for four clinical outcomes.
Methods: Details of patients (demographics, diabetes, co-morbidities), ulcers (site, number, area, depth, infection), limbs (ischaemia, neuropathy, associated Charcot disease) and clinical outcomes were extracted from the NDFA, the Core National Diabetes Audit, hospital episode data for England and Wales and the Office of National Statistics. Logistic regression models were built using a selection process to identify predictor variables consistently associated with outcomes.
Results: a. Being alive and ulcer-free -
Of 27 variables studied, those most closely associated with the patient not being alive and ulcer-free at 12 weeks were characteristics of the ulcer and limb (particularly ischaemia and ulcer area) and delay in expert assessment. But the predictive power of the model was weak (c statistic 0.69).
b. Foot disease-related admission to hospital within 6 months -
11 of the 12 variables selected for the foot disease model were the same as for (a) but the resultant model was stronger (c statistic 0.74).
c. Major amputation within 6 months -
The factors most closely associated with major amputation were also mainly ulcer characteristics (particularly ischaemia and ulcer area), but patient factors also contributed (renal replacement therapy, RRT, and smoking history). This model was more powerful (c statistic 0.79) than (a) and (b).
d. Death within 6 months -
The factors most closely associated with mortality were predominantly patient factors (including age, heart failure, RRT). The predictive power of this model was strong (c statistic 0.80).
Conclusions: Factors contributing to the different outcomes of DFUs managed in the UK universal health care service are typically dominated by ulcer characteristics (especially ischaemia) but patient factors are more closely associated with mortality. These findings emphasise the need for tailored case-mix adjustment when comparing ulcer outcomes between different populations.

O10.1

The Infected Diabetic Foot: Re-evaluating the Infectious Diseases Society of America Diabetic Foot Infection Classification

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Aim: To evaluate clinical outcomes and complication in patients with diabetes mellitus (DM) and moderate or severe foot infections to inform a revision of the Infectious Diseases Society of America diabetic foot infection (DFI) classification by the addition of a separate risk tier for osteomyelitis (OM).
Methods: We included 294 patients in this retrospective study of moderate and severe DFI. Diabetic foot OM was confirmed by bone culture or histopathology. Soft tissue infection (STI) was based on negative bone culture, magnetic resonance imaging (MRI) or single-positron emission computed tomography (SPECT). Patients were stratified by STI and OM and IDSA criteria for moderate and severe infection and compared clinical outcomes and post discharge complications.
Results: Among outcomes between moderate and severe STI, readmission was more common in those with moderate infection (46.2%% vs. 25.0% p<0.001). However, there were no differences in moderate and severe OM with the exception of the number of surgeries (2.8 ± 2.1 vs. 4.1 ±2.5) and length of stay for readmissions (18.5±17.5 vs. 28.2±19.8, p<0.001). However, patients with OM had worse outcomes than those with STI in every measured outcome: antibiotic duration (23.8±32.4 vs. 50.5±46.7, p<0.001), number of surgeries (1.1±1.4vs.3.3±2.3, p<0.001), amputations (25.5% vs. 83.4%, p<0.001), re-infection (39.4% vs. 56.7%, p=0.008), and length of stay (14.8±15.2 vs. 22.6±19.0, p=0.034) (Table 1).

Conclusions: The IDSA diabetic foot infection classification would better reflect clinical outcomes if the current criterion for moderate and severe infection was not used, and risk categories were stratified by soft tissue and bone infections.

TABLE 1. Hospital outcomes and follow-up complications in diabetic patients with soft-tissue or bone infections of the foot

	Soft Tissue Infections N = 137		Osteomyelitis N = 157			
Outcome[a]	**Value**	**(%)**	**Value**	**(%)**	**P-value[b]**	**OR[b] (95% CI)**
Inpatient Factors						
Initial duration of antibiotics, days (SD)	23.8	(32.4)	50.5	(46.7)	**<0.01**	
Surgical intervention[c]	74	(54.0)	156	(99.4)	**<0.01**	128.6 (17.5, 945.7)
No. of surgeries	1.1	(1.4)	3.3	(2.3)	**<0.01**	
Lower limb amputation	35	(25.5)	131	(83.4)	**<0.01**	14.5 (8.22, 25.7)
Foot	26	(19.0)	113	(72.0)	**<0.01**	9.98 (5.73-17.36)
BKA & AKA	10	(7.3)	18	(11.5)	0.31	1.64 (0.73-3.70)
Revascularization	12	(8.8)	18	(11.5)	0.43	1.36 (0.63, 2.93)
Length of Stay (days)						
1-Year Outcomes						
Healed[d]	92	(67.2)	114	(72.6)	0.41	1.24 (0.75, 2.06)
Days to healing	165.3	(102.5)	165.3	(112.3)	**0.03**	
Re-infection[d]	52	(38.0)	89	(56.7)	**<0.01**	2.25 (1.40, 3.62)
Re-admission[d]	80	(58.4)	105	(66.9)	0.06	1.40 (0.98, 2.60)
Related to initial diagnosis	54	(39.4)	84	(53.5)	**<0.01**	1.88 (1.17, 3.01)
Related hospital LOS, days	14.8	(15.2)	22.6	(19.0)	**0.03**	
1-year mortality	4	(2.9)	5	(3.2)	1.00	1.07 (0.28, 4.06)

STI = Soft-Tissue Infection; OM = Osteomyelitis; LOS = Length of Stay
[a]Mean and standard deviation (SD) presented for continuous variables.
[b]Determined using appropriate statistical analyses–Mann-Whitney U-test for continuous variables. Chi-squared test of homogeneity and Fisher exact test for categorical variables. Significant values are bolded.
[c]During initial hospitalization for STI or OM.
[d]After initial discharge from hospital.

Comparison of outcomes by infection type

O10.2

Postoperative Hyperglycemia Increases Infectious Complications in Operatively Managed Ankle Fractures with Diabetes

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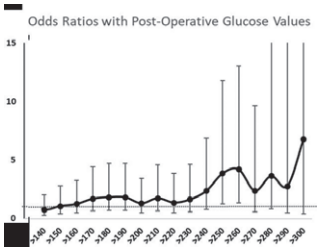
Aim: To evaluate the effect of perioperative hyperglycemia in patient with diabetes mellitus (DM) that undergo surgical management at an academic level 1 trauma center.
Methods: We reviewed 2,264 patients with surgically managed ankle fractures from 2009 to 2015 and identified 218 patients with diabetes mellitus (DM) at an academic level 1 trauma center. We evaluate glycated hemoglobin (HbA¬1C) and pre- and postoperative glucose with readmission, reoperation, and infectious and noninfectious complications. We performed receiver operating characteristic (ROC) analysis and odds ratios (OR) for outcomes.
Results: The mean postoperative glucose level was 176.8±59.7 mg/dL. No statistical difference in postoperative glucose was observed between patients who experienced infectious complications and those who did not (192.5±70.7 mg/dL vs. 174.8±57.9 mg/dL, p=0.33). However, ROC analysis found a postoperative glucose cutoff value of 260 mg/dL that demonstrated 4.21-fold (95% CI 1.37-13.0) increased odds of infectious complication. When multiple ORs for various postoperative glucose cutoffs were evaluated, an increase in OR was seen from 140 mg/dL to 260 mg/dL followed by a slight drop between 260 mg/dL and 300 mg/dL (Figure). A postoperative glucose of 140 mg/dL was associated with 59% reduced odds of readmission (0.41 OR, 95% CI 0.18-0.94). No significant cutoff values for HbA1C was predictive of postoperative infection.
Conclusions: This study suggests a role for glucose control after ankle fracture surgery and postoperative complications. Postoperative hyperglycemia appears to be predictive of infectious complications after ankle fracture surgery. Tighter postoperative glycemic management appears to be associated with reduced odds for infectious complications.



Odds ratios at various postoperative glucose cutoffs

O10.3

Basic Bone Biopsy (B3) or Bedside Blind Bone Biopsy (B4) for Suspected Diabetic Foot Osteitis?

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Aim: B4 performed by a diabetologist has been recently shown as a reliable tool to manage medical treatment in case of Diabetic Foot Ulcer (DFU) with suspected osteitis. To compare the samples quality collected either by B4 (center A, December 2015 to August 2018) or by B3 (center B, surgery or interventional radiology, September 2013 to August 2018), we performed a bicentric, observational, retrospective study.
Methods: Consecutive patients with Diabetes Mellitus (DM) admitted with foot ulcer and clinical and/or radiological suspicion of osteitis with an indication of Bone Biopsy (BB) on clean skin.
Center A: B4 performed by a diabetologist at patient bedside in the diabetology unit.
Center B: B3 performed by a surgeon or an interventional radiologist.
Main judgement criteria: contaminations, sterile BB and healing rates.
Results: 146 patients with DM were included. A: B4=97/415 DFU (23%) during 32 months, B: B3=49/697 DFU (7%) during 61 months (surgery n=33/49 [67.4%,], radiology n=16/49 [32.6%]). Males (74.7%), mean age (68.6±12.2years), mean duration of DM (18.4±10.9years), mean glycated hemoglobin (8.1±2.1%). Patients characteristics were similar between the 2 groups. No statistical difference for mean delay between time of BB decision and procedure (B4 16.2±13.3 days, B3 13.6±9.3 days, p=0.65) and for the rate of contaminations (B4 8.9%, B3 10.9%, p=0.29). The rate of sterile BB was significantly higher in the B4 group (44.3%, B3 18.3%, p=0.002) while the healing rate at 3 months was similar in the two groups (B4 45%, B3 49%, p=0,15).
Conclusions: B4 is an useful option in case of DFU with suspected osteitis as it provides similar quality of bone samples as B3.

O10.4

Utility of 99m-Tc UBI (29-41) SPECT/CT in the Diagnosis of Diabetic Foot Infections

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Diagnosis of diabetic foot Osteomyelitis is crucial for the proper management of the diabetic foot; however it is quiet challenging as well. Ubiquicidin (UBI) is an antimicrobial peptide and a part of human innate immunity. It has been successfully labelled with Tc-99m and could be utilized as an infection imaging agent. SPECT/CT (Single Photon Emission Tomography/Computer Tomography) technique is useful in localization of the lesion. Aims: The study was conducted to evaluate the potential role of 99mTc UBI (29-41) SPECT/CT in the diagnosis of diabetic foot infection. **Methods:** 41 patients (Males = 34, females=7, mean age=56 years and range=40-76) suspected of having diabetic foot osteomyelitis were included in the study. A dose of 407 MBq (11mCi) of 99mTc-UBI (29-41) with high specific activity (407MBq/0.5ml) was injected to patients. Immediate 1 minute dynamic study was followed by spot views at 15-30minutes and SPECT/CT at 30-45minutes in suspected diabetic foot infection patients. The scans were interpreted as true or false positive and true or false negative on the basis of bone biopsy/pus culture, history, clinical examination and follow up. Contributory role of SPECT/CT in the localization of infection was also evaluated. **Results:** Sensitivity, specificity, PPV, NPV and diagnostic accuracy for diabetic foot infection are 100%, 86%, 97%, 100% and 98% respectively. Overall a contribution of SPECT/CT in 19 (47.5%) patients was demonstrated. Conclusion: 99mTc UBI (29-41) SPECT/CT imaging is a promising imaging modality for diabetic foot infections. SPECT/CT precisely localizes infective focus with simultaneous discrimination between bone and soft tissues

O10.5

WBC-SPECT/CT to Assess Diabetic Foot Osteomyelitis Remission: Contribution of a Composite Severity Index

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Aims: Diabetic foot osteomyelitis (DFO) is a frequent complication of diabetes, and an important risk factor of amputation. We previously published that White Blood Cell (WBC)-SPECT/CT could be a useful tool to assess DFO remission and guide the duration of antibiotic treatment. The aim of the current study is to evaluate the performance of WBC-SPECT/CT to diagnose DFO remission using a standardized hybrid image–based scoring system, Composite Severity Index (CSI).

Methods: All WBC-SPECT/CT performed for patients with DFO at the end of antibiotic treatment in a single nuclear medicine department were retrospectively read by 2 nuclear physicians (1 senior and 1 junior), blind to clinical results. Classic visual assessment was performed and with CSI to classify images as follow: intensity of uptake, from 0 to 3 at 2 hours and 20 hours after injection on planar acquisitions and stage of bone erosion on SPECT/CT at 20h, from 0 to 3. Comparison between performances of composite score index and visual assessment was realized. Successful treatment of DFO was defined by absence of DFO relapse in the same site within 1 year.
Results: Fifty-eight patients with 60 DFO were included. Eight were excluded of analysis due to absence of follow-up or absence of SPECT/CT. Of the 52 DFO included in the analysis, 9 (17.6%) showed a relapse during follow-up. Sensitivity, specificity, positive predictive value, negative predictive value and accuracy of WBC-SPECT/CT to predict relapse of DFO in the same area with visual assessment were lower for junior physician (respectively at 60%, 80.4%, 40%, 89.9%, and 75%) than for senior physician (respectively 90%, 83.3%, 56.3%, 97.2%, and 84.6%) with moderate inter-rater agreement (Kappa at 0.587). Performances with the use of CSI were significantly better only for junior physician with good inter-rater agreement (kappa at 0.76).
Conclusion: We show in this study that classic interpretation of WBC-SPECT/CT with visual assessment to assess DFO remission needs experience and supports that CSI could be useful for junior nuclear physician to discriminate residual infections and inflammatory post-treatment uptake and to normalize interpretation of WBC-SPECT/CT.

O11.1

The Effect of Arterial Pedal Arch Patency on Wound Healing in the Setting of Angiosome-Specific Infrapopliteal Bypass Revascularization

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Objective: The aim of this study was to evaluate the effect of angiosome-specific revascularization on wound healing and amputation-free survival following infrapopiteal bypass (IPB) for tissue loss of the foot. The impact of pedal arch patency directly on tissue loss wound healing was also evaluated.

Methods: Our single-center Society for Vascular Surgery (SVS) Vascular Quality Initiative (VQI) registry was queried to identify IPB procedures in the setting of critical limb-threatening ischemia (CLTI) with tissue loss between 2010-2018. Screening was then performed to identify patients with pedal arch angiograms and those with outcomes of either complete wound healing or requiring amputation. We examined for variables associated with pedal arch patency and the ability to perform direct (DR) or indirect (IR) angiosome revascularization or mixed for complex wounds. Pedal arch patency was defined as either incomplete/no pedal arch (IPA), collateraized pedal arch (CPA), or fully patent pedal arch (FPA).
Results: 51 consecutive IPB procedures with complete pedal

angiograms and follow-up were identified. Direct angiosome revascularization resulted in 88.9% wound healing while indirect revascularization resulted in 58.8% wound healing (P = 0.190). 50% of patients who had wounds encompassing mixed angiosomes were able to heal after bypass (P = 0.371). Average time to heal for DR, IR, or mixed angiosome revascularization were 260 days, 181 days, and 166 days, respectively. One amputation occurred in each angiosome group after initial wounds healed. Pedal arch patency was associated with wound healing. In the FPA group, 100% healed their wounds (n = 9), while CPA and IPA groups had wound healing rates of 37.5% (n = 8) and 67.3% (n = 34), respectively (P = 0.017). FPA, CPA, and IPA were observed in 7.9%, 15.7%, and 75%, respectively, in diabetic patients (n = 38). Diabetes mellitus was strongly associated with a compromised pedal arch (P = 0.007) though not with whether direct or indirect revascularization could be performed (P = 0.098).

Conclusions: The degree of pedal arch patency was significantly associated with wound healing and inversely associated with diabetes mellitus. Direct angiosome revascularization did not significantly increase wound healing compared to indirect revascularization in our sample.

O11.2

Bypass to Peroneal Artery is More Effective than Bypass to Foot Arteries in Insulin-Dependent Diabetic Patients with Critical Limb Ischemia

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Aim: To compare results of bypass to the peroneal artery(BPA) and bypass to the foot arteries(BFA) in diabetic patients with critical limb ischemia(CLI).
Methods: A retrospective study was performed including all diabetic patients with CLI revascularized by bypass to the peroneal artery or to the foot arteries (anterior/posterior tibial arteries at ankle level or dorsalis pedis/plantar arteries) between Jan-2006 to Dec-2017. Patient's demographics and clinical characteristics were collected. Pre-operative angiograms were reviewed to determine patency of peroneal artery and foot arteries. End-point was to compare BPA and BFA results in terms of limb salvage(LS) and primary patency(PP). Kaplan-Meier analyses were used for survival, limb salvage and patency.
Results: A total of 104 bypasses (54 BPA and 50 BFA) were performed in 104 diabetic patients (median age=74yrs; 77.9% males). Ischemic heart disease, kidney disease and chronic obstructive pulmonary disease were present in 56.7%,37.5% and 33.6%, respectively. Insulin-dependent patents were 38(36.5%). All patients presented CLI with Rutherford stages-4,5 and 6 in 5.8%,39.4% and 54.8%, respectively. Infected lesions were found in 54.6%. The bypass graft was mainly (70.2%) great saphenous vein(GSV). Tissue loss was treated by: debridement, toe/ray amputation and forefoot amputation in 4.8%,58.1% and 31.3%, respectively. The mean follow-up was 36.1±30 months. LS at 1,12 and 24 months was 91.3%,80.5% and 77.8%, respectively. PP at 1,12 and 24 months was 90.4%,58.9% and 50.7% respectively. Secondary patency at 1,12 and 24 months was 90.4%,70.1% and 63.7% respectively. In overall population BPA and BFA had similar results in terms of LS and PP (P=0.4 and P=0.72). However, insulin-dependent patients had worse results if underwent BFA in terms of LS (at 12-month 33.3% vs. 81.1%; P=0.03) and PP (at 24-month 12.5% vs. 50.1%; P=0.031). Furthermore, in insulin-dependents, bypass to peroneal artery with 1 or no patent communicating branches still had better results than BFA in terms of LS(P=0.027) and PP(P=0.005).
Conclusions: Diabetic patients treated for CLI by bypass surgery to peroneal artery or to foot arteries have similar results with high limb salvage rates during follow-up. As an exception, insulin-dependent patients present higher limb salvage and patency rates if treated by bypass to peroneal artery.

O11.3

Characteristics, Treatment and 6-Month Outcomes of 738 Patients with a Diabetic Foot Ulcer and Critical Limb Ischemia

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Aim: Describe the characteristics, treatment and outcomes of patients with diabetic foot ulcers (DFU) and critical limb ischemia (CLI) treated in all recognized Belgian diabetic foot clinics (DFC).
Methods: 738 patients with DFU (Wagner grade ≥ 2) and CLI (PEDIS perfusion grade 3) were identified from 5,908 patients registered by 35 Belgian DFCs between 2008 and 2016 for quality assurance purposes. Data include characteristics at time of presentation with a new DFU and type of treatment and outcomes during a follow-up of maximum 6 months, or until death or loss to follow-up. Details of the study design have been published.[1]
Results: Mean (SD) age was 73.0 (10.5) years; 69.8% were male; median (P25-P75) diabetes duration was 15.7 (8.6-24.0) years. Prior lower-limb revascularization was reported for 53.9% and prior minor amputation for 29.5% and major amputation for 9.2%. Prior ischemic heart disease and/or stroke was reported for 52.5% and end-stage renal disease for 14.1%. Median follow-up was 4.6 (2.5-6.0) months. During follow-up, 68.2% were treated with lower-limb revascularization; 4.2% with primary major amputation, i.e. without prior revascularization; 27.6% were treated conservatively. Reasons for conservative treatment were not recorded. Primary DFU healing was achieved in 16.9% after a median of 3.0 (1.8-4.2) months. Healing with minor amputation was achieved in 16.1% after a median of 2.8 (1.9-4.4) months. DFU were resolved by major

amputation in 12.1% after a median of 1.6 (0.3-2.9) months. For 19.1% of these patients, this was the second major amputation. Death occurred in 13.4% after a median of 2.6 (1.3-3.9) months. At the end of follow-up, 44.6% were alive, without major amputation during follow-up and with a non-healed DFU.
Conclusions: This high-risk cohort of DFU patients with CLI was intensively revascularized. During a follow-up of 6 months, ulcer healing without major amputation was achieved in 33%. Rate of major amputation (12%) and death (13%) were high. Nearly half of the patients were alive with a non-healed ulcer at 6 months. Longer follow-up is needed to better understand the outcomes of these patients.

[1] Doggen K et al. Diabetes/Metabolism Research and Reviews 30 (2014): 435–43.

O11.4

TcpO2 Evaluation for the Prediction of Ischemic Diabetic Foot Ulcer Healing Following Revascularization.

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Aims: The effect of revascularization can be assessed by clinical evaluation, ABI, Doppler ultrasound or other imaging tests. However, these analyses require interpretation and frequently appear to be subjective. Especially when predicting ischemic diabetic foot ulcer healing. We conducted the study in order to compare different methods of lower extremity ischemia assessment and the efficacy of angiosomal revascularization in relation to transcutaneous oximetry (TcpO2) results.
Methods: Between February 2017 and July 20018, 64(16F/48M) patients underwent revascularization of 78 lower limbs, due to ischemic diabetic foot ulcer. 42 traditional and 36 endovascular interventions were performed. Operative procedure selection was based on precise clinical evaluation, Doppler ultrasound and diagnostic imaging. Adequate procedure was chosen, with the intention of the best revascularization effect. Additionally, optical fluorescence based TcpO2 measurement of each ischemic limb angiosome was performed, in order to verify diagnostic findings from previous analyses. Postoperatively, the same sequence of evaluations was performed, to compare revascularization effect results of different forms of analysis with the angiosomal TcpO2 changes.
Results: The level of correlation of the diagnostic results of clinical evaluation, Doppler ultrasound and imaging evaluation in comparison to the TcpO2 measures was 46.2%(36/78), 71.8%(56/78), 66,7%(52/78) respectively. Postoperatively, improvement of lower limb vasculature was observed in 82.1%(64/78) of clinical analyses and 100%(78/78) of Doppler ultrasound and imaging tests. However, the TcpO2 improvement of critical angiosomes was noticed just in 74.4%(58/78) of cases.
Conclusions: The optical fluorescence based TcpO2 measurement is a well-tolerated, noninvasive, objective and quantify analysis of the tissue angiosomal arterial supply. This may serve as a supplementary method to traditional vascular diagnosis, contributing to the decision of the most appropriate operative procedure selection. The TcpO2 measurement improves the adequacy of revascularization results assessment with regard to angiosomal theory and prediction of ischemic diabetic foot ulcer healing.

O11.5

Effects of resting hypertension on diagnosis of peripheral arterial disease with ankle-pressures, toe-pressures, transcutaneous oxygen and flowmetry with heating

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Aim: Despite resting patients before an assessment for peripheral arterial disease (PAD) in the diabetic foot, persistent hypertension in the arm is common. The aim was to investigate the possible influence of hypertension on parameters of PAD in the foot of patients with diabetes.
Method: Consecutive patients attending a diabetic foot clinic with foot ulceration, had both limbs assessed for PAD with: ankle-pressures (ABPI), toe-pressures (TBI), transcutaneous oxygen (tcpO2) and percentage increase in forefoot flowmetry with heating (FU). Individual limbs were analysed within 3 groups depending on their simultaneous systolic arm pressure during assessment; Group 1, low arm systolic pressure, <115mmHg; Group 2, normotensive at rest, (arm systolic ≥115mmHg but <150mmHg); and Group 3, hypertensive at rest, (arm systolic ≥150mmHg). ANOVA analysis were done for differences across three groups and correlation coefficient of PAD parameters with arm systolic pressure.
Results: There were 135 patients, mean age 65±12yrs, 82% male and 256 limbs with a paired ankle and toe parameters. Group 1; 28 limbs, Group 2; 160 limbs and Group 3; 68 limbs. The ABPI was significantly different across the 3 groups of differing blood pressure; 1.30±0.50 vs 1.14±0.36 vs 1.05±0.22 respectively [p=0.006]. However, there was no significant difference in TBI; 0.60±0.25 vs 0.63±0.26 vs 0.57±0.22 respectively [p=0.237]. Forefoot tcpO2 was also not affected by systolic blood pressure as indicated by a non-significant negative correlation (r=-0.0847, [p=0.175]). Mean percentage increase in forefoot flowmetry with heating was also unaffected by differing blood pressure across 3 groups; 343% vs 413% vs 394% respectively, [p=0.451]. Analysis of PAD per toe/ankle gradient was also unaffected by the 3 hypertensive groups; 0.49±0.20 vs 0.57±0.19 vs 0.55±0.20 respectively, [p=0.149]. The proportion of limbs with ulceration across the 3 groups was also not significant; 52% vs 57% vs 64% respectively [p=0.285].
Conclusion: Toe pressures, tcpO2 and heating flowmetry are not significantly affected by resting hypertension in contrast to ankle pressure measurement, in which there is difficulty in occluding the pulse compared with the arm. Thus, the widespread use of ABPI in the diagnosis of PAD including disease below the ankle is not justified in patients with diabetes.

O12.1

Is There a Vacancy for the Nutritionist in a Multidisciplinary DFU Team?

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Introduction and Aim: Malnutrition is suggested to negatively influence wound healing. As such, it is deleterious for the patient with a diabetic foot ulcer (DFU).
This study determined the prevalence of malnutrition in patients admitted for a DFU.
Patients and Methods: This prospective, observational, single-centre cohort study ran from July 1st, 2016 till June 30th, 2018. Patients were included after informed consent. Nutritional status was investigated within 48 hours of admission using 3 methods.
Two screening (NRS-2002 and MNA-SF) and 2 assessment questionnaires (SGA and MNA) were performed. All questionnaires have been previously developed for and validated in hospital patients.
Impedance measurements determined body composition. Nutritional status was assessed by the standardized phase angle (SPA), with a SPA < -0,8 indicating malnutrition.
After scoring according to each of the above individual methods, nutritional status was arbitrarily assigned as follows: 'normal', if all methods revealed no abnormalities; 'at risk', if one method revealed abnormalities, and 'malnourished', with 2 or more abnormal results.
Results: In total, 139 admissions were recorded. After exclusion per protocol, data of 94 admissions could be fully analyzed. The cohort included 73 males; median age was 70 years (30–92).
Both screening questionnaires (NRS-2002 and MNA-SF) were combined for analysis, revealing 41 patients with normal nutritional status, and 53 patients with a potential risk of malnutrition based on at least one questionnaire. Based on the MNA questionnaire, normal nutritional status was attributed to 34 patients, increased risk of malnutrition to 41 patients, and malnutrition to 8 patients. The SGA questionnaire found 72 patients to have a normal nutritional status, and 25 patients to have malnutrition.
Fifty-two patients had a SPA < -0.8, indicating malnutrition, whereas 39 patients had a normal SPA.
Based on the combined results of screening, assessment questionnaires and impedance measurements, 60 patients (63.8%) showed 'malnutrition', 21 patients (22.3%) were 'at risk' and only 13 patients (13,8%) were categorized as 'normal nutritional status'.
Conclusion: In this study, a compromised nutritional status was identified in 86,2% (n=81) of patients hospitalized for DFU. This high and alarming number highlights the need for a thorough nutritional assessment of this population.

O12.2

What do They Want: Patient Priorities in the Diabetic Foot Clinic and VBHC

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Aim: Patient perception differs from the clinical presentation by understanding patient-expectations we can engage, improve decision-making and outcomes. Here we identify and tier patient-outcomes in a value-based-approach to help providers target-treatment-pathways.
Methods: Over a-period of 2-months we administered a questionnaire to assess potential treatment outcome in 5-principle domains Social Interaction or Fuctioning; Socio - Economic (Employment Opportunities); General Health; Subjective-Symptoms (Pain and Deformity) and Physical-Functioning (Walking/Standing problems). Each domain was assessed using specific questions and answered on a 5-point Likert scale (each item is scored from 0 to 4, with 4 denoting 'most severe'). In combination with the EQ-5D & PHQ4 for general health & depressive-symptoms.
Patients were defined according to foot-disease, symptoms and limb-salvagability.
Results: We interviewed 100 patients; 73 completed questionnaire were assessed. The mean duration of diabetes was 12.2months (6-64 months). 46.4% had Type 2 Diabetes and 48.6% were in employment; 20.3% were not in employment due foot disease.
We identified 2-groups; patients with chronic diabetic foot disease leading to ulceration (41%) or a new episode of charcot neuroarthropathy (18.8%). 33% of patients were presenting with their 1st foot related problem since onset of diabetes.
23.5% of the ulcer group stated this was their 1st presentation, staging it as moderate-severe. They placed mobility as 1st-priority followed by social-interaction, pain (1.5+/- 0.2), admission to hospital (1.5 +/- 0.2); whilst limb-loss was their greatest fear (100%).
Of the patients with charcot-neuroarthropathy, 19.0% were new-episodes, 50.0% were employed. Mobility and social domains were equally first priorities (4.0 vs. 3.9+/-0.2). Their greatest desire was a return to walking; limb loss was a feared in 41.7%. If swelling was an associated symptom there was more concern of hospital admission (1.5 +/-0.2 vs. 2.7 +/-0.2).
No correlation was made between psychological-outcomes and general health (6.4 out of 10 (range 3-10).
Conclusion: Our data suggests patient-outcomes are not disease-specific but dependent on limb-integrity as fears of limb-loss is expressed more by those with tissues loss.

Even-so, mobility, and social-economic factors are perceived to have a higher value and can be used in a tiered philosophy in-keeping with value-based-healthcare to improve patient care.

O12.3

Reducing Diabetes-Related Lower Extremity Amputation at a National Level: Lessons from Retinal Screening

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Background: The Health Service Executive (HSE) is responsible for healthcare delivery in Ireland and has identified chronic disease management as a priority. The Euro Diabetes Index 2014 ranked Ireland 20th of 30 European countries surveyed citing lack of a national diabetes register and a GP contract that does not reimburse for preventive services as major deficiencies.(1) In 2013 the HSE established Diabetic RetinaScreen, a national screening service to detect and treat diabetic retinopathy.(2) A Model of Care for the Diabetic Foot was published in 2011 and updated in 2018. This recommends foot screening in General Practice, referral of at risk patients to Community Podiatrists or Foot Protection Teams and referral of active foot disease to Multidisciplinary Foot Teams.
Aim: To compare the approaches being used to reduce vision loss and limb loss from diabetes in Ireland. **Methods:** data from the 2015 Report of Diabetic RetinaScreen are compared to existing data on staffing of foot services in Ireland.
Results: Table 1 highlights the major findings of our analysis.
Conclusion: If Ireland is to impact on rates of diabetes-related lower extremity amputation then an essential first step is to develop a population wide approach to foot screening. This has been done for retinopathy and is likely to impact on rates of vision loss.(3) Key elements include maintaining a register, developing and implementing quality assurance standards, incentivising the screeners financially and using modern technology for screening and communication.

References:

1. https://old.healthpowerhouse.com/publications/euro-diabetes-index-2014/
2. https://www.diabeticretinascreen.ie/
3. https://bmjopen.bmj.com/content/4/2/e004015

Parameter	Diabetic RetinaScreen	Diabetic Foot Screening
Maintains a Register	Yes	No
Ring-fenced funding	Yes	No
Staff dedicated to primary screening	Yes in 123 screening sites outsourced and funded by the programme	No; approx. 2500 GP's and 1800 Practice Nurses but currently no dedicated funding
Quality Assurance maintained	Yes	No
Integrated IT system for screening and treatment	Yes	No
Technology used for screening	Yes; digital photography and grading	No; traditional foot examination recommended
Referral Pathway for Treatment	Yes; to one of 7 hospital Ophthalmology Centres	Yes; at risk patients to Community Podiatry or hospital based Foot Protection Teams

Table 1: Comparison of approaches being used to reduce vision loss and limb loss from diabetes in Ireland

O12.4

Late Referral as the Great Problem to Diabetic Foot Ulcers Management

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Aim: Late referral to Diabetic Foot Unit (DFU) is considered the great problem across the world. Fast-Track Pathway (FTP) has been launched to get earlier referral from primary care to DFU. We aim to evaluate the previous clinical practice before FTP implementation in a second level Hospital.
Method: A multidisciplinary team of diabetic foot experts have created a FTP to improve the patients´referral with active ulcer from Primary Care Center (PCC). It is a simple tool to refer the diabetic patient, identifying three categories of severity, considering patient´s comorbidities, vascular status, infection and ulcer findings. From January to June 2018, before FTP adaptation process was initiated, we collected all risk diabetic foot patient referred from a PCC to DFU.
Results / Discussion: In 2017, area population was 170,380 patients, of which 22,636 belonged to PCC choosed for this study. In this PCC, followed-up diabetic patients were 1847.
From January to June 2018, PCC total referrals were 6521 patients, of which 158 patients were referred to the Vascular Surgery Department and 26 patients were referred to DFU (risk foot), presenting 8 of them an active ulcer.
Mean age of ulcerated patients referred to DFU was 80.12 +/- 14.94 years and 37.5% were male. Mean number of delayed days to be assessed by the specialist was 45.37 +/- 44.99 days (Median 24.5 days).
Conclusion: Data obtained, evidenced the need FTP implementation to patients who suffering diabetic foot ulcer, using standard of care. The main aim is achieve an early referral to DFU to get limb salvage, better QoL and decrease the mortality.

O12.5

Differences Between the International Working Group on the Diabetic Foot Guidance and National Diabetic Foot Guidelines in the Western Pacific

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Aim: To the best of our knowledge, no studies have investigated if national guidelines to manage diabetic foot disease differ in terms of recommendations from international guidelines. This study aimed to compare national diabetic foot guidelines of Western Pacific nations with the peak International Working Group on the Diabetic Foot (IWGDF) guidance documents.
Methods: The 77 recommendations across five chapters of the 2015 IWGDF guidance documents were used as the international gold standard reference. The IWGDF national representative(s) from 12 Western Pacific nations were invited to submit their nation's diabetic foot guideline(s). Four investigators rated information in the national guidelines as 'similar', 'partially similar', 'not similar', or 'different' when compared with IWGDF recommendations. National representative(s) reviewed findings. Disagreements in ratings were discussed until consensus agreement was achieved.
Results: Eight of twelve nations (67%) responded: Australia, China, New Zealand, Taiwan, and Thailand provided national guidelines; Singapore provided the Association of Southeast Asian Nations guidelines; and Hong Kong and Philippines advised no formal national Diabetic Foot guidelines existed. Collectively, the six national guidelines included were 39% similar/partially similar, 58% not similar and 2% different compared with the IWGDF recommendations. Within individual IWGDF chapters, the six national guidelines were similar/partially similar with 53% of recommendations for the IWGDF prevention chapter, 42% for wound healing, 40% for infection, 40% for peripheral artery disease and 20% for offloading.
Conclusions: National diabetic foot disease guidelines from a large and diverse region of the world showed limited similarity to the recommendations made in the peak international guidelines. The differences between the recommendations may contribute to differences in national diabetic foot disease outcomes and burdens.

O13.1

Gait Inefficiency Induced by Offloading – Critically Unintended Consequences For the Diabetic Foot in Remission

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Aim: Recurrence rates of diabetic foot ulcers (DFU) are alarmingly high, which may partially link to alteration in biomechanics of lower extremities because of prolonged offloading. Most of irremovable offloading boots are functioning based on locking ankle joint. However, prolonged immobilization of ankle joint can lead to muscle wasting and ankle joint flexibility during early remission once the offloading was removed. In this pilot study, we examined the effect of prolonged offloading on gait and plantar pressure.
Methods: Five patients with recently healed DFU (patient-group) with at least 5 weeks of offloading treatment and five healthy age-matched participants (control-group) were recruited. They were asked to walk at their normal gait speed after wearing standard footwear. Gait and propulsion (heel-off) performance were quantified using a wearable sensor attached to subject's shin. Plantar pressure under regions of interest were measured using computerized pressure insoles. Peak-pressure response to shin's angular velocity during population was used to identify foot at risk. Effect size using Cohen's d was calculated for comparing between groups difference.
Results: Range of angular velocity during propulsion phase was on average 48% lower in patient-group compared to controls, indicating high foot-stiffness during propulsion (140.1±10.5 deg/s for control-group and 73.1±46.0 deg/s for patient-group, d = 2.0). This reduction led to increase in peak-pressure on average by 52% (d=1.7) and reduce mid-swing speed by 27%, indicating that increase in foot stiffness during propulsion not only increases the peak pressure but also reduces gait speed.
Conclusions: This pilot study suggests that prolonged offloading in geriatric patients could lead to an increase in ankle stiffness, poor propulsion, slower gait, and increase in forefoot plantar pressure, which in turn may increase risk of recurrence of DFU. The magnitude of alteration in propulsion performance after offloading was similar to frail populations reported in our previous study [1], suggesting potential frailty induced by prolonged offloading. Further study is warrant to validate observations in a larger sample and clinical application of this finding to prevent recurrence of ulcers.
References: [1] Rahemi et al., Sensors, 2018 (18) 1763.

O13.2

Gait Abnormalities Present in People with Non-Healing Diabetes-Related Plantar Foot Ulcers During Six-Months Follow-Up

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Aim: This study aimed to identify gait parameters consistently associated with non-healing diabetes-related plantar foot ulcers during a six-month period when compared to diabetes controls without ulcers.
Methods: This was a longitudinal observational study. Gait assessments were performed using a standardised protocol at entry, three months and six months in 12 participants with non-healing foot ulcers (cases) and 62 controls with diabetes and no ulcer history. Linear mixed effects random-intercept models were used to assess which gait parameters consistently differed between cases and controls after adjusting for age, sex, body mass index, presence of peripheral neuropathy and follow-up time. Standardised mean differences (SMD) were used to measure effect sizes.
Results: Five gait parameters were significantly different between cases and controls at all three time points. Cases had a more abducted foot progression angle (SMD= 0.37, p=0.036), higher pelvic obliquity at toe-off (SMD= -0.46, p=0.009), greater minimum pelvic obliquity (SMD = -0.52, p=0.015), a slower walking speed (SMD= -0.46, p=0.009) and smaller step length (SMD= -0.46, p=0.008) than controls.
Conclusions: This study identified five gait parameters consistently associated with non-healing diabetes-related plantar foot ulcers. These abnormal gait parameters may contribute to higher mechanical loading of parts of both feet and potentially infer a higher-risk of falls. Future studies should investigate gait retraining options for the prevention and management of diabetes-related plantar foot ulcers and evaluate how offloading devices may influence an already compromised gait pattern in this population.

O13.3

The Effect of Removable Cast Walker Form Features on Neuropathic Diabetic Individuals' Compensatory Response to Perturbations

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Aim: Adherence with removable offloading devices is suboptimal and is influenced by self-perceived postural instability. A short removable cast walker (RCW) paired with a contralateral shoe lift might improve stability relative to a traditional knee-high RCW. This study compared compensatory responses to perturbations under both offloading conditions.
Methods: Eleven individuals (36% male; age:67±8 years) with diabetic peripheral neuropathy participated. The majority had moderate (n=4) or high (n=4) fear of falling according to Falls Efficacy Scale-International scores. Each participant completed trials under three conditions: bilateral standard shoes, knee-high RCW, and short RCW with contralateral shoe lift. Stepping thresholds (ST) were assessed for two types of perturbations:
1) While standing on a programmable treadmill, the treadmill rapidly accelerated at 3.5m/s² to reach a set peak velocity that increased between trials. The trial in which participants could not avoid taking a step was noted as ST. Participants were separately oriented on the treadmill so as to elicit anterior and lateral stepping responses; 2) An investigator pulled a waist-mounted spring scale until a target load was reached and then released the spring, resulting in a rapid dissipation of load. ST was the lowest load necessary to force a step upon release. Waist-pull perturbations were applied both anteriorly and posteriorly.
Participants also rated their perceived stability in each footwear condition via a 10cm visual analog scale. For analyses of outcome variables, percent changes from standard shoes were calculated for each offloading condition.
Results: The knee-high RCW caused moderate to large decreases in STs relative to the short RCW paired with a lift, as determined by Cohen's d (treadmill: anterior= -0.73, lateral= -0.51; waist-belt: anterior-pull= -0.97, posterior-pull= -0.65). Paired t-tests indicated ST differences were significant for anterior treadmill trials and for anterior waist-pulls (p=0.020 and p=0.036, respectively). Participants reported a large and statistically significant reduction in perceived stability with the knee-high RCW (Cohen's d=-0.96; p=0.014).
Conclusions: STs and self-reports indicate participants were more stable in the short RCW paired with a contralateral lift than the knee-high RCW. Future studies should evaluate whether these results translate into corresponding differences in offloading adherence by diabetic foot ulcer patients.

O13.4

Ventral Windowed Total Contact Casts (VW-TCC) to Offload Diabetic Foot Ulcers and Immobilise Charcot Feet

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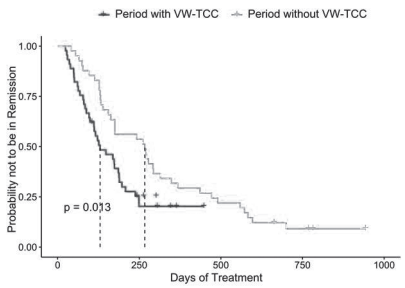
Aim
Ventral windows in total contact casts (VW-TCC) are a new approach. They allow access to the foot while the cast remains irremovable. Since July 2017, we used VW-TCCs instead of removable TCCs whenever patients with high risk conditions showed a tendency towards risk-friendly behaviour. This abstract describes the experience with the new technique.
Methods: In a bivalved TCC, the front shell is divided into an upper and a lower half. The upper half is at least 10 cm large and closed again leaving a ventral window in the lower part. This single-centre study evaluates retrospectively treatments with TCCs applied after the introduction and control treatments within 18 months before. PAD was deliberately not considered as contraindication.
Results: 45 treatments after introduction (17 with the VW-TCC) showed a 52.8 % lower median time to reach remission than 41 controls (128 / 267 days, log-rank test p= 0.013, see figure). Motives to not use the novel design were: sufficient offloading with a removable TCC (16), patient's rejection (6), anatomical conditions (2), cooperation with facilities unable to manage non-removable TCCs (3), and ulcers at the calf (1).
Complications were rare, short lasting and didn't differ between groups (VW-TCC, PAD).
Conclusions: This publication presents for the first time, to our knowledge, a TCC that is partially removable due to its architecture, meeting medical requirements and practicability at the same time.
Introducing the VW-TCC may reduce treatment time.
There are few contraindications, mainly in patients who want to decide when to wear the TCC.



Kaplan-Meier curve for time to remission

O14.1

Lower-Extremity Necrotizing Fasciitis in Diabetic and Non-Diabetic Patients: Reoperation and Readmission

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Aim: To determine and compare rates of reoperation and readmission after treatment of lower-extremity necrotizing fasciitis (NF) in patients with and without diabetes mellitus (DM).
Methods: Patients who were treated for lower-extremity NF selected from the American College of Surgeons-National Surgical Quality Improvement Program® (ACS-NSQIP®) database between years 2012 and 2017.
Results: Out of 562 patients with lower-extremity NF, 326 (58.0%) patients had DM, and 236 (42.0%) did not have DM. Patients with DM were more likely to undergo amputation (p<.00001). However, 30-day post-operative mortality was higher in non-DM patients (9.5% vs. 16.9%, p=.016). The overall unplanned reoperation and readmission rates were 9.4% (53 out of 562) and 5.3% (30 out of 562) respectively. In the univariate analysis, DM status did not correlate with reoperation (odds ratio [OR] 0.79, 95% confidence interval [CI] 0.45-1.40) or readmission (OR 1.48, 95% CI 0.68-3.22). Factors associated with reoperation included serum blood urea nitrogen (BUN) >20 mg/dL (OR 2.24, 95% CI 1.17-4.30), thrombocytopenia (OR 2.05, 95% CI 1.09-3.89), duration of surgery >45 minutes (OR 2.50, 95% CI 1.05-5.98), hospital length of stay >24 days (OR 3.31, 95% CI 1.83-5.98), post-operative surgical site infection (OR 8.47, 95% CI 4.40-16.3), post-operative respiratory distress (OR 2.26, 95% CI 1.24-4.12) and post-operative septic shock (OR 2.20, 95% CI 1.21, 4.02). Only body-mass index (BMI) >30 kg/m2 was associated with readmission (OR 0.36, 95% CI 0.16, 0.83). In the regression analysis, surgical site infection was the only factor associated with reoperation (adjusted OR 7.32, 95% CI 2.76-19.1), and amputation procedure was associated with increased risk of readmission (adjusted OR 4.53, 95% CI 1.20-29.6).
Conclusion: The 30-day reoperation and readmission rates after lower-extremity NF in this cohort were 9.4% and 5.3%, respectively. Diabetes was not associated with reoperation or readmission in the univariate or the multivariate regression analysis. Lower-extremity NF is associated with significant morbidity and mortality. Further study is needed to understand patient characteristics to better direct management. However, the current study elucidates patient outcomes for a relatively rare condition.

O14.2

Clinical Factors and Treatment Outcomes Associate with Systemic Inflammatory Responsive Syndrome in Patients with Diabetic Foot Infection

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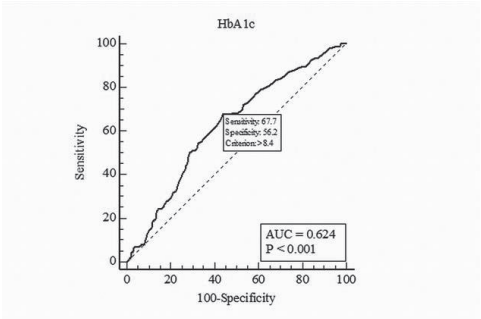
Aim: Infection accompanied with systemic inflammatory responsive syndrome (SIRS) presentation usually is a medical emergency. This study aimed to evaluate the clinical factors and outcomes between limb-threatening diabetic foot infection (DFI) with or without SIRS.
Method: From 2014 to 2017, 722 consecutive patients with limb-threatening DFI (203 DFI patients presented SIRS and 519 without SIRS) in a diabetic foot center were analyzed. The wound assessment was recorded as PEDIS scoring. The treatment outcomes were classified as: limb-preserved, minor lower-extremity amputation (LEA), major LEA, and in-hospital death. The outcomes were compared between the two groups. Their clinical profiles were analyzed for the association with SIRS.
Result: Patients with DFI presented SIRS had worse treatment outcomes in comparing subjects without SIRS (14.3% vs. 6.6%, for major LEA and 6.4% vs. 3.5% for death). Patients with SIRS were younger (median 60.0 vs. 66.0 years), with larger wounds size (median 15.0 vs. 9.0 cm2), and poorer glycemic control (median HbA1c: 9.6 vs. 8.1 %). Following multi-variables regression model, the young age, larger wound and higher HbA1c level were the independent factors predicting DFI with SIRS. Receiver operating characteristic curves revealed HbA1c > 8.4% is a valuable marker in determining SIRS presentation in DFI patients with sensitivity 67.7% and specificity 56.2%.
Conclusion: The presence of SIRS in patients with DFI has higher major LEA and death rate. Young age, large wound and poor glycemic control are the factors associated SIRS presentation in DFI patients.



O14.3

Longitudinal Study of the Bacterial Microbiome of Diabetic Foot Ulcers: the HUMID Study

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Aim: The diagnosis of infection of diabetic foot ulcers (DFUs) is primarily clinical and traditional (phenotypic) microbiological sampling is largely restricted to identifying potential causative pathogens. Little is known of the complex interrelationships which must exist both between different bacteria and between bacteria and the host tissues as they variously colonise or infect chronic ulcers. The literature on the bacterial microbiome of DFUs is relatively slight and largely confined to small cross-sectional studies. We have therefore conducted a prospective longitudinal study of the microbiome with repeated sampling of 28 DFUs.
Method: 237 rigorously collected swab samples were taken at fortnightly intervals for up to six months or until healing from 28 chronic DFUs of the heel. Microbiome samples were generated by16S rRNA analysis, supplemented by targeted nanopore sequencing.
This study was conducted under the umbrella of a parent randomised controlled trial designed to assess ulcer off-loading which was funded by the National Institute for Health Research, UK.
Results: The microbiota identified 63 genera from 37 families, of which the 10 most abundant accounted for 89.6% of those identified. The most abundant taxonomic groups were Corynebacteria, Staphylococcus, Enterobacteriaceae, Anaerococcus, Pseudomonas and Streptococcus. Individual ulcers tended to retain a particular pattern of organisms (PERMANOVA 63.7% variance explained, $p<0.001$) and clustering analysis indicated that the samples could be separated into six distinct groups. 20 of 28 ulcers failed to heal and were likely to be persistently colonised by a heterogeneous community of bacteria including anaerobes and Enterobacteraceae (log likelihood ratio 9.56, $p=0.008$). Those that healed showed a higher rate of transition to clusters with a predominance of Corynbecteria and Staphylococci. 13 of 28 DFUs were associated with one or more episodes of clinical infection and these were characterised by a temporary reduction in the diversity of organisms.
Conclusions: Longitudinal profiling of the bacterial microbiota is a valuable tool for improving understanding of the complex microbiology of DFUs and demonstrates the potential for unravelling some of the complex relationships between bacterial species and host tissues.

O14.4

Differences in Microbiomes Between Intact Diabetic Skin, Diabetic Foot Ulcers, and Non-Diabetic Skin

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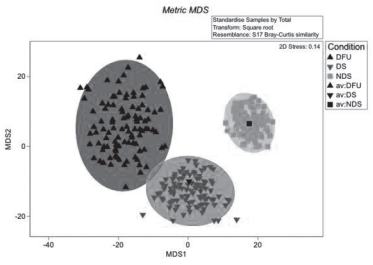
Aim: People with diabetes are more susceptible to infections. This study assessed differences in skin microbiomes between intact diabetic skin (DS), diabetic foot ulcers (DFU), and non-diabetic skin (NDS) from healthy controls
Methods: 40 subjects total, 20 with a non-infected plantar DFU and 20 age and gender matched controls were recruited. For subjects with diabetes, cultures were obtained from their foot ulcer and from the contralateral foot at the equivalent ulcer location. Bilateral foot cultures were obtained from healthy controls. Culture samples were quantified and analyzed via16S rRNA gene sequencing. Analysis of similarity (ANOSIM) was performed to determine if the microbial community structure between the three groups was significantly different. A boot-strap averages algorithm was used to assess centroids for sample groups and Alpha-diversity measurements were made to assess genus-level richness, evenness, and Shannon index.
Results: ANOSIM results indicated significant differences between groups (global R=0.256, p<0.001). Both DS and DFU microbiomes were significantly different from NDS (Figure 1). While Staphylococcus and Stenotrophomonas dominated in all samples, taxon richness was significantly lower in DFU and DS samples compared to NDS samples. Other diversity metrics were not significantly different.
Conclusions: NDS and DS harbored similar quantity of microbiome while DFU harbored significantly greater microbiome, however taxon richness was significantly lower in DFU and DS versus NDS. Predilection of select taxons of microbiome to both DS and DFUs as compared to the variability of numerous taxons noted in NDS may help contribute to the increased prevalence of infections in people with diabetes.



Non-metric multidimensional scaling (mMDS) plot of the NDS, DS and DFU samples using bootstrap-average analysis, showing the envelope of 100 bootstrapped samples (colored symbols) around their centroid (black symbols) for the three sample types.

O14.5

The Research of Autophagy on Pseudomonas Aeruginosa in Patients with Diabetic Foot Infection

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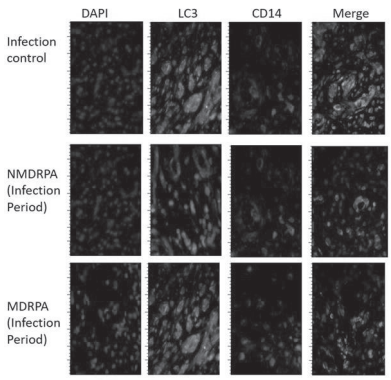
Aim: In order to study the interactions between PA and autophagy, the expression of autophagy-related proteins in the wound tissue with and without Pseudomonas aeruginosa (PA) infection were detectd and compared. To explore the influence of infection with multidrug-resistant Pseudomonas aeruginosa (MDRPA) and ischemia on autophagy.
Methods: 24 patients hospitalized in Metabolic Disease Hospital of Tianjin Medical University from March 2016 to February 2017 were collected who had PA infection with DF. The clinical data of the patients were collected and analyzed. The tissue samples were collected by debridement. Double immunofluorescent staining assay was used to detected the level of autophagy in macrophages. Ganulation tissue were quantified determination of LC3-II/I, Beclin-1 and P62 by western blotting assay.
Results: After the infection were cleared, the number of new blood capillary and fibroblasts in granulation tissue was increased compared with PA infection, the inflammatory cells were less. Western blotting showed that the expression of LC3-II/I and Beclin-1 were higher, P62 were significantly decreased($P < 0.05$). Compared with N-MDRPA group, the number of inflammatory cells in granulation tissue were lower in MDRPA group, new blood capillary and fibroblasts had no statistical differences. LC3 in macrophages were lower in infection period compare with infection control. Compared with NMDRPA, LC3 in macrophages were lower in MDRPA (see figure)
Conclusion: After the infection were cleared, the level of autophagy was increased. PA may downregulate or even escape autophagy by some mechanism. What's more, the level of autophagy decreases furtherly, indicating that MDRPA may be more capable of escaping autophagy.



LC3 in macrophages

O15.2

Ten Year Review of the Implementation of the Step by Step Programme in The Caribbean: Lessons Learned and Ways Forward

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[1]Dfoot International, Christ Church, BB, [2]Rotary Clubs of the Region

Aims: Step by Step (SBS) courses are designed to help health care professionals improve the quality of foot care and to reduce diabetic foot amputations. and have been run in the Caribbean since 2008. The aim of this study was to review their effectiveness.
Methods: Data from the pre and post course reports, evaluation and general feedback forms from all countries participating were reviewed. An overall assessment was performed of the achievements and barriers encountered in the implementation .
Results: Grenada, Antigua, Barbados, St. Kitts and Nevis, St. Maarten, Tobago and Dominica responded, to the review (50% of the total in the region) 320 health care providers (65 doctors, 204 nurses, 51 other). 97% participants reported improved knowledge in the management of the diabetic foot, and confidence levels in managing the diabetic foot rose from 34% to 85%. 88% required further information on wound care (including debridement; osteomyelitis management) and 60% requiredinformation on biomechanics, offloading and total contact casting. The lack of specialist podiatrists and Diabetic foot teams was noted to be a key barrier to providing high quality care.
One country had a 50% reduction in amputations, but this was not sustained due to limitations in access to podiatrists, absence of care protocols or funding. There was also natural attrition within the trained teams. One country developed a diabetic foot committee, and a diabetic foot unit within a diabetes management center but it was not possible to translate these changes into significant reductions in amputations.
Conclusions: The Step by Step program was much appreciated by participants, and improved their perceived capacity to provide good foot care. But it has not yet been possible to demonstrate clear improvement in clinical outcome. Each island has its own specific requirements, but there is a clear need to define the key principles of foot care in diabetes throughout the region, and for all stakeholders to work together to make sure that they are available to all those who need it.

O15.3

Presentation and Outcomes of Charcot's Neuroarthropathy of Foot in Patients with Diabetes: a Nested Cohort Prospective Study from North India

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Background: Charcot neuroarthropathy (CN) is an uncommon complication of diabetes but is associated with increased mortality independent of foot ulcer. However, the mortality data for individuals with CN is scarce, based on retrospective analysis and inconclusive.
Aim: We studied presentation and mortality outcomes in individuals with diabetes and CN compared to individuals without foot complications.
Methods: Prospective patients attending foot care facility with CN (acute CN, chronic CN or acute on chronic CN) of foot were evaluated. The patients' details pertaining to duration of diabetes, microvascular (neuropathy, retinopathy and nephropathy) and macrovascular complications [prior coronary artery disease (CAD), peripheral vascular disease (PVD)], prior foot ulcer or amputation were recorded in electronic format. Another cohort of individuals (2:1 match for duration of diabetes) with diabetes but without foot complications were enrolled for comparison of mortality rate between two groups.
Results: Data for 260 patients with CN and 520 patients without CN was analyzed. Mean age at presentation with CN was 55.8±9.1 years and duration of diabetes was 12.9±7.8 years. 56.9% individuals presented with chronic CN, 18.8% with acute on chronic CN and 24.2% with acute CN. 39.8% patients with CN had prior foot ulcer and 15.3% had prior amputation. Patients with CN were younger (55±9.1 vs 59.9 ±8.1 years, p<0.001), had higher prevalence of neuropathy (80% vs 17.9%, p<0.001), retinopathy (64.1% vs 15.8%, p<0.001) and nephropathy (50.2% vs 21.1%, p<0.001), but CAD was more prevalent in those without CN (14.9% vs 8.9%, p=0.02). A total of 39 (15%) patients with CN and 50 (9.8%) patients without CN died (p=0.03) during median follow up of 3.2 (2-4) years. At presentation with CN, prevalent CAD and low eGFR predicted higher mortality. Matched for the duration of diabetes, patients with CN have 1.6 times (OR 1.62, 95% CI 1.03-2.5) higher mortality risk, and 2.7 times (OR 2.72, 95% CI 1.4-5.2, p=0.003) compared to those without CN, when matched for all other baseline parameters. **Conclusions:** Patients with CN are younger, have higher prevalence of microvascular complications at presentation and have three times increased mortality risk compared to individuals without CN.

O15.4

Long Term Outcomes Amongst Asian Indians with Diabetic Foot Ulcer: a Large, Multicenter, Nested Cohort Study (EDI-FOCUS investigators)

Dr. Ashu Rastogi[1]*, Dr Ghanshyam Goyal*[2]*, Dr Rajesh Kesavan*[3]*, Prof Arun Bal*[4]*, Prof Anil Bhansali*[1]*, Prof Harish Kumar*[4]*, Dr Vivek Lakshman*[4]*, Dr Mangala Nandan*[4]*, dr Amarjeet Singh*[4]
[1]Post Graduate Institute Of Medical Education And Research, Chandigarh, India, [2]ILS Hospital, Kolkata, India, [3]Hycare for Wounds, Chennai, India, [4]Amruta Institute of Medical Sciences, Kochi, India

Background: Diabetic foot ulcer (DFU) is an outcome of concurrent neuropathy and vasculopathy that contributes to significant morbidity and mortality in individuals with diabetes. Data for long-term limb outcomes and survival after incident DFU are sparse.
Aim: We studied limb amputation and mortality over long term follow up after an incident first DFU.
Methods: Patients with incident (first) DFU from tertiary foot care

centers across India were evaluated between January 2005 and August 2018. The details pertaining to demographics, diabetes duration, microvascular (neuropathy, retinopathy and nephropathy) and macrovascular complications [prior coronary artery disease (CAD), peripheral vascular disease (PVD) and stroke], ulcer characteristics (duration, Wagner grade) were recorded in pre-designed electronic format. Patients were followed and outcome was defined as survival or death while amputation was assigned as covariate.
Results: A total of 2876 out of 4789 patients with DFU were followed for a median duration of 8 (3-11) years . 844 (29.3%) patients had minor (22.1%) or major amputations (7.2%) and overall 477 (16.8%) patients died during follow up. The amputation rates was less in survivors (19.5% versus 35.4%, p<0.001) as compared to those who died. Cardiovascular events (31.3%) were the most common cause of mortality followed by infections (21.2%), renal causes (13.4%) and hypoglycemia (4.2%). Patients who died had significantly longer duration of diabetes, increased prevalence of nephropathy, neuropathy, prior CAD, PVD at first presentation with DFU. There was no difference in the duration of ulcer, prevalence of hypertension, HbA1c, serum albumin between two groups. Prevalent nephropathy (HR 1.63; 95%CI, 1.25-2.13;p<0.001), PVD (HR 1.69; 95% CI, 1.29-2.21;p<0.001); minor amputation (HR 2.89; 95%CI, 2.19-3.83;p<0.001) and major amputation as outcome of first DFU (HR 4.7; 95% CI, 3.2-6.9; p<0.001) were significantly associated with mortality on multivariate regression analysis. Median survival after incident DFU was 9 (7.7-10.3) years and 11 (6.8-15.2) years (p<0.001) in patients with and without PVD, respectively.
Conclusions: One-third individuals with incident DFU have amputation and every one in six individual die during long term follow up. Prevalent nephropathy, PVD and incident amputation following first DFU predicted higher mortality.

O15.5

Analysis of Diabetic Foot Patients Before Standardized Diagnosis and Treatment in Grade-A Tertiary General Hospitals

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Objective To investigate the diagnosis and treatment of diabetic foot patients before treatment in grade-A tertiary general hospitals with professional diabetic foot multidisciplinary team, and to explore its related factors, so as to provide basis for the standardized treatment of diabetic foot.Methods In this study, a total of 326 patients with diabetic foot ulcer Wagner1-5 level who were admitted to 13 grade-A tertiary general hospitals from October to November 2017 were included. General information, foot wound condition, diagnosis and wound management data, etc. of the patients were collected.Based on the 2015 IWGDF Guidelines on use of interventions to enhance the healing of chronic ulcers of the foot in diabetes, the standardization of diagnosis and treatment was evaluated, and the correlation analysis was conducted by χ2-test.Results Among the 326 diabetic foot patients, the rate of misdiagnosis and undiagnosed were 25.8% and 20.2% respectively.Home treatment accounted for 33.7% of patients, and patients who change dressings at home accounted for 25.3%.Patients' wound were debrided at home accounted for 24.2%, while 4.9% of them were debrided by a professional Enterostomal/wound therapist.The use of normal saline for wound cleaning accounted for 28.2%.The utilization rate of the new dressing was 20.9%.The utilization rates of anti-inflammatory drugs, insulin and Chinese herbal medicines on wound were 23%, 15.6% and 23.9% respectively.According to the guidance, the non-standard rate of use of wound cleaning fluid is 71.8%, and the non-standard rate of use of wound topical medication is 62.5%.The choice of wound cleaning fluid was related to the level of the hospital patients visited and the wound manager(p<0.05).Wound topical medication was related to the location of treatment and the dressing manager(p<0.05).Conclusion Diabetic foot patients have irregular medical treatment before entering grade-A tertiary general hospitals with professional diabetic foot multidisciplinary treatment team.The training of medical staff in primary hospitals on the diagnosis and treatment of diabetic foot and wound care should be strengthened, especially the training of stomatology /wound therapists.Improve the awareness of timely referral of grassroots medical staff, encourage patients to take the initiative to seek medical treatment, and reduce the occurrence of non-standard diagnosis and treatment.

Poster Sessions

P1.01

Proposal for a Simple Ulcer Prevention Scoring System in Diabetic Foot Syndrome

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Aim: To develop a score for assessing the individual ulcer risk in patients with diabetic foot syndrome that is easy to use and serves to identify high-risk patients during clinical routine.
Methods: A literature search using PubMed was performed using keywords (“diabet**”, “ulcer” AND “risk”), relevant guidelines screened, risk factors for ulcer development and/or amputation identified, weighed based studies with ulcer development as the primary endpoint, and collated into a scoring system.
Results: The developed scoring system can be performed within 3 minutes and consists of three categories for assessing individual ulcer risk: I. Major criteria; II. Moderate criteria; III. Minor criteria (Figure). Because of insufficient evidence the following risk factors were not integrated into the score: age; education; social status; marriage status; ethnicity; depression; diabetes type; insulin resistance; limited joint mobility; plantar pressure; oedema; or lack of awareness, training or participation in screening programmes. An electronic capture system displays the risk category using a colour system similar to traffic lights with red, amber and green and gives recommendation for the check-up intervals.
Conclusions: In view of the current literature on the matter, we have developed a semi-quantitative scoring system using just a few items to allow rapid and visual risk assessment for diabetic foot ulcers alongside recommendations for prevention and a sensible follow-up strategy to match the risk.

Prediction score for diabetic foot ulceration		
Major criteria (3 points each)	**Moderate criteria** (2 points each)	**Minor criteria** (1 point each)
Patient history of foot ulcer	Pronounced foot deformity	Foot or nail fungus
History of non-traumatic amputation	Pronounced hyperkeratosis	Limited joint mobility
Pronounced PNP More than two of the following: Path. tuning fork test Path. microfilament (SWMF) Path. Neuropad® test Path. neuropathy symptom score (NSS) Path. neuropathy deficit score (NDS)	PAD (at least one absent pedal pulse or path. ABI)	Lack of visual or cognitive capability for own healthcare or foot care
	Renal insufficiency (GFR < 30 ml/min) or dialysis	Poor diabetes management (HbA_{1c} > 9% or diabetes duration > 10 years)
	Slight PNP One of the following: Path. tuning fork test Path. microfilament (SWMF) Path. Neuropad® test Path. neuropathy symptom score (NSS) Path. neuropathy deficit score (NDS)	Ill-fitting or too tight socks or footwear Male gender
Risk assessment	**Consistent use of prevention opportunities**	**Diabetic check-up intervals**
≥5 points Very high risk	Intensive prevention measures	Every 3 months
≥4 points High risk	Extended prevention measures	Every 6 months
≥2 points Moderate risk	Basic prevention measures	Once a year

Score for the prediction of diabetic foot ulceration

P1.02

Barriers and enablers to Preventative and Early Intervention Diabetes-Related Foot Care: A Scoping Review of Healthcare Professionals’ Perceptions

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Aim: The purpose of this scoping review was to describe the existing evidence of the barriers and enablers to preventative and early intervention foot care among people with diabetes, focussing on the perceptions of healthcare professionals.
Methods: MEDLINE, CINAHL and Scopus databases, as well as Google Scholar, were searched in September 2018. Inclusion criteria were: English language, qualitative and quantitative studies, since the year 1998 reporting, on the barriers and/or enablers to preventative and/or early intervention foot care among people with diabetes, as reported by healthcare professionals. Studies must have included healthcare professional participants. Studies reporting on a person with diabetes’ perspective, or reporting on patient factors including self-management barriers were excluded from this review.
Results: A total of 339 studies were identified. Of these, seven met inclusion criteria. The scoping review highlighted several key factors healthcare professionals perceive as barriers to diabetes-related foot care. These included geographical, administrative and communication factors, referral and care guideline factors, human resources, availability of specialists and multidisciplinary high risk foot services, time and funding factors. Further, a resistance to changing professional roles, healthcare professionals’ lack of knowledge, education and training, and patient foot hygiene represented additional barriers encountered by healthcare professionals in the delivery of preventative and/or early intervention diabetes-related foot care. Enablers to foot care were identified to include the implementation of foot care programs, education and training of

staff, the clear definition of staff roles, reminder systems for healthcare professionals to conduct foot assessments and reminders for people with diabetes to remove their shoes at appointments.
Conclusion: The barriers to foot care faced by healthcare professionals are multifaceted, existing on multiple levels. Further investigation into these are recommended to ensure the effective contribution towards intervention strategies. Before diabetes-related foot care can improve, barriers to care must be clearly identified, then managed through the development of comprehensive cost-effective strategies. Policy/decision makers and healthcare professionals must work collaboratively to eliminate the barriers to preventative and early intervention foot care among people with diabetes, thus promoting the enablers and provision of adequate foot care.

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P1.03

A New Clinically Viable Screening Method for Leg-Muscle Weakening to Improve the Prevention of Falls in People with Diabetes

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Aim: Diabetes accelerates the decline in muscle strength in older people and substantially increases the risk for falling and injury. Even though leg-muscle weakening is a strong predictor for falls, currently there is no established method for its assessment in clinics. The paper grip test (PGT) has been used to assess hallux plantar flexor strength[1], but its qualitative nature and operator dependency has limited its clinical use[2]. The aim of this study is to propose an enhanced PGT for the operator-independent quantitative assessment of leg-muscle strength.
Methods: The conventional PGT involves the examiner placing a small piece of cardboard (card) under the patient's hallux and then pulling it with increasing power while the patient offers resistance[1]. The patient passes the test if they successfully hold the card. Instead of this simple pass/ fail outcome we propose to use a dynamometer to record the minimum pulling force that is needed to remove the card. Moreover, in contrast to the conventional PGT no external support is applied to the foot during testing. Two independent examiners (one male one female) used this technique in the same participant (10 measurements/ examiner) to verify if this method reduces the operator-dependency of results. The net gripping force applied by the participant's hallux during testing was also recorded using a pressure mat (MatScan, Tekscan).
Results: The difference between the measured strength was only 4% and was not statistically significant (P> 0.05). The measured strength was strongly correlated to the maximum hallux force measured using the pressure mat (r=0.928, N=10, p<0.001).
Conclusions: These results indicate that the EPGT can minimise the operator-dependency of results and offers a quantitative assessment of strength. The hallux gripping strength (as measured here) was found in a separate study to be significantly correlated to the isometric strength of all muscle groups of the foot/ankle complex. This indicates that it could potentially be used as a marker for foot/ankle weakening to identify people that are losing their ability to maintain balance.

P1.05

Efficacy of a Pro-Active Screening for Diabetic Foot Ulceration in the Community Autonomously Performed by Nurses

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Aim: the late diagnosis and referral of patients at high risk of Diabetic Foot Ulceration (DF) to specialist care is one of the most important determinant for the progression of the disease towards late stages and amputation. We tested the efficacy of a pro-active screening strategy in a community setting autonomously managed by nurses in detecting patient at high risk of DFU.
Methods: in a community in north-west Tuscany, where 421382 people live in a mixed urban/rural area, we trained 324 nurses according to the International Working Group on Diabetic Foot (IWGDF) guidelines for the screening of DF. The nurses were committed to screen yearly DF in the population of known diabetic patients, which were referred to them by their GPs. Patients at high risk or with active DFU, when detected, were promptly referred to a specialized DF clinic; all patients screened received education on how to prevent DFU. The results of the screening were retrospectively collected and analyzed for the years 2014-2016. Results are reported in the Table.
Results:

Year	N. Diabetic Patients (%)	N. Screening (%)	N. High Risk (%)	N. DFU (%)
2014	6767 (1.6%)	2442 (36.1%)	21 (0.8%)	5 (0.2%)
2015	7016 (1.7%)	3856 (54.9%)	52 (1.3%)	8 (0.3%)
2016	9435 (2.2%)	6817 (72.2%)	144 (2.1%)	31 (0.5%)

Conclusion: Our data, although possibly biased by an underestimation of the actual prevalence of diabetes in the population, show how increasing the rate of subject actively screened in the population of known diabetic patients, the rates of high risk patients detected increases in parallel, as well as the rate of active DFUs, making it possible to early detect them and to intervene promptly, possibly interrupting the progression of the disease.

P2.01

Cold Atmospheric Pressure Plasma is a Safe Therapy for Diabetic Foot Ulcers and Reduces S. Aureus Colonization

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Aim: Cold Atmospheric Plasma (CAP) devices generate an ionized gas with electric fields, UV light and highly reactive oxygen species. CAP can be used to treat bacteria in chronic wounds. CAP has advantages over antimicrobial treatment; It disinfects efficiently, painlessly and instantly, without development of antimicrobial resistance. Furthermore, plasma can stimulate both human cell proliferation and migration and microcirculation. We studied the safety of a novel CAP device that could be applied at a patient's home.
Methods: We included subjects with diabetic foot ulcers (maximum depth 5 millimeters) without signs of infection or exposed bone or joint in the wound. Subjects received treatment with CAP daily for ten days in a two-week period. Primary endpoint was the occurrence of serious adverse events (SAE) as a result of treatment. Safety was defined as ≤ 10% of subjects experiencing SAE related to treatment other than infection, and ≤ 60% of subjects developing infection within 30 days after treatment. We deployed standard protocols for wound treatment. Bacterial load was measured weekly before and after treatment, by both culture and molecular techniques.
Results: We enrolled twenty subjects. Three SAEs (infections) occurred at the site of application within one month of treatment, of which one took place during treatment. Three SAEs unrelated to treatment occurred. 55% of the subjects reported transient, grade 1 adverse events during one or more applications. Median wound surface decreased 70%. The total number of colonies did not decline significantly (p=0.08) before start of treatment compared to directly after the last treatment. S. aureus bacterial load reduced significantly directly after CAP application compared with before application (p=0.01).
Conclusions: No SAE other than infection occurred as a result of treatment and only 15% of subjects developed an infection in the foot. The AEs were mild and transient. Wounds decreased in size during treatment and S. aureus colonization declined after treatment. Application of CAP in diabetic foot ulcers is safe and results are promising with regard to reduction of bacterial load and wound healing.
Funding: Dutch Diabetes Research Foundation.

P2.02

Negatively Charged Polystyrene Microspheres Technology Experience About Non-Responding Diabetic Foot Ulcers. Two Cases Report

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Aim: To describe the outcome, of a new product based on Negatively Charged Polystyrene Microspheres (NCM) technology1, in non-responding Diabetic foot Ulcers (DFU) because Critical Limb Ischemia (CLI) without possibilities of revascularisation.
Method: Two cases of non-responding DFU were treated, through NMC technology, in Specialized Diabetic Foot Unit. Ulcers were treated daily with NCM technology during 4 weeks. Wollina Wound Score2 (granulation, color and consistency tissue), wound area (cm2) and percentage reduction were measured.
Results: Case 1: Male, 80 years old, CLI diagnosed and presenting 1st toe gangrene in right lower limb. 1st transmetatarsal amputation was made after non-viable revascularisation. Ulcer was classificated as Texas 3D3, IDSA moderate infection4 and probe to bone positive (PTB+). Follow-up with Good Wound Care (GWC) treatment was performed. According to its bad evolution, after 4 months, NCM treatment was implemented. After 4weeks of NMC treatment, the results were: Wollina score 2 (Day 0 Wollina score was 2), wound area 1.28cm2 including 80,95% in area reduction comparing with Day 0 (6.72cm2).
Case2: Male, 64 years old, CLI diagnosed and presenting a 1st toe gangrene in left lower limb. 1st transfalangical amputation was performed after non-viable revascularization. Ulcer was classificated as Texas 3D, IDSA moderate infection and PTB+. Follow-up with GWC treatment was performed. According to its bad evolution, after 4 months, NCM treatment was implemented. After 4weeks of NMC treatment, the results were: Wollina score 5 (Day 0 Wollina score was 0), wound area 3.22cm2 including 38.07% in area reduction comparing with Day 0 (5.2cm2).
Conclusion: Experience obtained, show us how a reactivation of non-responding DFU is possible, even in cases without possibilities to get better foot revascularisation. After NCM use, we find a significant improvement in "hard to heal" DFU in patients with a major amputation as the next step.
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P2.03

HypoxiamiR-210 Accelerates Wound Healing in Diabetes by Improving Energy Metabolism

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Aim: Diabetes ulcer is a devastating complication of diabetes that lacks specific pharmacologic therapy. Hyperglycemia-dependent impaired reaction to hypoxia is a central defect in the wound healing in diabetes. Mir-210 is a hypoxia-induced microRNA that regulates several cellular processes with potential role for wound healing. We have therefore investigated the role of mir-210 in the wound healing in diabetes.
Methods: The miR-210 expression was evaluated in vitro (human dermal fibroblasts (HDF), mouse dermal fibroblasts (MDF) and in vivo (peripheral mononuclear cells from subjects with diabetes or controls exposed to hypoxia (13% O2), skin of different models of diabetes) by RT-PCR. The proliferation and migration of fibroblasts was assessed by BrdU incorporation and wound cell migration respectively after exposure to different oxygen tensions and glucose concentrations. The db/db mice were used as model for impaired wound healing in diabetes. In biopsies, the granulation and epidermal regeneration were evaluated by haematoxylin eosin staining, proliferation by ki 67 staining and angiogenesis by CD 31 immunostaining. The mitochondrial function was evaluated SeaHorse. Mitochondrial genes were evaluated by RT-PCR.
Results: Hyperglycemia repressed hypoxia-dependent induction of mir-210 both in vitro and in vivo in subjects with diabetes. Moreover, the mir-210 expression was decreased in the skin of rodent models of diabetes and it was not induced during wound healing process as it was in nondiabetic animals.
The impaired regulation of miR-210 in diabetic wounds is pathogenic since local administration of mir-210 accelerated wound healing rate specifically in diabetic mice but not in non-diabetic mice. Mir-210 administration improved the dermal regeneration and several energy demanding cellular processes (proliferation and angiogenesis) secondary to an improvement of the oxygen consumption rate (OCR). We identified two key mitochondria enzymes (ISCU and SDHD) that were normalized by mir-210 administration.
Conclusion: Mir-210 improves specifically wound healing in diabetes by improving the cellular metabolism.

P2.04

A Phase 1b, Randomized, Multiple Ascending-Dose Study of Subcutaneous UTTR1147A (IL-22Fc) in Patients with Diabetic Foot Ulcers

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Aim: UTTR1147A is a novel human interleukin (IL)-22-IgG4 Fc fusion protein that mimics IL-22 effector function to promote epithelial proliferation and wound healing. This randomized phase 1b trial evaluated safety, tolerability, and pharmacokinetics, and assessed preliminary healing activity of local subcutaneous (SC) injection of UTTR1147A in patients with neuropathic, non-healing, uninfected diabetic foot ulcers (DFUs).
Methods: After screening, patients received standard-of-care DFU treatment (IWGDF 2015), including a below-knee offloading device that was rendered unremovable and weekly debridement and irrigation during a 2-week run-in period. Patients with a non-healing index ulcer then received SC injections of placebo or 1000-µg, 2500-µg, or 5000-µg UTTR1147A around the ulcer circumference every 3 weeks (4 doses total) plus continuing standard-of-care treatment for 12 weeks.
Results: The study enrolled 61 patients with mean baseline ulcer areas of 2.75 cm² and 2.04 cm² in UTTR1147A (n=41) and placebo (n=20) cohorts, respectively (range, 0.7 cm²–7.5 cm²). UTTR1147A appeared to be safe and well tolerated; no deaths occurred. Serious adverse events in 14 patients were related to the underlying ulcer/disease and deemed unrelated to treatment. Most other adverse events were mild. Serum drug exposure was detected at all dose levels. Wound fluid drug levels were also detectable at 3 days post dose. No treated patients exhibited anti-drug antibodies. The proportion of patients in UTTR1147A cohorts with complete wound closure was numerically but not significantly higher than in the placebo group (6 weeks, 23.7% vs. 10.5%; 12 weeks, 45.71% vs. 38.9%). Mean percent decreases from baseline in ulcer area in UTTR1147A cohorts were comparable to the placebo group (6 weeks, 60.2% vs. 52.0%; 12 weeks, 74.6% vs. 74.1%).
Conclusions: UTTR1147A had a favorable safety profile in patients with neuropathic, non-healing, diabetic foot ulcers and appeared to achieve exposure at ulcer sites. However, no meaningful improvements in wound healing over current standard-of-care were observed in this patient population. Following the IWGDF-prescribed standard-of-care for non-healing neuropathic DFUs significantly reduced ulcer areas in all cohorts.
Acknowledgements: This work was funded by Genentech, Inc.

P2.05

Clinical Effectiveness of a Silicone Foam in the Management of Diabetic Foot Ulceration

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Aim: This case series considers the clinical effectiveness and clinician satisfaction of a silicone foam with 3DFit Technology® in the management of diabetic foot ulceration.
Method: A convenience sample of 24 patients with diabetic foot ulceration was opportunistically selected across primary and secondary care settings. Silicone foam with 3DFit Technology ®was used at the discretion of the clinician in all cases.
9 evaluation parameters were recorded utilising a 5 point likert scale including patient comfort, ease of application and removal, conformability to the wound bed, ability to manage exudate and ability to stay in place, condition of the wound bed, wound edge and periwound skin.
Results / Discussion: Results of the evaluation parameters will be graphically represented as well as the clinician's feedback on the overall dressing performance compared to the previously used dressing regime.
This case series shows that the use of silicone foam in these wounds was an improvement in 72% of cases when compared to the previous dressings used. There are a large number care providers represented in this series across a variety of care settings. Despite the large number of variables in this case series the overall consensus of both patients and clinicians is that this product has shown to be useful in the management of diabetic foot ulceration.
Conclusion: This case series has shown that silicone foam with 3DFit Technology® has the potential to be a useful dressing for diabetic foot ulceration given the clinical improvements observed.

P2.06

The Effect of Medical Grade Honey in Diabetic Wound Care and Controlling Drug-Resistant Bacteria

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Aim: Antibiotic resistance is an increasing threat to the public's health. Antibiotic-resistant infections also emerged in diabetic lower limb wounds and affect the quality of life of these patients. Honey is a natural substance used for wound healing and appears to be a promising alternative to counter this global concern as medical grade honey (MGH) exerts antimicrobial action, reduces malodour and promotes wound repair. This is of particular interest in diabetics as even the smallest punctures, especially in the presence of bacterial infection, can lead to severe chronic wounds or amputation. Strikingly, the use of MGH is reserved and often limited to later lines of therapy. This case study series aims to show the effectiveness of MGH against antibiotic-resistant bacteria in wounds of patients with diabetes mellitus.
Method: Following a multicentre approach, we selected seven cases of which four presented antibiotic-resistant infections, two received treatment of amputation wounds, and in three cases the patient was at risk of (further) amputation. Initial treatment strategies included silver and alginate dressings, antibiotics, surgical closure, and maggot therapy and typically ranged from one week to three months before being declared ineffective. Subsequently, the treatment was switched to the application of MGH as monotherapy in all but one of the cases, in which systemic antibiotics had to be administered as part of the hospital regulations.
Results: Whereas the previous therapies had proven ineffective to treat the selected diabetic wounds, the application of MGH effectively enhanced wound repair. As soon as two days after the application of MGH, the wound's malodour was neutralized and inflammation and infection were controlled within ten days, including against antibiotic-resistant bacteria. Additionally, the honey enhanced autolytic debridement, leading to quick elimination of slough, and the appearance of healthy granulation tissue within five weeks. Due to the underlying pathologies, healing time ranged from 1,5 to 8 months.
Conclusion: MGH is safe and cost-effective for the treatment of severe diabetic wounds with or without antibiotic-resistant infections and risk of amputation. The application of MGH in diabetic wounds forms a promising strategy as the first line of therapy.

P3.01

A Prompt Surgical Management of Necrotizing Fasciitis in Diabetic Foot (DF) Patients Saves Limbs and Lives

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Aim: Necrotizing fasciitis (NF) is a rapidly progressive, life-threatening infection, involving skin, soft tissue and deep fascia. We aimed to evaluate the outcomes of the surgical management of NF in DF patients in a tertiary referral centre.
Methods: We retrospectively searched for NF the database of our DF Section from January 2012 to December 2014. All cases were treated according to international guidelines, with prompt extensive surgical debridement and systemic antibiotic therapy. We analysed the short-term evolution, in terms of number of surgical procedures and major amputation required, and long-term outcomes, in terms of healing rates.
Results: In this period 68 patients was referred to our DF clinic for a suspicion of NF. The diagnosis was excluded in 14 of them and confirmed in the remaining 54 (79.4%; male/female 40/14; type 1/ type 2 diabetes 6/48; age 62.8±8.1 yrs; duration of diabetes 13.6±10.1 yrs). According to the clinical characteristics and the microbiological results the cases was classified as Type 1 (33-61.1%), Type 2 (7-13.0%) and Type 3 (14-25.9%). No significant differences were observed between the three groups, in terms of demographical and clinical features. All patients underwent to a decompressive fasciotomy. 6 patients (11.1%) required also a forefoot amputation and 12 (22.2%) a toe or ray amputation. No major

amputation was performed in short-term period. Of the 54 patients, 23 (42.6%) required a second and 5 (9.2%) a third look. During the follow up we achieved complete healing in 46 patients (85%). Healing time was 94±11 days. Of the remaining 8: 5 (9.2%) died for other reason before healing, 2 (3.7%) recurred during the follow up and one patient (1.9%) required a major amputation one year after the surgical procedure.
Conclusion: Our experience speaks of a high prevalence of NF in DF; despite these high rates, we observed how, when promptly and aggressively treated, NF has a relatively good prognosis and it is not massively associated with an excess of limb loss and death.

P3.02

Current Insight in the Chopart Amputation; A Multidisciplinary Approach

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Aim: The Chopart amputation has clear advantages compared to a below knee amputation because of limb salvage with an end-loadable stump. However, Chopart amputations are seldomly performed due to the high incidence of complications. We want to provide a team approach for the Chopart amputation addressing surgerical technique, perioperative management and prosthetization.
Methods: This article describes three cases of diabetic patients with adequate vascularisation with severe infections of the forefoot and midfoot who underwent a Chopart amputation and were followed up for >18months.
Results: In two cases the Chopart amputation was successful and the patients were satisfied with their end-loadable stump. A third case with low self-management required a below knee amputation after 5 months because of a new ulcer plantar with fulminant infection of the foot.
Conclusion: A Chopart amputation should be considered in any patient with adequate vascularisation and sufficient self-management. The assessment, perioperative management and prosthetization demand a multidisciplinary team approach.

The result of the Chopart amputation with an end-loadable stump.

P3.03

LisFranc Amputation with EHL and Split Tibialis Anterior Tendon Transfer (STATT) to Prevent Equinovarus: A Case Report

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Aim: Our main goal is to discuss technique pearls to help better balance the patients who are at the transmetatarsal and Lisfranc amputation level. Most of these amputations over time deviate into equinovarus deformity; but if we can add more strength in aiding dorsiflexion of the ankle joint and assist in holding the ankle closer to neutral.
Methods: Patient is a 83 y/o male retired veteran with past medical dementia, history of atrial fibrillation (diagnosed on this stay), PAD, Diabetes type II with peripheral neuropathy s/p Left transmetatarsal amputation at outside hospital. Patient presents brought in by family with a dehisched, malodorous wound along the lateral aspect of the stump with approximately a 3.8 x 1.5 centimeter wound with positive probe-to-bone. Pulses were biphasic PT and monophasic AT. Non-invasive testing results and given patient was non-ambulatory there were discussions regarding a below the knee amputation (BKA). Angiogram was not done by request of Vascular Surgery recommending a BKA. Tourniquet was applied but not inflated. Plain 0.5% bupivicaine was utilized as a preoperative ankle block. Our team resected back to the LisFranc joint where we found healthy, hard, white bone. Bleeding was minimal.
Results: We have high-definition images to show where the tendons should be routed to provide the best vector force. We began with the anterior tendon and found its insertion in which we detached 50% of and tracked up the anterior ankle where you will utilize the uterine packing forceps. These forceps are designed in the shape of a lazy “s” which is near perfect angle to use as a tendon passer. Use the same instrument to feed harvested 50% of the anterior tibialis tendon toward the cuboid. The Extensor Hallucis Longus tendon was dissected out and wrapped around the intermediate cuneiform and drill hole was made from dorsal-plantar in the distal aspect of the intermediate cuneiform and tendon was whip-stitched and passsed through the the drill hole and hand-tied to tension after split tibialis tendon was transferred with the ankle kept in neutral. Wound was primarily closed and healed.
Conclusion: EHL/split tib ant transfer for lisfranc amp

Uterine packing forceps used to pass split portion of tibialis anterior tendon, curvature of instrument is perfect route from anterior leg to lateral foot region.

P3.04

Tibiotalocalcaneal Arthrodesis with Retrograde Endomedular Nail in Patients with Diabetes Mellitus: an Approach to Consolidation Determinants

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Aim: The aim of this study is to describe the characteristics of patients with Diabetes Mellitus with deformity of the hindfoot and ankle who underwent a tibiotalocalcaneal (TAC) arthrodesis with a compressive retrograde intramedullary nail and the factors associated to bone union.
Methods: We report a series of retrospective cases. Patients were evaluated with load weight-bearing radiographs and computed tomography. We also studied the demographic and metabolic characteristics.
Pseudoarthrosis was denominated when the arthrodesis evolved more than 12 months without consolidation. The procedures that required the use of a bone graft and postoperative complications were recorded.
Results: Nine patients were operated between 2011-2016 with at least 1 year post-surgical follow-up. Four patients had Charcot arthropathy, 3 ankle fractures malunion and 2 neurological equine foot.
Four patients had ulcers previously, 2 of them had osteomyelitis and underwent specific treatment. All ulcers were closed at the time of the surgery.
Consolidation was observed in 6 patients. Two patients required revision surgery.
Five procedures were performed with bone graft. All patients achieved limb salvage.
Five major complications were observed in 4 patients: all had an albumin less than 3.5 gr/dL preoperative.
Among our patients who developed major complications, 3 of 4 were diagnosed with Charcot arthropathy and had had ulcers on the affected limb.
Two of the three patients who progressed to pseudoarthrosis (one infected) had a preoperative HbA1c>7%.
Conclusion: TAC arthrodesis with retrograde intramedullary nail may be a procedure of choice in patients with ankle deformity and hindfoot with DM as an alternative to a major amputation. There is a high rate of complications and pseudoarthrosis in this group of patients. It would be advisable for patients to achieve controlled metabolic and nutritional parameters at the time of surgery and patients with a history of ulcerations, the diagnosis of osteomyelitis should be previously ruled out.
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P3.05

Proximally-Based Split Abductor Hallucis Turnover Flap for Medial Hindfoot Reconstruction: A Case Report

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Aim: Limited reconstructive options exist for soft tissue defects of the foot and ankle due to a lack of surrounding tissue. While microsurgical free flaps have become a popular treatment modality for this anatomic region, pedicled muscle flaps can provide robust coverage of small foot wounds with significantly less donor site comorbidity. One such muscle is the abductor hallucis, which can be utilized as a proximally-based turnover flap to cover medial hindfoot defects. However, complete distal disinsertion of the muscle may lead to loss of support over the medial arch and first metatarsophalangeal joint, leading to pes planus and hallux values.
Methods: In this case report, we describe a modified technique of a split abductor hallucis turnover flap for a young patient with a chronic, traumatic medial heel wound complicated by calcaneal osteomyelitis.
Results: The patient was discharged on postoperative day three with non-weight bearing restrictions in a posterior splint. Upon two-week follow up, she began toe-weight bearing exercises. Upon one-month follow up, her skin graft was well adhered, the muscle flap appeared well perfused, and full weight bearing status was reinstated. The patient remained on intravenous cefazolin for four weeks, then transitioned to oral cephalexin for six weeks. Six months after reconstruction, the flap remains viable and the patient has completely resumed normal physical activity without signs
Conclusion: In the present case, we demonstrate the efficacy of the proximally-based split AH turnover flap in the treatment of a medial hindfoot defect complicated by osteomyelitis, leading to complete wound healing and functional recovery upon long-term follow up.

P3.06

Functional and Quality of Life of Diabetic Patients Undergone Complete Resection of Achilles Tendon due to Ulcer: 3 Cases Reports

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Aim: To evaluate the quality of life and functionality of diabetic patients submitted to debridement of ulcers in the posterior region of the ankle, attending to their complete resection of the Achilles tendon without performing any type of reconstruction or tendon transfer.

Method: Retrospective evaluation of 3 patients who underwent complete resection of the Achilles tendon through extensive debridement, negative pressure therapy, and reverse sural flap rotation or flap repair of the fibular artery to close the wound. It was decided not to proceed with reconstruction because of the possibility of osteomyelitis of the calcaneus in all cases, observed in the MRI. SF-36 quality of life and ATRS-Br questionnaire were applied.
Results: Patient 1, woman, 70 years, presented ATRS: 55 and SF-36 domain related to functional capacity (CF): 50; Patient 2, male, 73 years, presented ATRS: 55 and CF: 65; Patient 3, male, 66 years old, presented ATRS: 31 and CF: 65. All presented a score 0 regarding the limitation by physical aspects.
Conclusions: Functional capacity, as measured by the SF-36, reveals patients with high scores and with high levels of satisfaction when compared with normative data in the Brazilian population adjusted for age, although low score in relation to the limitation by physical aspects and in the score functional ATRS. Patients' expectations should be respected and aggressive reconstructions should not be undertaken, as new procedures could have undesirable outcomes because these patients are patients with a variety of comorbidities due to diabetes.

P4.01

Mini-Invasive Drainage Technique to Treat Deep Diabetic Foot Infection

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Aim: Diabetic foot ulcer is often complicated by infection spreading along tendons' sheaths, over a deep foot area. Surgical drainage of any recess is mandatory to avoid exudate stasis: stasis is the main condition for persistent infection.
Methods: We have designed a mini-invasive drainage named ulcer-piercing (UP) which allows daily irrigation of any surgically pierced tract (figure). This procedure has been utilized in a continuous series of 74 selected diabetic patients affected by Wagner stage-3 ulcer toe (n=33), metatarsal midfoot (n=27), heel (n=4) or plantar Charcot foot (CF) (n=10). Limb's arterial blood supply was considered as adequate in the presence of foot arterial pulses or with ABI> 0,6 and/or TcPO2>30mmHg. 44 patients were considered neuroischemic (59%) on the basis of their peripheral arterial disease: 9 patients (20%) underwent endovascular angioplasty to improve arterial supply. All patients have been treated with systemic specific antibiosis.
Results: 70/74 ulcer have completely healed within a maximum of 8.5 months (in 6 cases, 20%, after distal toe amputation), 1 patient, on hemodialysis, is still recovering after 11 months, while 3 cases of acute Charcot foot, after being cleared their infection, underwent below-the-knee amputation.
Conclusions: In our opinion, the UP procedure represents an effective step toward an easier and safer approach in the treatment of complicated diabetic foot because it could avoid unnecessary and untimely extended surgical incisions which can result in long and uncomfortable scaring, exposing to recurrent complications and inadequate rehabilitation.

Deep plantar phlegmon, drained and healed after 7 months

P4.02

Laser Therapy for Onychomycosis in Patients with Diabetes at Risk for Foot Ulcers: A Randomised, Quadruple-Blind, Sham Controlled Trial (LASER-1)

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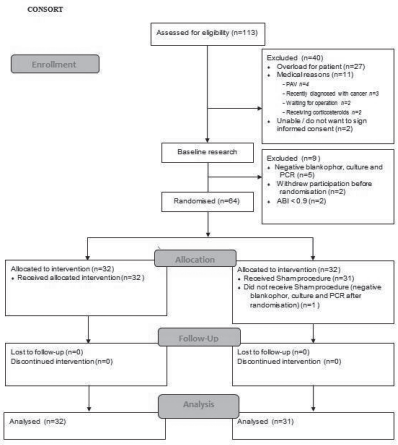
Aim: Patients with diabetes mellitus are at high risk for onychomycosis and the subsequent development of foot ulcers. Aim of this study was to evaluate the safety and efficacy of the treatment of onychomycosis with laser therapy.
Methods: The presented study was single-centre, randomised (1:1), quadruple blind, sham-controlled trial. Patients with diabetes mellitus, medium- to high risk for developing diabetic foot ulcers (Sims classification score 1,2) and a clinical suspicion on onychomycosis were recruited.
Patients were randomised after microbiologic confirmation to either 4 sessions neodymium- doped yttrium aluminium garnet (Nd-YAG) 1064nM laser or sham treatment performed by a diabetes-podiatrist. The primary outcome was clinical and microbiological cure of onychomycosis after one-year follow-up.
Results: From March 2015 to July 2016 a total of 64, patients were randomised; 63 could be analysed (see consort flow diagram). Trichophyton rubrum was the most detected pathogen. Two patients reached primary outcomes. There was no difference in primary outcomes between laser and sham treatment. With the exception of a subungual hematoma in the fifth toenail occurring 2 weeks after laser treatment, the results suggest that treatment with Nd-YAG 1064nM laser is safe.
Conclusion: There is no evidence of any effect of laser treatment for onychomycosis in patients with diabetes at increased risk for foot ulcers, at least not within one year after treatment.
Trial registration number: NCT01996995
Funding: "This work was supported by the Dutch Diabetes Research Foundation [2014.00.1741]. The Hein Hogerzeil foundation funded starting costs and microbiological costs in the form of a grant. The Diabetes Research Foundation, Zwolle, provided funds for this study. Innofeet podiatry, Zwolle, provided funds for this study."



Consort flow diagram

P4.03

Does the PRP of Those with Diabetes Have Antimicrobial Properties?

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This study aimed to determine the inherent antibacterial properties of Platelet Rich Plasma (PRP) from 40 study participants. The participants consisted of 3 groups. Healthy diabetics and healthy age, gender matches (n=13) and a discreet group of 14 participants with a non-healing DFU . Ethical approval was obtained from ORECNI (10/NIRO2/30).

A sample of 24ml of whole venous blood was drawn from each participant and prepared as per the manufacturer's instructions to produce PRP.

The antibacterial efficacy of PRP was established using the well diffusion assay. Five wells were aseptically created in each nutrient agar plate seeded with lawns of S. aureus (NCTC 8329), Ps. aeruginosa (NCTC 10780), Methicillin resistant S. aureus (MRSA) (NCTC 8323), MRSA - clinical isolate, S. pyogenes (β Haemolytic Streptococcus) (NCTC10876), Proteus vulgaris (NCTC10031) and E. coli (NCTC09001). These bacteria are of significance in diabetic foot wounds (Lipsky & Berendt 2000, Vardakas et al. 2008). PRP from the study participants was aseptically transferred into 4 of the wells; the 5th (control) well contained Ringers solution. The plates were incubated at 37 °C /24 hours, and the resultant zones of inhibition were used to provide a semi-quantitative estimation of antibacterial activity.

Results: Zones of inhibition (ZOI) were observed on the lawns of S.aureus, S. pyogenes, and Proteus vulgaris, of all participants. ZOI were also observed on the lawns of MRSA (both types) in the age gender matched group and participants with an active diabetic foot wound.

Enhanced growth of Ps. aeruginosa was observed in the healthy participants (n=11), as previously found by Bielecki et al. (2007) but was also observed in participants with diabetes and participants with diabetes (n=10) and an active diabetic foot wound (n=13).

Discussion: These findings demonstrate that PRP has a wider than previously recognised range of antimicrobial activity against infecting/contaminating bacteria. Zones of inhibition were not identified for all the participants on the plates with lawns of these organisms.

The lack of antimicrobial properties against Ps. aeruginosa is important as it causes 9.3% to 31% of diabetic foot infections; is known to form biofilms, and has been linked to the migration of keratinocytes.

P4.04

A Retrospective Analysis of Intramuscular Antibiotics in Treating 'Borderline-Severe' Diabetic Foot Infection – An Update to Our Admission Avoidance Strategy

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Aim: To determine whether there is any benefit in using intramuscular (IM) antibiotics to avoid hospital admission in patients presenting with a 'borderline severe' diabetic foot infection.

Methods: 92 patients (accounting for 102 episodes) were treated for 'borderline severe infection' between January 2009 and December 2017. 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, 450 contacts per month during the study period. Approximately 1 person per day was admitted with a severe infection through a variety of routes – e.g. the emergency department or vascular outpatients. Of those seen in the specialist foot clinic, only 1 person per month was deemed appropriate to receive IM treatment.

The mean (±SD) number of injections was 12.8 (18.4). Only 26/102 needed hospital admission after IM antibiotics were deemed to not be controlling the infection. The remaining 76 people were successfully treated as outpatients. The 26 who were admitted had a mean length of stay (LOS) of 11.0 days (8.9). Of the 76 people who had their infection successfully treated, 17 later required surgery. Their LOS was 14.2 days (17.0).

If the ulcer was new, then IM antibiotics were more likely to prevent admission ($p<0.001$), but receiving previous oral antibiotics led to an increased risk of admission ($p=0.03$). Being male was associated with a higher risk of admission (88% vs 12%).

Conclusions: Health care institutions are under increasing pressure due to a variety of factors. Admissions avoidance policies are generally welcomed. In 2013 we published outcome data on our admission avoidance strategy for people presenting with diabetic foot infections. This included IM administration as an outpatient. This has been recommended by NICE and the updated IDSA guideline. The current data updates the previous work and confirms the use of IM antibiotics significantly reduced the chances of acute hospital admission in those who under the previous recommendation would have required intravenous antibiotics.

P4.05

Novel Wound Healing Thermoresponsive Biomatrix with Antimicrobial and Anti-inflammatory Properties

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Each year, up to 26 million people with diabetes worldwide develop foot ulcers. More than 50% of foot ulcers become infected, and 20% of these infections lead to amputation. Cutaneous wounds provide a complex microbial ecology due to the inflammatory immune response of the hosts and create a uniquely hostile environment for microorganisms. We have created a novel thermoresponsive biomatrix designed to incorporate antimicrobial and anti-inflammatory therapeutics. Here we present data from the biomatrix prior to and post embedding non-toxic curcumin into our unique biomatrix.
Methods: The biomatrix is a biosynthetically derived elastin like polypeptide (ELP) produced from E.coli. Curcumin was encased in micelles at ratios of 1:10 and 1:50 and infused into the ELP matrix. Uptake and release of curcumin was determined at various temperatures. Antimicrobial efficacy was demonstrated with three unique S. aureus strains and cytotoxicity was evaluated using human fibroblasts.
Results: Using spectral data, the thermoregulatory properties of the matrix revealed a marked burst release of curcumin-micelles at high temperatures and uptake was optimal at low temperatures. Once isolated and fully processed we demonstrate the matrix is free from microbial contamination and contains less than 0.125 EU/mL endotoxin. Using clinical as well as ATCC strains of S. aureus we demonstrate that 0.1mg/mL curcumin encased within micelles at 1:50 and 1:10 ratios killed between 75-95% of the organisms after 2hrs exposure. Remarkably, 1cm2 chips of the fully processed pre-curcumin imbedded biomatrix showed no impact upon human fibroblasts after 6 days culture in 12well dishes. The curcumin embedded micelles had a dose dependent impact upon human fibroblasts cytotoxicity and morphologic response after 45 minutes exposure. Morphology after 24 hours revealed minimal impact of the 1:50 micelles, yet the 1:10 micelles revealed marked impact with cell balling and sluffing of the monolayer again in a dose dependent manner.
Conclusion: We have made curcumin more stable and bioavailable as well as control its release by utilizing a combination of micelles for solubilization followed with incorporation into our novel biomatrix. The combination of these unique properties, once optimized, will provide a much-needed preventive/therapeutic for a devastating health condition.

P4.06

Adtec Cold Plasma Treatment to Assist in Treating Diabetic Foot with Multi Resistant Infection

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Aim: A retrospective review of the impact of the Adtec Cold Plasma (ACP) treatment on 3 patients with chronically infected diabetes foot and leg ulcers.
Methods: Three patients (Type 2 diabetes mellitus) with chronic non healing foot and leg ulcers with multiple antibiotic resistance,had at least 3 courses of >6 weeks (in total) intravenous antibiotics each, prior to ACP treatment. 2 out of 3 patients had adequate vascular supply, based on vascular clinical assessment and arterial duplex +/- CT angiogram. 2 out of 3 patients had an HbA1c <55mmol/mol. All patients were treated for 15 minutes per head size area of machine, twice a week (total 8 to 11 sessions) in addition to standard wound care. This was delivered by specialist diabetes podiatrists. Treatment was stopped due to the loss of access to the ACP treatment rather than that an active clinical decision. The patients' wounds were regularly assessed by the podiatrist and the consultant based on clinical assessment, inflammatory markers and microbial swab growth.
Results: One patient has healed up without antibiotics post treatment and remained stable upto 8 months after treatment. The 2nd patient had a reduction in severity of all wounds with one course of Clindamycin during ACP. In the last 7 months her wounds are improving and only oral antibiotics have been required. The 3rd patient had a ~20% reduction in wound size and severity but has since deteriorated requiring multiple courses of IV antibiotics alongside worsening limb arterial disease.
Conclusion: Despite n=3, with 2 positive outcomes there is a potential benefit. The improvement of diabetic foot and leg ulcers ,we postulate , is due to a reduction in microorganisms load of the wound with a different mode of action to that of antibiotics. However, more research is required including randomized controlled trials focusing on diabetic foot and leg ulcers separately, with or without osteomyelitis.
References: A proof of concept evaluation of the efficacy of non-thermal gas plasma in the treatment of diabetic foot ulcers that are stalled by sub clinical wound infection, McCardle J., Haycocks S., Chadwick P., EWMA 2018

P5.01

The Enhanced Functional ability of Charcot Osteoclasts to Resorb Bone Extensively is Associated with Increased Activity of Cathepsin K

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Background and aims: Using advances in cellular biology we have previously shown that osteoclasts, generated from monocytes from patients with acute Charcot foot, are overactive and resorb bone extensively. We hypothesised that this enhanced resorbing function could be due to increased activity of cathepsin K, the main proteinase responsible for collagenase degradation.
Methods: To test this hypothesis, the activity of osteoclasts, generated from peripheral blood mononuclear cells derived from five Charcot patients and cultured on bovine bone discs in the presence of macrophage-colony stimulating factor (M-CSF) and receptor activator of nuclear factor-κβ ligand (RANKL), was assessed in cultures before and after the addition of the cathepsin K inhibitor, Odacanatib (ODN). After 21 days in vitro, the bovine bone discs were stained with toluidine blue and examined for pit formation under light microscopy. The erosion profile of the resorbed bone discs was assessed with surface profilometry (Dektak 150, Veeco).
Results: In both culture conditions (M-CSF+RANKL-treated cultures and M-CSF+RANKL+ODN-treated cultures), the newly formed osteoclasts exhibited their functional ability to resorb bone as indicated by the presence of resorption pits on bovine bone discs after toluidine blue staining and evidence of eroded bone surface after surface profilomety.
However, there was a remarkable difference in the pit morphology between the two culture treatments. In MCSF+RANKL+ODN-treated cultures, the resorptive events appeared round or slightly elongated in contrast to the trenches and trails observed in M-CSF+RANKL-treated cultures. Furthermore, surface profilometry revealed that there was a 2-fold reduction in the area of below surface osteoclast resorption in MCSF+RANKL+ODN-treated cultures compared with M-CSF+RANKL-treated cultures ($p<0.05$). In addition, there was a 20% reduction of the maximum erosion depth in MCSF+RANKL+ODN-treated cultures compared with M-CSF+RANKL-treated cultures.
Conclusion: The addition of the cathepsin K inhibitor, Odacanatib, to M-CSF+RANKL-treated cultures reduced the below surface resorption of newly formed osteoclasts from Charcot patients as well as reversed the resorptive behaviour from lacunae and trenches (bulldozer-type resorption) to formation of clusters of pits (drilling mode of resorption). These observations shed light to the mechanisms of enhanced osteoclastic activity of the acute Charcot foot.
Supported by Diabetes UK.

P5.02

Multifactorial Comparison in the Charcot Neuroathropathic Patient with Diabetic versus Non-Diabetic Etiology in a 1:2 Risk Adjusted Matched Cohort

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Aim: The aim was to compare risk adjusted matched cohorts of Charcot neuroarthropathy patients with diabetes and without diabetes. The two arms of the study were analyzed for preoperative infection rates, Charcot breakdown location, and postoperative outcomes.
Methods: Patients who underwent osseous reconstruction for Charcot neuroarthropathy were identified by retrospective review and divided into two arms: patients with diabetic Charcot neuroarthropathy and those with non-diabetic Charcot neuroarthropathy. The two arms were matched based on age, BMI, history of ESRD, HTN, PAD and smoking. Bivariate analysis was performed for preoperative infection (preoperative ulcer location, presence of soft tissue infection or osteomyelitis), location of Charcot breakdown, and post-operative outcomes (dehiscence, major lower extremity amputation, delayed osseous union, recurrence or new location of Charcot breakdown, return to ambulation).
Results: The presence of preoperative ulceration ($p=0.0499$) was found to be statistically higher in the diabetic cohort via bivariate analysis. Bivariate analysis found delayed osseous union ($p=0.0051$) and return to ambulation ($p<0.0001$) to be statistically higher in the non-diabetic arm. In the non-diabetic cohort delayed osseous union was increased by 16.4 fold [OR 16.4 (95% CI (1.9-139.6)] and return to ambulation was increased by 17.6 fold [OR 17.6 (95% CI (3.5-87.6)]. No other factors were found to be statistically significant.
Conclusion: The diabetic arm had higher rates of preoperative ulcers and the non-diabetic arm was 16.4 times more likely to have delayed osseous union and 17.6 times more likely to return to ambulation. The higher rates of preoperative ulcers in the diabetic population were likely due to chronic hyperglycemia and immunocompromised state as the two arms were matched for peripheral arterial disease and neuropathy, two other common risk factors for ulcerations. The higher rates of delayed osseous union in the non-diabetic arm were likely due to impaired osseous metabolism commonly seen in patients with alcoholism, rheumatologic disease (rheumatoid arthritis, lupus) on chronic steroids, or post stroke patients due to disuse osteopenia. The higher rates of ambulation in the non-diabetic population are likely due to the increased functional state compared to poorly controlled diabetics with extensive comorbidities additionally contributing to the decreased functional state.

P5.04

Use of Ultrasound in the Diagnosis of Charcot Foot

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Background: Charcot Neuroarthropathy (CN) occurs in patients with pre-existing diabetic peripheral neuropathy and can result in destruction and deformity of weight-bearing joints in the foot. The aetiology is poorly understood and late presentation limits the abil-

ity to preserve the shape of the foot through off-loading.
Aim: To describe the sonographic Doppler and greyscale characteristics of the Charcot Foot.
Methods: 30 feet of 15 patients with suspected Charcot Foot had ultrasound (US) of their feet over a 3 year period. Greyscale and doppler characteristics of the symptomatic and contralateral foot were recorded on initial referral to radiology. 8 patients had follow up US during or after a period of off-loading. Morphological abnormalities of the foot such as erosions, arthropathy and malalignment were noted. Peak systolic velocity (PSV) and resistive indices (RI) of the Dorsalis Pedis artery were recorded in both feet on initial and where relevant on follow-up visits. Presence of periarticular and intraarticular blood flow was also recorded.
Results: Morphological abnormalities were seen in 12 feet; 8 symptomatic and 4 asymptomatic. Intra-articular or peri-articular colour flow was seen in 8 feet clinically suspected of having acute CN. PSV (>30 m/sec difference) was higher in the symptomatic foot compared to the contralateral foot in all but one patient. Monophasic arterial waveform with RI less than 1 was seen in all symptomatic feet and one asymptomatic foot. On follow-up ultrasound 5 of 8 patients showed reduction in PSV in the treated foot (<10m/sec difference compared with the contralateral foot), triphasic arterial waveform and no detectable intraarticular colour flow. These 5 patients had all completed their off-loading treatment phase. Of the remaining 3 patients who showed persistent Doppler abnormalities on follow up, 2 had not completed their off-loading treatment phase.
Conclusions: This clinical review of cases shows the potential use of ultrasound to diagnose CN and monitor response to treatment. Greyscale imaging can detect morphological abnormalities in the symptomatic and asymptomatic diabetic foot. Doppler characteristics has potential for diagnosing acute CN and monitoring response to treatment. Ultrasound is a simple imaging technique which may help achieve earlier diagnosis of acute CN.

P5.05

Continuous Temperature Monitoring Socks for Home Use in Patients with Diabetes and Charcot Foot

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Aim: Charcot neuroarthropathy (CN) is a progressive disease that is a severe and costly complication in persons with diabetic peripheral neuropathy (DPN). CN can result in hospitalization, ulceration, deformity, loss of mobility, infection, and amputation. For persons with DPN, diagnosis, and monitoring of CN can be difficult. This is often due to a failure to recognize the signs of the disease, or misdiagnosis due to comorbidities. Continuous temperature monitoring is a promising technology to assist with the early diagnosis and monitoring of CN. In this report, we introduce sensor-embedded socks designed for home use and daily wear, which perform continuous temperature monitoring of the plantar surface of the foot. The aim of this study was to assess the accuracy of the socks, obtain user feedback on how comfortable socks were for home use, and examine whether observed temperatures correlated with clinical observations for persons with CN.
Methods: Temperature accuracy of the sensors was assessed prior to incorporation in the socks as well as in the completed sock design. A total of 35 patients with diabetic peripheral neuropathy (DPN), a subset of which had CN were enrolled at a single site pilot study. Patients with CN were provided with socks and instructed to wear the socks continuously for 6 hours after which the socks could be removed, and returned to the clinic.
Results: The temperatures measured by the standalone sensors were within 0.2°C of the reference standard. For patients with CN, cases are presented that show how temperature differences observed between the feet were consistent with clinical observations.
Conclusions: We report the first use of wireless continuous temperature monitoring for daily wear and home use in patients with DPN and CN. The wearers found the socks to be no different from standard socks. The temperature studies conducted show that the sensors used in the socks are reliable and accurate at detecting temperature, and the findings matched clinical observations. The socks serve as a promising tool for the early diagnosis and monitoring of CN in patients with DPN.

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P5.06

Effect of Charcot Foot on Wound Healing and Foot and Ankle Deformity at First Clinical Presentation

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Aim: It is well- assumed that Charcot foot lead to foot and ankle deformity, cause ulceration and may impede wound healing. King Saud University diabetes center is a referral center dealing with diabetic foot ulcers. We sought to assess the effect of Charcot Foot among our diabetic foot patients at first clinical presentation.
Methods: 350 diabetic patients with foot wound between 2008 – Nov 2015 were collected. Diabetes control was based on the HbA1c values, Sensory testing was performed by using a VPT, vascular status evaluation was based on pedal pulses palpation and/or ankle brachial pressure index (ABPI). Wound care was done up on the standard of the IWGDF (debridement, infection control, vascular control, and offloading). Healed wound was defined as complete closure without discharge.
Results: 17.71% was found to have Charcot foot and 60% were male. Mean age, diabetes duration, and HbA1c were 56 years, 21years, and 9% in the Charcot group. Among the Charcot group: Type 2 DM were 66.67%, 100% had DPN, 18% had PVD, and Wound baseline was 21.39 weeks, History of ulceration and Amputation were 72.22% and 23.02% respectively and the healing time was 14.5 weeks.
Conclusion: Charcot foot was quite common complication among

our community patients revealing the poor screening and delayed management of Charcot. In contrary the presentation was less late that the ulcer group due to foot deformity and pain. It seems to be that Charcot foot deformity bring patient earlier. Furthermore, anyone who experience discomfort, unexplained swelling, redness or foot shape changes should seek care right away.

P6.02

A Retrospective Descriptive Audit of Diabetes-Related Lower Limb Amputations in Metro Auckland, New Zealand; July 2015-June 2016

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Aim: To understand the cohort of people who had diabetes related lower limb amputations (DRLLA), the causes of DRLLAs and identify potential improvements to health care delivery to reduce the numbers of preventable DRLLAs.
Methods: People who underwent a DRLLA, July 2013 to June 2016 inclusive, were identified from the national minimum dataset (NMDS). Information on DRLLAs, hospital admissions and demographics were also obtained from the NMDS. More detailed clinical data and information on podiatry services utilisation was obtained for those with an amputation July 2015 to June 2016.
Results: There were 862 DRLLAs during 635 admissions for 488 people in the three year cohort. Major amputations (above and below knee) comprised 25% of total DRLLAs. The age standardised amputation rate was three times higher in males than females at 41.1 per 100,000 population (95% CI: 37.3 – 44.9 per 100,000) and 13.6 per 100,000 (95% CI: 11.6 – 15.6 per 100,000) respectively. The rate per 100,000 population was much higher in indigenous Māori and Pacific (75.9, 95% CI: 63.8 – 88.1 and 81.6, 95% CI: 68.5 – 94.7) than Asian/Other (13.8, 95% CI: 9.6 – 18.1 and 16.6, 95% CI: 14.7 – 18.6 respectively).
In the one year cohort the prevalence of comorbidities was high with retinopathy recorded in 73.6% of admissions, neuropathy in 75.6%, diabetic nephropathy in 58%, vascular disease in 78.8%, with 21% on renal replacement therapy. Foot ulcers, skin infection, ischaemia and osteomyelitis were all significant precursors to amputation. Despite this more than half the admissions had not been seen by either secondary or community podiatry services leading up to amputation. Mortality was high, with 7.3% of admissions dying within one month of amputation and 12.4%.within three months.
Conclusions: The audit showed significant discrepancies in DRLLAs by ethnicity and gender and a high number of people not receiving podiatry care. Sub-optimal documentation of diabetic foot risk factors and underlying causes of amputation was identified. Findings have facilitated increased regional collaboration and improvements are being implemented to increase appropriate referrals and improve record keeping. The audit tool is now being refined to support further quality improvement initiatives.

P6.03

National Incidence of Foot Disease-Related Hospitalisation in Australia in People with and Without Diabetes

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Aim: Foot disease is a leading cause of hospitalisation and amputation across the world. Burdens of foot disease are typically monitored by investigating the incidence of amputation in a population over time. However, amputation is only part of the burden. Very few studies have monitored the burden more broadly by investigating the incidence of foot disease-related hospitalisation in a population over time. This study investigated the national incidence of foot disease-related hospitalisation, including in people with and without diabetes.
Methods: The Australian National Hospital Morbidity Database was used to identify all inpatient hospitalisations for foot disease from 2008 to 2015. Thirty-nine International Classification of Diseases (ICD-10-AM) primary diagnosis codes were used to identify hospitalisations caused by three overarching foot disease-related disorders: ulceration, infection or ischaemia. Similarly, diabetes-related codes (ICD-10-AM) were used to identify people with or without diabetes. Incidence rates for hospitalisations were expressed per 100,000 person-years using Australian resident population data and chi-squared test for trend was used to test differences over time.
Results: Overall, 680,023 foot disease-related hospitalisations occurred in Australia, equating to a national incidence of 380 per 100,000 person-years; 272 (71.5%) were in people without diabetes and 108 (28.5%) in people with diabetes. The incidence of foot disease-related hospitalisation increased by 18.1% (348 in 2008 to 411 in 2015); in those without diabetes this increase was 5.4% (246-to-260) and with diabetes was 48.8% (101-to-151) (all $p<0.01$).
Infection incidence increased by 31.4% (175-to-229); without diabetes increased by 20.7% (142-to-171) and with diabetes 77.2% (33-to-58) (all $p<0.01$). Ulcer incidence increased by 7.9% (85-to-92); without diabetes decreased by 24.6% (45-to-34) and with diabetes increased by 44.8% (40-to-58) (all $p<0.01$). Ischaemia incidence increased by 1.5% (88-to-89) ($p>0.05$); without diabetes decreased by 8.2% (60-to-55) and with diabetes increased by 22.2% (28-to-34) (both $p<0.01$).
Conclusion: This study provides important new information for monitoring the burden of foot disease. The national incidence of foot disease-related hospitalisation increased in Australia between 2008 and 2015, primarily driven by those with diabetes. These findings indicate that more work is needed to reduce the national burden of foot disease in Australia, in particular in people with diabetes.

P6.04

20 Years with Diabetes and Amputations: A Retrospective Population-Based Cohort Study

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Aim: Amputation is the final outcome of severe disease in the lower extremities and is often preceded by years of neuropathy and/or atherosclerosis. Over the last decade, there has been an increasing interest in amputation-prevention as well as revascularization. This study sought to investigate the progression of amputations amongst patients with and without diabetes.
Methods: From the Danish National Patient Register a cohort of diabetic people (n=501,724) with either type 1 or type 2 diabetes as well as a group of matched controls without diabetes (controls, n=1,375,567) was identified. Amongst these 26,291 amputations were identified between 1996-2011 and stratified into three groups based on location using surgical codes. Amputations due to traumas were excluded (n=310).
Results: Amongst diabetic patients amputations on ankle and foot has increased more than 35%, while amputations on knee and lower leg has decreased more than 30%. Interestingly, a slight increase is also seen in amputations on hip and thighs. In controls, the development is more or less the same; however, the groups differ significantly at amputation site, where controls more often receive more proximal amputations. Furthermore, diabetic patients are often younger at first amputation at any site compared to controls, and exhibited increasingly improved survival rates. Amongst all amputations, the percentage of preceding revascularization has increased significantly at most sites.
Conclusion: Over the last decades, there has been a development in amputations favouring more distal sites and more often preceding revascularizations. In addition, the five-year mortality has decreased significantly, with diabetic patients having the greatest overall reduction.

P6.06

Clinical Analysis of 326 Diabetic Foot Cases in Several Tertiary General Hospitals of China

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Objective: To explore the clinical characteristics, risk factors and factors affecting the severity of the disease in patients with diabetic foot at the current stage through a multi-center cross-sectional survey, and provide a scientific basis for the prevention and treatment of diabetic foot.
Methods: Clinical data of 326 diabetic foot patients from 13 tertiary general hospitals nationwide were collected from October to November 2017 using a unified clinical data collection table for diabetic foot patients. The clinical characteristics were analyzed and divided into the mild group (level 1-2) and the severe group (level 3-5) according to Wagner classification, logistic regression analysis of the factors affecting the occurrence of severe diabetic foot.
Results: Among 326 patients with diabetic foot, 205 males and 121 females, 68.4% of the patients were >60 years old, and 60.1% of the patients had primary or junior high school education; 96.3% of the patients developed type 2 diabetes, 80.1% of patients had glycated hemoglobin (HbA1c) ≥ 7%. Improper wearing of footwear (38.5%) is the main cause of diabetic foot. Diabetic neuropathy (76.7%), diabetic retinopathy (62.3%) and lower limb vascular disease (57.4%) were the most common complications. Logistic regression analysis showed that diabetic nephropathy, diabetic lower extremity vascular disease, and HbA1c levels were independent risk factors for severe diabetic foot, and receiving foot care education as a protective factor.
Conclusions: This group of diabetic foot occurs mostly in male patients, type 2 diabetes patients with older age, lower education level and poor glycemic control. Its occurrence often has inducement, accompanied by multiple complications of diabetes. Diabetic nephropathy, diabetic lower extremity vascular disease, HbA1c, and receiving foot care education are independent influencing factors for the severity of diabetic foot.

Clinical Analysis of 326 Diabetic Foot Cases in several Tertiary General Hospitals of China

P7.01

Concordance of Skin Autofluorescence Measurements Between Body Sites in a Cohort with and Without Diabetes, Peripheral Neuropathy and Foot ulcersU

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Aim: To evaluate the within and between anatomical site measurement variability of skin autofluorescence (a surrogate measure of tissue glycation) of the volar arm, posterior leg and the plantar forefoot in people with and without type 2 diabetes and foot ulcers.
Methods: 132 participants (16 with diabetes-related foot ulcers, 63 with diabetes and no foot ulcer history, and 53 without a history of diabetes) participated. Skin autofluorescence was assessed using a skin autofluorescence measurement device, a validated measure of tissue glycation. Three consecutive measurements of the volar aspect of each forearm, the mid-point between each popliteal fossa and the gastrocnemius muscle belly, and the plantar forefoot distal to the 3rd metatarsal head of each limb were taken using a standardised protocol on the same day. Measurement variability between measurement and between anatomical sites was assessed with concordance correlation coefficients (CCC) and 95% confidence intervals (CIs) using the average left and right arm measurement as the reference standard. Bland-Altman plots with limits of agreement were constructed. The strength of agreement based on CCCs were considered as: Almost perfect >0.90; Substantial 0.80-0.90; Moderate 0.65-0.80; Poor <0.65.
Results: The mean age of the cohort was 61 years (± standard deviation 10.4 years), 76 (57.6%) were male and 68 (51.5%) had a smoking history. In those with diabetes, the mean diabetes duration was 11.4±8.5 years, HbA1c was 55.2±14.2 mmol/mol, 30 (22.7%) had peripheral neuropathy and none had peripheral arterial disease. Out of three measurements, the lowest CCCs for the intra-limb measurements were 0.949 [95% CI 0.930-0.963] for the arm, 0.965 [0.948-0.976] legs and 0.936 [0.908-0.956] feet. The CCCs for between site measurements were 0.460 [0.309-0.855] for the arm vs. leg and 0.05 [0.001-0.104] for the arm vs. foot.
Conclusions: This study suggests that skin autofluorescence measurements have almost perfect level of agreements within the same site for these different populations, but a poor level of agreement between sites. The findings require further investigation to determine whether skin autofluorescence of the lower limbs has an advantage over arm measurements in screening for people at risk of foot ulcers.

P7.02

Is it Possible to Measure Reliably Trancutaneous Oxygen Tension in Areas Other than Dorsal Foot?

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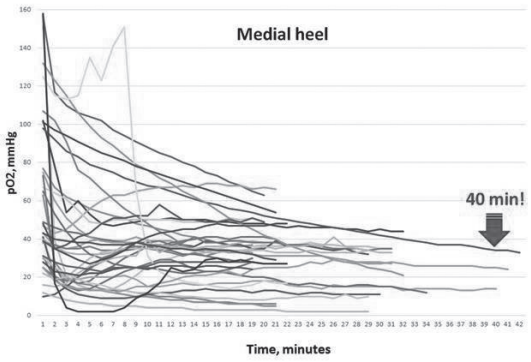
Aim: Dorsal foot is a standard area for measurement of transcutaneous oxygen tension (pO2) with well established cut-off points for ischemia but it reflects circulation only in part of the foot angiosomes. So establishing of reference range for pO2 in other foot regions would be important for practice.
Methods: We retrospectively analyzed results of 160 pO2 measurements in 35 consecutive patients with diabetes mellitus. Measurements were made in dorsal, plantar, medial heel, medial calf and subclavian areas. TCM400 device (Radiometer, Denmark) was used. Measurements were conducted by one experienced operator in strict accordance with recommendations of the device manufacturer. We analyzed mean pO2 value between 15th and 19th minutes and characteristics of the pO2 curve (plateau / ascendance / descendance) in this period of time.
Results: Mean patients' age was 68 (47-87), diabetes duration 14 (1-24) years. 60% were males. 77% had ulcers, 34% underwent revascularization.
Mean pO2 value on the medial heel was significantly higher than dorsal foot one (35 +/-17 vs. 22+/-18, p=0.002). Some patients demonstrated continuous decrease of the pO2 during this time frame, and even up to 40th minute (Figure). We elaborated criteria of the reliable stable phase measurement (coefficient of variation <10% and results of multiplication of difference between 15th-19th minutes and 11th-15th minutes within 95% CI for subclavian measurements). In subclavian, calf, dorsal foot, medial heel and plantar regions 92%, 100%, 76%, 77% and 43% of patients met these criteria, respectively (p=0.003).
Conclusions: 1). Continuous decrease of pO2 value in part of the patients need careful investigation.
2). Nature of this phenomenon is unknown but skin lotions may play a role.
3). Manufacturers of the equipment should elaborate special software to confirm the plateau phase and calculate mean pO2 value during it.



Medial heel

P7.03

Assessment of Microcirculation in the Diabetic Foot with Laser Speckle Contrast Imaging

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Aim: A major challenge for treating diabetic foot ulcers is estimating the level of ischemia, as currently used non-invasive diagnostic techniques provide rough indications. Laser Speckle Contrast Imaging (LSCI) is a promising non-invasive technique to assess microcirculation. Our aim was to investigate the stability and reproducibility of LSCI for the assessment of microcirculation in the diabetic foot, the relation of LSCI results to currently used non-invasive blood pressure measurements, and the ability of LSCI to discriminate between levels of ischemia.
Methods: Thirty-three participants with diabetic foot ulcers were included in this prospective, single centre, observational cohort study that was conducted in the Netherlands. They were classified as non-ischemic, ischemic or critical-ischemic based on criteria formulated in the international guidelines. Two clinicians performed LSCI scans of the foot, consisting of baseline measurements, followed by two stress tests (post-occlusion peak and elevation test). With 3 measurement conditions and 5 regions of interest of the foot per patient, a total of 15 measurements were available for analyses.
Results: The intra-observer agreement of LSCI was high (r=0.711-0.950; p<0.001) for all 15 measurements. The inter-observer agreement was high (r=0.728-0.861; p≤0.001) for 10 measurements and moderate (r=0.476-0.570; p≤0.005) for the remaining 5 measurements. The inter-assessor agreement was high and significant (r=0.857-0.996; p≤0.001) for all measurements. Correlation between LSCI and non-invasive blood pressure measurements was low (r=-0.272–0.582). During both stress tests, microcirculation was significantly lower in critical-ischemic feet compared to non-ischemic feet (67.5 Perfusion Units (PU) vs. 96.3 PU and 41.0 PU vs. 63.9 PU; p<0.05).
Conclusions: LSCI is a stable and reproducible technique for assessment of microcirculation in people with diabetic foot ulcers and can discriminate between non-ischemic, ischemic and critical-ischemic patient populations.
Acknowledgements: No competing financial interests exist.

P7.04

The Association Between Microcirculation in the Foot Measured with Laser Speckle Contrast Imaging and Healing of Diabetic Foot Ulcers

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Aim: Critical ischemia in diabetic foot ulcers is currently insufficiently diagnosed with non-invasive blood pressure measurements. Laser Speckle Contrast Imaging (LSCI) is a promising non-invasive technique to measure microcirculation in the outermost layers of the skin. It is stable and reproducible for assessment of microcirculation in people with diabetic foot ulcers. However, its relation with clinical outcomes has not yet been investigated. The aim of this study was to investigate the association between microcirculation in the foot measured with LSCI and healing of diabetic foot ulcers within 12 weeks.
Methods: Thirty-two patients with diabetic foot ulcers were included in this prospective, single centre, observational cohort study. They were classified as non-ischemic, ischemic or critical-ischemic based on IWGDF criteria. LSCI scans of the foot, ulcer and ulcer edge were conducted, via baseline and post-occlusion hyperemia measurements. Healing was defined as complete re-epithelialization and scored at 12 weeks. Pearson's correlations, chi-square and one-way ANOVAs were conducted.
Results: Eighteen patients (56.3%) healed within 12 weeks. Average healing percentages for the non-ischemic, ischemic and critical-ischemic groups were respectively 57.1%, 61.1% and 57.1%, with no significant difference between the groups (p=0.146). Furthermore, we found no significant association between microcirculation and healing. Mean LSCI perfusion units did not differ between groups at baseline (foot: 47.3±12.5 vs 48. 9±13.0, p=0.164; ulcer: 105.4±27.7 vs 94.7±27.7, p=0.696; ulcer edge: 92.5±28.7 vs 86.9±22.8, p=0.792), and during post-occlusion hyperemia (foot: 72.8±24.0 vs 78.5±20.1, p=0.715; ulcer: 103.4±28.4 vs 94.1±23.7, p=0.741; ulcer edge: 101.5±30.6 vs 96.0±22.3, p=0.881). Non-invasive blood pressure measurements also did not differ between groups : arm-pressure: 133.5±22.7 vs 131.0±21.3mmHg (p=0.834), ankle-pressure: 113.8±47.0 vs 124.6±42.4mmHg (p=0.799); toe-pressure: 90.2±46.3 vs 86.4±47.2mmHg (p=0.528); ABI: 0.69±0.35 vs 0.63±0.31 (p=0.877); TcpO2: 42.9±16.4 vs 53.2±24.4mmHg (p=0.147).
Conclusions: No association between healing and microcirculation measured with LSCI or non-invasive blood pressure measurements was found. With no ischemia-related measurements associated with healing in this cohort, healing will more likely be related with an intricate interplay between foot, personal and treatment factors. A separate role of microcirculation and non-invasive blood pressure measurements could not be identified in this research.
Acknowledgements: No competing financial interests exist.

P7.05

Rapid Non-Invasive Quantitative Optical Imaging of Microcirculation for Prediction of Reulceration for People in Diabetic Foot Remission

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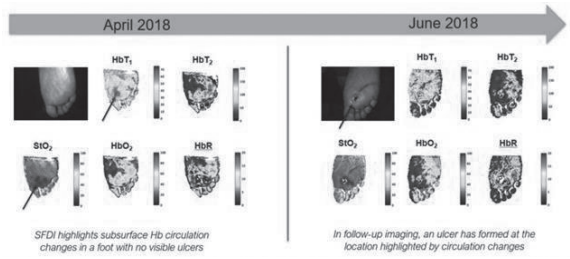
Background: There are few tools that can currently assess microcirculation quantitatively in a rapid non-invasive fashion. Previous work by our group have correlated Spatial Frequency Domain Imaging (SFDI) to current non-invasive testing methods (ABIs, TBIs) in subjects with diabetes. Here, we present the first prospective longitudinal data (data collection every 4-6 weeks) of the first 10 subjects enrolled in remission over the course of the year.
Methods: In this pilot study, we enrolled the first 10 of a planned 50 subjects in diabetic foot remission, evaluated with SFDI scanning every 4-6 weeks during their preventative remission visits. SFDI is a non-contact optical imaging method that uses visible and near-infrared structured illumination to quantitatively assess super-

ficial and subsurface (0-4mm) tissue optical properties to quantify hemoglobin oxygen saturation and distribution over large fields of view (15cm x 20cm).
Results: Reulceration occurred in one of ten patients followed over the first year. In that patient (see illustration), we measured a localized increase in tissue oxygen saturation (16% increase StO2) and decrease in hemoglobin (69% decrease in superficial HbT1; 49% decrease in deep HbT2) in the pre-ulcerative region (Figure 1) one month before the ulceration. These characteristics were not seen in the remaining patients who remained in remission.
Conclusion: The results of these early data suggest that SFDI signatures of local tissue hemoglobin oxygen saturation and distribution may provide early predictive signs of reulceration for patients in diabetic foot remission.



SFDI shows localized changes in foot circulation in area that develops ulcer

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P7.06

Screening Tests for the Detection of Peripheral Arterial Disease - a Source of Uncertainty?

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Aim: The aim of this study was to compare six different screening modalities in the detection of PAD in a primary care setting.
Methods: Fifty participants with Type 2 diabetes were recruited. Pulse Palpation, waveform analysis, ankle brachial pressure index, absolute toe pressure, toe brachial pressure index and transcutaneous oxygen pressure were compared in the detection of peripheral arterial disease. One hundred limbs were included for analysis.
Results: This study showed different results in peripheral arterial disease screening tests in the same group of participants. The highest percentage of participants who had PAD was for the Doppler Waveform (93.0%). This was followed by TBPI (72.0%), ABPI (57.0%), ATP (35.0%), TCPO (30.0%) and Pulse Palpation (23.0%). The difference between these percentages is significant ($p<0.0005$). The magnitude of the effect size is medium/moderate (Cramer's V=0.498).
Discussion/Conclusion: This study demonstrates that inconsistencies exist between the agreement of the 6 different modalities used to detect PAD. The authors postulate that one possible reason for the increase of both minor and major amputations worldwide could be the untimely and/or incorrectly diagnosed PAD due to inconsistency exhibited between these 6 widely used tests. Patients who are falsely identified as having no PAD when indeed this could be present could pose a threat to this high risk population since if they are not appropriately detected, they would be denied early beneficial and effective secondary risk factor control together with further investigations to determine the extent of the condition. Furthermore, accurate diagnosis also safely reduces unnecessary secondary care referrals when it is known that these appointments could be utilized by those patients who truly have the condition and are denied of prompt attention due to long waiting lists. The authors advocate for urgent, more robust studies utilizing a gold standard modality for the diagnosis of PAD in order to provide evidence regarding which screening modalities would yield the most valid results. This could significantly reduce the proportion of patients with diabetes who would be falsely identified as having no PAD and subsequently denied beneficial and effective secondary risk factor control.

P8.01

Outcomes of Complex Diabetic Foot Heel Ulcers – the Role of the Multidisciplinary Surgical Management

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Aim: Diabetic heel ulcers are difficult to heal and often require surgical debridement especially in cases complicated by osteomyelitis. The aim of the study was to assess treatment outcomes at 6-months (ulcer healing) and at 12-months (patients' ability to return to function, ulcer recurrence, amputation and mortality) in patients who have undergone surgical debridement for infected heel ulcers.
Method: A retrospective review of electronic theatre log over a seven year period (2010-2017) was performed. A total of 30 patients (32 heel ulcers) who had undergone surgical debridement were identified. Presence of osteomyelitis in the calcaneum was confirmed by cortical irregularity on lateral foot radiographs and/ or increased bone marrow signal intensity on magnetic resonance imaging. Post-surgery, all patients were monitored in the diabetic foot clinic by the multi-disciplinary team and received podiatric treatment, offloading and control of infection. Outcomes at 6 and 12 months were recorded from patients' medical notes.
Results / Discussion: At presentation, all patients had peripheral neuropathy, 4 patients were on dialysis and 6 had undergone previous revascularization. Heel ulcers were complicated by osteomyelitis in 84% of the patients. The mean ulcer duration was 1.7 years (range 4 months to 9 years). Surgical treatment included soft tissue debridement with or without partial calcanectomy. Postoperative wounds were left open to allow healing by secondary intention. Six month post-surgery 17 patients (56%) had healed. At 12 months, 4 patients had re-ulcerated (12%) and 4 patients had died (12%). One further patient who presented with bilateral heel ulcers and calcaneal osteomyelitis had healed unilaterally but had undergone a below knee amputation on the opposite side. Func-

tional outcome data at 12 months were available for 16 subjects, of whom 11 returned to independent weight-bearing.
Conclusion: This study shows that more than 50% of heel ulcers can heal at 6-months with prompt surgical debridement and multidisciplinary-management. Aggressive treatment of infection and intensive podiatric therapy resulted in a very low amputation rate and acceptable mortality rate. Patients with heel ulcers are best managed within a multidisciplinary team and early referral to diabetic foot surgeons is essential to avoid adverse outcomes.

P8.02

Better Wound Healing Outcomes After Diabetic Foot Surgery After a Revised Protocol. Comparing Two Cohorts Over Time

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Two cohorts of patients who underwent minor diabetic foot surgery were compared in outcomes of wound healing, additional surgery and the effect of revascularisation.
Aim: To assess improvement of wound healing after introduction of a new protocol about vascular examination and treatment.
Method: Retrospective analyses of two different cohorts over time.
Results: 209 cases were included. The second cohort demonstrated an improved healing rate of 10% (p=0,01) and a trend of a decrease in the need of additional surgery. Significant more (p=0,05) patients received a revascularisation around their surgical procedure, however the relation between success of revascularisation and wound healing between groups was not significant.
Conclusion: It is assumable that healing rates improved after introduction of a new protocol for vascular examination and treatment, however there are a lot of different factors that also enhance wound healing outcomes.

P8.03

Evaluating Podiatry Services for Indigenous People with Diabetes in New Zealand

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Aim: This work seeks knowledge from other countries about the effectiveness of funded community podiatry services in reducing lower limb amputation and how these lessons can be transformed into practice specifically for the indigenous people of New Zealand.
Māori are the indigenous people of New Zealand, and account for almost 15% of the population. Under the Tiriti o Waitangi (signed in 1840), Māori are in partnership with the Crown. This partnership promises that the Crown and its' entities (the New Zealand Government) will collaborate with Māori communities to ensure health gain; involve Māori in decisions related to health; and, provide protection for Māori to achieve equitable health outcomes. However, despite this, Māori are consistently featured in all-cause morbidity and mortality health statistics, particularly for diabetes mellitus (DM). The prevalence of DM among Māori is two times that of non-Māori; with rates for DM related renal failure being five times higher in Māori. Criterion-based podiatry assessment and management is funded for people with DM in New Zealand in which Māori ethnicity is a key priority for inclusion into the service. However, outcome data is scarce to support the effectiveness of the podiatry services, particularly in terms of whether or not these services meet the aspirations of Māori. This is reflected in lower limb amputation data in which Maori are 1.7 times likely to experience compared to non-Māori. More recently, it was reported that Māori were at a 65% greater risk of a major LLA even after adjusting for deprivation and comorbidity, compared to non-Māori. Death is common in more than half of those who undergo a major LLA within 3 years.
Methods: A literature review was conducted in 2018.
Results: Ninety-seven studies were identified through database and citations of the literature. Removal of duplicates and final analysis excluded twenty-eight articles. Three articles were included in this review for appraisal.
Conclusion: The information regarding the effectiveness of podiatry services for people with diabetes was limited. There is an opportunity to transform the current podiatry practices in New Zealand to meet the aspirations of Māori to improve lower limb amputation rates.

P8.04

Improving Foot Care Services Across Auckland and Waitemata District Health Boards in Auckland, New Zealand

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Aim: To assess the foot screening and foot care services available for people with diabetes and recommend changes that could improve their experience and health outcomes.
Background: The review was undertaken in 2016/17, commissioned by the local diabetes service governance group following a 2014 diabetes service stocktake. Concerns were flagged regarding access to appropriately funded and resourced diabetic foot services and a lack of robust population information and outcomes measures.
Methods: The review encompassed services from foot screening through to inpatient care. A scan of the literature offered background and context whilst stakeholder feedback; an in-depth stocktake of current podiatry services; a review of diabetes-related foot care pathways; an appraisal of clinical governance of the diabetes related foot care; and review of local quality improvement strategies provided information for recommended changes. The New Zealand 'Quality standards for diabetes care' and the 'Diabetes foot screening and risk stratification tool' were used for benchmarking. Recommendations were reviewed against the three questions promoted by the Model for Improvement advocated by the Institute for Healthcare Improvement.
Findings: Foot screening in primary care was suboptimal with only

30-40% of the eligible population receiving an annual foot screen. Less than half (39%) of the estimated population with identified risk were referred to podiatry services and only 21% were receiving podiatry care. There was no mandatory training for foot screening, no accreditation of services, no prerequisite knowledge and skills for podiatry and minimal local data on the epidemiology of diabetes related foot disease.
Forty recommendations for change were made within seven areas of service delivery including: Foot screening; Clinical model; Access to services; Funding and contracting; IT and data; Governance and quality improvement; and Workforce. Additionally a new model of care was proposed to support the intensive management of the in-remission foot (I-RF).
Conclusions: The review reiterated the service stocktake concerns. Findings have resulted in dedicated clinical leadership to develop workforce competency and capability for foot screening and management of the high risk and I-RF. The clinical leader is also developing quality standards, knowledge and skills framework, service standards and clinical governance oversight for foot services.

P8.05

Internal Audits of Foot Care at Diabetic Foot Clinics in the Czech Republic

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Aim: was to better understand the scope of diabetic foot complications, evaluate whether current assessment and management strategies are in line with best practice guidelines, and to formulate future models of care.
Methods: An internal audit of foot care was carried out at foot clinics from different parts of the Czech Republic. Data were collected at baseline and 6 months on 30 consecutive patients with diabetic foot ulcers in each foot clinic between April and October 2018. A detailed chart review was undertaken to assess a number of characteristics and outcomes, including demographics, type and duration of diabetes, presence of infection, ischaemia and Charcot foot, usage of offloading, healing and amputation rates, revascularization and surgery rates, hospital admission.
Results: A total of 399 cases with 435 ulcers (age from 61.9 to 70.5 years in average per site; 60-93.3 % male; duration of diabetes 14.8-22 years) were assessed from 14 centres. Of these, 50.4% of patients had active infection (18.3 % with osteomyelitis), 8.4 % of patients had previous revascularization. 79.6% of patients used some of offloading device, but only 30.9 % of these used it more than 12 hours per day, 56.3% were treated with antibiotics and 30.1% were admitted to the hospital during follow up period. After 6 months, the healing rate was 51.1% (from 33% to 64 % in average per site), 19.9 % underwent revascularization (3-40%), major amputation rate was 2,7% (0-6.6%). In 13.5% (3-32%) of patients new ulcer was occurred during follow up period.
Conclusions: This audit of foot care showed large differences in characteristics and outcomes of treatment in patients with diabetic foot ulcers in individual foot clinic in the Czech Republic. These findings are important, and warrant further research on how to improve foot care in the Czech Republic.

P8.06

Are Diabetic Ankle Fractures Adequately Evaluated?

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Aim: To evaluate the standard of assessment of diabetic ankle fractures that undergo surgical management at an academic level 1 trauma center.
Methods: We reviewed 2,264 patients with surgically managed ankle fractures from 2009 to 2015 and identified 218 patients with diabetes mellitus (DM) at an academic level 1 trauma center.
Results: For ankle fractures in patients with DM evaluated dorsalis pedis and posterior tibial pulses, these factors were not documented in 7.8% and 20.6%, respectively. Capillary refill time was not documented in 27.1% of patients. For the assessment of neuropathy, light tactile sensation was performed 93.6% of patients. However, vibratory sensation was only performed 1.0% of the time and 5.07 Semmes Weinstein monofilament testing was performed in 4.0% of patients. For perioperative glycemic monitoring, glycated hemoglobin was available in 67.4% of patients preoperatively. Preoperative glucose was not evaluated in 28.0% of patients and postoperative glucose was not performed in 30.7% of patients.
Conclusions: Patients with DM undergoing ankle fracture fixation are at increased risk for infectious and noninfectious complications compared to patients without DM. The presence of peripheral neuropathy, peripheral arterial disease and poorly controlled blood glucose are risk factors that increase risk short-term complications of surgical site infection and wound dehiscence and long-term complications of nonunions/malunions. While there is no established evaluation standard for patients with DM that undergo ankle fracture surgery, recognition of comorbid manifestations of DM and glycemic control could identify patients that are at higher risk for postoperative complications and require modified treatment strategies.

Description of documented patient evaluation on presentation for ankle fracture

Table. Performed and missing evaluations for diabetic patients presenting with ankle fracture

Parameter	Normal N (%)	Abnormal N (%)	Not Reported N (%)
Peripheral circulation			
Dorsalis pedis pulse	185 (84.9)	16 (7.3)	17 (7.8)
Posterior tibialis pulse	157 (72.0)	16 (7.3)	45 (20.6)
Capillary refill	158 (72.5)	11 (5.1)	59 (27.1)
Neuropathy			
Light touch sensation	176 (80.7)	28 (12.9)	14 (6.4)
Vibratory sense (128 hz)	1 (0.5)	1 (0.5)	216 (99.0)
5.07 SWMFT	4 (1.8)	0 (0.0)	214 (98.2)
Laboratory tests*			
HbA_{1C} >7%	53 (24.3)	94 (43.1)	71 (32.6)
Glucose >180 mg/dL			
Random	106 (48.6)	86 (39.4)	26 (11.9)
Fasting	4 (1.8)	2 (0.9)	212 (97.2)
Pre-operative	98 (45.0)	59 (27.1)	61 (28.0)
Post-operative	88 (40.4)	63 (28.9)	67 (30.7)
WBC >10,000 cells/mcL	180 (59.6)	37 (17.0)	51 (23.4)
Serum creatinine >1.2 mg/dL	133 (61.0)	32 (14.7)	53 (24.3)
Pre-albumin <16 mg/dL	1 (0.5)	6 (2.8)	211 (96.8)
Serum albumin <3.5 g/dL	35 (16.1)	16 (7.3)	167 (76.6)

SWMFT = Semmes-Weinstein Monofilament Test, HbA_{1C} = Glycated Hemoglobin, WBC = White Blood Cell Count
*Specified values indicate cutoff values used to determine "normal" and "abnormal" values.

P9.01

Secondary Prevention in a High-Rrisk Population of Veterans with Diabetes –Findings from Patient and Provider Interviews

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Aim: Toe amputations are often performed because of limb-threatening infection yet may be naively viewed as an inconsequential procedure. Instead, a toe amputation is often the inciting event in a cascade of progressive loss of function and quality of life, involving subsequent amputation(s) and a high risk of death. This study aimed to understand patient and provider perspectives related to secondary prevention after a toe amputation and to identify potential opportunities to address patient, provider, and/or system-level shortcomings.
Methods: We conducted semi-structured telephone interviews with a national sample of United States Veterans Health Administration (VHA) patients with diabetes who had undergone a toe amputation in the prior year (n=32) and VHA clinicians who care for patients with toe amputations (n=21). Interviews were conducted in 2018 and recorded, transcribed, and analyzed using inductive content analysis.
Results: Patients reported delayed care-seeking for diabetes-related wounds that ultimately led to toe amputation. Patient-reported reasons for delayed care-seeking included not knowing what to look for, not understanding the seriousness of the wound, and having competing priorities (e.g., other health conditions and work demands). Barriers encountered by patients who sought foot care (e.g., with a primary care provider or urgent/emergency care) included: being told to 'watch and wait' and not being referred to podiatrists or other specialists. To prevent amputation through early detection and treatment, providers described regular contact with patients as essential and reported system-level barriers such as a lack of: clinic capacity to see patients as frequently as needed, time in appointments to communicate about and address complex health needs, and interdisciplinary collaboration.
Conclusions: Patients often lacked understanding of what to look for and when to seek care, suggesting a need for more explicit or frequent instructions and a way for patients to easily and directly contact a knowledgeable provider (in-person or remotely) to assess risk and formulate an appropriate treatment plan. Addressing system-level and patient-specific barriers will be critical to reducing major limb loss in this high-risk population.
Acknowledgements: This study was funded by the US Department of Veterans Affairs Health Services Research & Development (15-372).

P9.02

The Associations of Health Literacy with Diabetic Foot Outcomes – a Systematic Review and Meta-Analysis

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Aim: Health Literacy (HL) refers to the cognitive and social skills that determine the motivation and ability of individuals to access, understand and use health information(1). Studies examining links between HL and diabetic foot disease are few and the findings are inconsistent. This systematic review aimed to determine if HL is associated with the frequency and nature of adverse diabetic foot outcomes.
Methods: We searched PubMed, EMBASE, CINAHL, Web of Science, Scopus and Science Direct, using terms for HL and diabetic foot disease descriptors. Studies in English with valid and reliable measures of HL and diabetic foot disease were included. Two reviewers independently assessed articles for inclusion, performed data extraction, and assessment of methodological quality. Authors were contacted requesting additional data if there were no published measures of association. Where possible, results of studies were pooled using random effects modelling.
Results: Sixteen studies were included in the systematic review, with eleven in meta-analyses. Most studies (68.8%) were cross-sectional in nature. Pooling 2 studies of 1278 participants, for people with inadequate HL the odds of having diabetic foot disease was higher than in those with adequate HL, though this was not statistically significant (Odds ratio 1.99, 95% CI 0.83, 4.78). From pooling 2 studies with 399 participants, there was no statistically significant difference in HL levels between people with and without peripheral neuropathy (standardized mean difference of -0.14 (95% CI -0.47, 0.18). In pooling 7 studies of 1033 participants there was no association of HL with frequency of foot care (correlation coefficient 0.01, 95% CI -0.07, 0.10). Assessment of publication bias indicated no studies were missing.
Conclusions: There is insufficient data to rule out associations between HL and diabetic foot disease and its risk factors, but HL appears unlikely to have a role in foot care. Although the cross-sectional nature of studies included prohibits attribution of causation, future research needs to move beyond measures of functional HL to those that encompass social and cognitive dimensions of HL in order to explore the link between HL and more complex self-care actions.

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P9.03

The Southern Tasmanian Health Literacy and Foot Ulcer Development in Diabetes Mellitus Study (SHELLED study)

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Aim: Diabetic foot disease is the leading cause of non-traumatic amputations globally, but is largely preventable. Individuals with inadequate Health Literacy (HL) struggle to understand and conceptualise health information, which is detrimental to self-care. Poor HL is associated with poorer health outcomes, reduced preventative healthcare and increased adverse outcomes in diabetes but little is known about its effects on foot health and foot disease. The SHELLED study aimed to determine the associations between HL and diabetic foot disease in adults with diabetes.
Methods: SHELLED is a prospective study of foot ulceration risk factors with 2 of 4 years of planned follow-up completed. This is a cross-sectional analysis of baseline data. Participants were recruited from the Royal Hobart Hospital's Diabetes outpatient clinics between January 2015 and July 2016. Individuals under 40 with a history of foot ulceration, amputation, psychotic disorders or dementia were excluded. Participants underwent a foot risk factor assessment for peripheral neuropathy, peripheral arterial disease and foot deformity according to published guidelines. HL was measured using the short form Test of Functional Health Literacy in Adults (s-TOFHLA) and the Health Literacy Questionnaire (HLQ). Other covariates included demographic details, medical and smoking histories, diabetes and foot care self-efficacy, depression, diabetes distress, diabetes knowledge and foot care behaviour.
Results: 222 participants were assessed. 204 had adequate HL (Mean (SD) s-TOFHLA scores were 31.9 (6.7)). Higher s-TOFHLA scores were associated with lower overall risk for foot disease (OR 0.96, 95% CI 0.93, 0.99), loss of protective sensation (OR 0.95, 95% CI 0.91, 0.995) and peripheral arterial disease (OR 0.96, 95% CI 0.92, 1.003) in univariable analyses, however this did not persist after including covariates. There were no associations between HL and foot deformity.
Conclusions: This is the first study to objectively assess associations between HL and risk factors for foot disease. Our findings provide little support for there being clinically important impacts of health literacy on risk factors for diabetic foot disease. Longitudinal studies measuring incident diabetic foot disease is required to adequately judge the potential for health literacy interventions to reduce the incidence of diabetic foot disease.

P9.04

Re-Ulceration and Mortality in Patients with Diabetes and Healed Foot Ulcer After Participation in Foot Ulcer Preventive Education

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Background: Patients with diabetes mellitus and a healed foot ulcer often re-ulcerate after healing. Patient education and adjusted footwear has been recommended to reduce the risk of re-ulceration.
Aim: To explore the number of ulcer free days during 24 months in patients with diabetes and a healed foot ulcer below the ankle, who have participated in foot ulcer preventive education and been provided with adjusted foot wear.
Method: A cohort of 138 patients with a healed diabetic foot ulcer was randomized to either patient driven group education or standard information, and followed up during 24 months. Inclusion criteria: Diabetes mellitus, neuropathy, age 35–79 years, and healed index ulcer (Wagner grade 1 or more) below the ankle, with or without minor amputation. Exclusion criteria: Present ulcer on either foot below the ankle, co-morbidity or living conditions that inhibited participation and 24 months follow up, previous major amputation, reliance on an interpreter. NNT 174 was not met due to recruitment difficulties.
Result: 109 patients completed the study. Ulcer free days until the first re-ulceration: 368 (range 4-720) days (n=48, 40%), second re-ulceration: 404 days (range 206-631) (n=26, 22%) and third re-ulceration: 660 days (range 505-701) (n=9, 7,5%). n=44 patients (37%) remained ulcer free, 12 patients (9%) deceased and 17 patients (12%) dropped out during 24 months follow up after intervention. Reasons for ulceration were plantar stress ulcer, external trauma, fissures, pressure ulcers, burns and freezing. All ulcers were located at new sites on the feet. Prescribed adjusted shoe wear was used by the patients at 88% of the follow up visits.
Conclusion: This is the first study to follow up consecutive patients with diabetic foot ulcer after healing with a pre- defined protocol and inclusion exclusion criteria. Re-ulceration rate is high and so is co-morbidity and mortality. This patient group needs assisted self-care to a larger extent than previously described: tight surveillance in order to prevent from future re-ulceration and un-necessary suffering. Patient education should target patients in lower risk categories and future education efforts should target persons performing assisted self-care to high risk patients with diabetes and a healed foot ulcer.

P9.05

Structured Group Education Project as an Intervention Tool in Prevention of 1st Diabetic Foot Ulcer

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Aim: Prevention of 1st diabetic foot ulcer (DFU) development and its recurrence is of critical importance to reduce the burden. Current guidelines emphasise the need for early interventions applied to diabetic patients with feet at risk. There is a lack of data on 1st DFU prevention. Aim was to analyse retrospectively whether patients involved in structured group diabetes education programme developed 1st DFU during following years.
Methods: Since 2016, our diabetes education center has been participating in a national pilot structured group education project. Schedule included 4x2hrs of structured outpatient interactive education lessons realized in group of 5-12 Type 2 diabetics within the interval of 2 weeks. We included a group of 7 individuals in 2016 and group of 5 individuals in 2017, respectively (71.2±6.7yrs, 67% of men, diabetes duration 14.2±8.2yrs, 33% of smokers, no history of 1st DFU, all on basal insulin once-daily with oral antidiabetics). In both years, an education lesson on foot self-management care has been involved, performed by specialized podiatric nurse at our foot outpatient (other structured lessons included insulinotherapy with selfmonitoring, food&diet, exercise). In this pilot project, metabolic parameters were measured at baseline and within 6 months.
Results: 41.7% of individuals had a history of neuropathy and 50.0% history of peripheral arterial disease at baseline. All subjects attended the foot care education lesson. In retrospective analysis, 33 and 21 months after inclusion (for 2016 and 2017 groups, respectively) none of the patients developed a 1st DFU. One individual died of oncological disease, others are on regularly 3 months diabetology outpatient visits at our center. Concerning metabolic parameters at baseline and in 6 months, HbA1c declined from 76.8±17.7mmol/mol to 67.6±11.3 (p=0.137), fasting plasma glucose declined from 9.9±2.7mmol/l to 7.3±1.2 (p=0.003).
Conclusions: Self-management foot interventions enable early detection of pre-ulcerative signs. The results suggest that inclusion of structured outpatient education programmes involving foot care education, followed by regular patient visits, could be one of useful interventions in 1st DFU prevention. Project was supported by National Diabetes Society.

P10.01

Effect of a Topical Gel Based on Adelmidrol + Trans-Traumatic Acid in the Treatment of Diabetic Foot Ulcers

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Aim: Diabetic foot ulceration is a severe complication of diabetes that lacks effective treatment. Evidence reports that chronic inflammation in diabetes skin and defective inflammation resolution in diabetes wounds impairs the healing process. In particular chronic mast cells degranulation in diabetes wounds appear to significantly contribute to abnormal healing. Adelmidrol is a derivative of azelaic acid suitable for topical use which performs its action through an endogenous increase of Palmitoylethanolamide, a physiological mast cell modulator ensuring a local anti-inflammatory and anti-fibrotic effect; the trans traumatic acid promotes the natural keratinocyte convergence process. The aim of this study is to evaluate the effect of a medical device gel based on adelmidrol+trans traumatic acid, in re-epithelialization and cicatrization of diabetic foot ulcers.
Methods: 37 diabetic patients with foot ulcers of grade 1 A/B/C, 2 A/B according to the Texas Wound Classification System were treated with a gel based on adelmidrol+trans-traumatic acid applied daily for 4 weeks on the affected area, after careful cleansing of the wound. The following parameters were evaluated at baseline and weekly for each patient: a)wound area, obtained drawing a map on a polyurethane film grid, which was scanned and measured with Photoshop CS6; b)clinical appearance of the ulcer, assessed recording the presence/absence of dry/wet necrosis, infection, fibrin, neoepithelium, exudate, redness, granulation tissue.
Results: Topical treatment with adelmidrol+trans-traumatic acid led to a progressive healing of diabetic foot ulcers: the mean wound area moved from 77.5±14.9mm2 at baseline to 36.7±10.2mm2 at the end of treatment ($p<0.05$), corresponding to a reduction of 52.6%; clinical appearance of the ulcers showed a reduction in the percentage of dry/wet necrosis, infection, fibrin, exudate, redness paralleled to an increase in neoepithelium and granulation tissue from baseline to the end of treatment. No adverse events treatment-related were observed.
Conclusions: Results of this open-label study suggests the potential benefits of adelmidrol+trans traumatic acid topical administration to promote a good re epithelialization of diabetic foot ulcers.
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P10.02

Adequate Management of Oxidative Stress in Wound Environment Significantly Improve the Healing of Neuroischemic Postsurgical Diabetic Foot Ulcers

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Aim: The excess of free radicals induces the expression of inflammatory cytokines, matrix metalloproteases and cell senescence, importantly contributing to healing process arrest. In addition oxidative stress is behind several pathogenic events that characterize diabetes disease. It is produced do to a higher free radicals pro-

duction and a decrease in the physiological antioxidant defenses. Indeed, it has been observed that patients with diabetic foot ulcers (DFU) have even more level of oxidative stress. In this work we have treated five patients with neuroischemic postsurgical DFUS with a new antioxidant treatment, with the aim to eliminate the excess of free radicals in the wound environment, help to overcome faster the inflammatory phase and avoid chronification.
Methods: Wounds presented a size ranged from 10 to 33 cm2, with presence of soft non viable tissue in the wound bed and moderate exudate level. Three of them were positive to "probe to bone" test. Previous treatments included NWPT and classic moist wound healing, without positive results. Treatment* consist on a vegetal absorbent matrix, obtained from galactomannan from Carob Tree and a solution containing Curcumin and N-Acetylcisteine. These components together present a potent antioxidant activity. The matrix, previously hydrated with the solution, was applied directly to the wound bed, a barrier system was used to protect perilesional skin and hydrofiber foam with silicone border was used as secondary dressing, to help to manage the wound exudates. Wound size, exudates level, percentage of granulation tissue and inflammation signals were recorded every week for wound evolution assessment.
Results: Total healing was achieved in four cases, showing a very good evolution. One of the patients did not complete the treatment due to adverse events occurrence not related with the antioxidant dressing, showing a fast an rapid evolution until the withdrawal. An appropriate exudates management was achieved without maceration, rapid formation of granulation tissue and decrease of inflammatory signs (eritema). Wound closure was obtained ranged from 14 to 59 days.
Conclusions: Antioxidant treatment showed good debriding capacity, eliminated fibrinous and sloughy tissue, obtained a nice wound bed, avoided wound arrest and achieved a fast wound closure.

*Reoxcare

P10.03

Hyaluronan Based Dermal Substitute in Surgical Treatment of Diabetic Foot Infection With Bone Exposure: Conservative Reconstructive Surgical Approach

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Aim: to value safe and efficacy of Bioinductive Dermal Substitute made by 100% Hyaluronic Acid Benzil Esther in coverage of cancellous bone exposure after deep surgical deep debridement for severe diabetic foot infection (3 C-D TUC).
Method: from September 2006 to December 2009 we enrolled 129 pts with following characteristics: 1) DM type 1/11 type 2/118 2) mean age 65±12 yy 3) PVD 115/129 with TcPo2 < 30 4) CHD 93/128mmHg Infection sites were: a) Forefoot (ray amputation) 41 b) Midfoot 61 (Chopart amp. 25, TMA amp. 20, Transcuneiform amp 16) c) Heal Area 24 d) Achille region area 3 Bone exposure was present in 111/118 pts. Treatment protocol consisted of: 1)First Surgical look aggressive surgical debriment to remove infected and non vital tissue performing minor amputation reaching vital and bleeding tissue and cancellous bone. 2)Peripheral PTA 3) Daily dreassing 4) Empiric antibiotic Therapy (Piperacillin-Tazobactam + Daptomicin) followed antibiotic therapy cultural swab guided 4) Second Surgical Look (reconstructive surgery): meticulous debridement of soft tissue and bone , bionductive dermal substitute (with and without silicon) fixed on wound edges with clips and covered by grease gauze and secondary dressing. We considered as ulcer healing both second intention healing and skin graft. At Hospital discharge a visit was programmed at Out-patient Diabetic Foot Clinic for weekly dressing change. Patients were not allowed to load the foot.
Results / Discussion: Bone coverage was observed in 94/111 pts (84%) in 38±25 days. Ulcers healed on 81/129 pts (62%) as follow: a) Skin graft 24 pts in 19±16 days b) second closure in 57/129 (44%) in 227±122 days 3) 30 patients were nearly healed 4) Residual bon exposure in 3 pts 5) 10 reinfections were observed treated successfully with debridment and antibiotic therapy 5) 5 patient submitted to BTK amputation due to intractable soft tissue and bone infection.
Conclusion: our study demonstrated that Based Hyaff Dermal Substitute con be used in reconstructive surgery of severe deep infection of diabetic foot with bone exposure allowing rapid bone coverage and less demolitive surgical approach.

P10.04

Treatment of Diabetic Foot Ulcers with Dehydrated Human Amnio/Chorion Membrane (dHACM): Significant RTC Results

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Aim: The aim of this presentation is to present compelling evidence that dehydrated human amnion/chorion membrane (dHACM) can substantially impact the healing and closure of diabetic foot ulcers (DFUs) as an adjunct to best practice multicomponent DFU therapy.
Methods: Multiple randomized controlled trials involving dHACM as a treatment component in DFU care have all demonstrated statistically significant improvements in wound healing kinetics and complete closure in patients with chronic non-healing wounds.
Results: An early pilot RCT with a limited number of patients demonstrated over 92% healing of patients treated with dHACM versus control at six weeks, with both groups receiving major elements of standard of care including regular sharp debridement, a moist environment, and offloading. Confirmatory results were demonstrated in other controlled studies using weekly vs biweekly application, and against a leading industry competitor tissue substitute. Most recently, a large, multicenter study again demonstrated statistically significant healing rates in a group of over 100 patients, with 70% closure rates by 12 weeks.
Conclusions: Amniotic membrane has been documented as a viable therapy for the treatment of chronic wounds since the early

20th century. Problems with sourcing and preservation of this material have made regular use problematic. Recent developments in processing this material have resulted in the creation of an ambient temperature-stable material that can be easily applied in a number of venues. Now the most commonly used skin substitute in the United States, dHACM represents a noteworthy development in the contemporary treatment of DFUs.

*dHACM = EpiFix®, MiMedx Group Inc., Marietta, GA

P10.05

A Prospective, Multicenter, Randomized, Controlled Study Confirming Efficacy of Dehydrated Human Amnion/Chorion Membrane* Allograft in Management of Diabetic Foot Ulcers

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Aim: To confirm the efficacy of dehydrated human amnion/chorion membrane (dHACM) allograft for the treatment of chronic lower extremity ulcers in patients with diabetes.
Methods: A randomized, controlled, multicenter clinical trial was conducted at 14 centers in the United States. Patients with an ulcer of minimum 4 weeks duration were entered into a 2-week study run-in and treated with alginate wound dressings and offloading. Those with <25% wound closure after run-in were randomized to weekly dHACM application or standard care with alginate wound dressings, for 12 weeks. One-hundred-ten patients were included in the intent-to-treat analysis (n=54, dHACM group, n=56, no-dHACM group). Primary outcome was percent of study ulcers completely healed within 12 weeks.
Results: Participants receiving weekly dHACM were significantly more likely to experience complete wound healing than those not receiving dHACM (70% vs 50% at 12 weeks, p=0.0338). Rates of healing at 12 weeks for those completing the study per-protocol (n=98) were 81% and 55% for dHACM and no-dHACM groups respectively, (p=0.0093). Cox regression analysis showed subjects treated with dHACM were more than twice as likely to heal completely within 12 weeks than those not receiving dHACM (HR: 2.15, 95% confidence interval 1.30-3.57, p=0.003) and subjects having inadequate debridement were 64% less likely to heal within 12 weeks. At 16-week follow-up, 95% of dHACM healed ulcers and 86% of healed ulcers in the no-dHACM group remained closed.
Conclusion:
These results confirm that dHACM is an efficacious treatment for hard to heal lower extremity ulcers in a heterogeneous patient population.

*dHACM = EpiFix®, MiMedx Group Inc., Marietta, GA

References
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This study was sponsored by MiMedx Group, Inc. Dr. Tettelbach, Dr. Cazzell, Dr. Reyzelman, Dr. Sigal, Dr. Caporusso, and Dr. Agnew were among the clinical trial investigators and received research funding. None of the authors had a financial interest in any of the products mentioned. Although Dr. Tettelbach did not have any financial interest or conflicts of interest during the course of study, he discloses that he is now an employee of MiMedx Group, Inc.

P10.06

A Multicenter Prospective Randomized Controlled Comparative Parallel Study of Dehydrated Human Umbilical Cord Allograft* for Treatment of Diabetic Foot Ulcers

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Aim: To determine safety and effectiveness of dehydrated human umbilical cord (dHUC) allograft for treatment of chronic, non-healing diabetic foot ulcers (DFUs).
Methods: A multicenter, randomized, controlled trial was conducted at 11 centers in the United States. Individuals with diabetes and a 1-15 cm2 DFU below the ankle for at least 30 days were eligible for the 14-day run-in with weekly debridement, moist wound therapy and off-loading. Those with ≤30% wound area reduction were randomized to receive weekly application of allograft (n=101) or standardized therapy with alginate wound dressing (n=54). Primary outcome was percent of DFUs with complete closure within 12 weeks. Data were evaluated using intent-to-treat (ITT) analysis (n=155). Additional analysis was conducted on subjects completing the study per-protocol (PP), (n=134) (allograft, n=86, alginate, n=48), and for those receiving adequate debridement (allograft, n=67, alginate, n=40).
Results: ITT analysis showed that DFUs treated with allograft had higher healing rates, 71/101 (70%) within 12 weeks versus 26/54 (48%) healing with alginate dressings, p=0.0089. PP healing rates at 12 weeks were 70/86 (81%) for allograft-treated and 26/48 (54%) for alginate-treated DFUs, p=0.0013. For those DFUs with adequate debridement (n=107, ITT population), 64/67 (96%) of the allograft-treated ulcers healed completely within 12 weeks, compared with 26/40 (65%) of alginate-treated ulcers, p<0.0001. One-hundred-sixty adverse events were reported from 75 subjects. None were related to either allograft or alginate dressings.
Conclusion: These results demonstrate the importance of adequate wound debridement and the safety and efficacy of dHUC allograft as a treatment for non-healing DFUs.

*dHUC = EpiCord®, MiMedx Group Inc., Marietta, GA

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This study was sponsored by MiMedx Group, Inc. Dr. Tettelbach, Dr. Cazzell, Dr. Sigal, Dr. Caporusso, Dr. Agnew, Dr. Hanft, and Dr. Dove were among the clinical trial investigators and received research funding. None of the authors had a financial interest in any of the products mentioned. Although Dr. Tettelbach did not have any financial interest or conflicts of interest during the course of study, he discloses that he is now an employee of MiMedx Group, Inc.

P11.01

"Needle Tenotomy Treatment of the Hallux with Hammer, or Claw Toe Deformity of Patients with Diabetes, what is the Outcome."

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Aim: The aim of the study is to evaluate the effect of flexor tenotomies performed with needle on patients with diabetes, hammer or claw toe deformities of the hallux, and ulcer(s) associated with the deformities.
Methods: Over a 24-month period 11 patients underwent percutaneous needle flexor tenotomy of the hallux due to hammer or claw toe deformities with an associated ulcer. The tenotomy was performed with a needle with a diameter of 1.2 mm and length of 40mm. The needle was introduced through the skin proximal to the web level in the hallux, corresponding to the placement of the flexor hallucis longus tendon.
Results: The average follow up was 97.4 weeks. In the follow up period all surgical incisions healed uneventfully, 91% of treated ulcers healed (one lost to follow up), in a median time of 29.8 days, three (3/11 or 27.3%) of the treated ulcers recurred during the follow up period, there were no infections or amputations related to the procedure and four patients (36,4%) had transfer complications requiring additional tenotomies.
Conclusion: These data are taken from a larger cohort of patients (82 patients) undergoing needle flexor tenotomies due to ulcers associated with hammer, mallet or claw toe deformities of any toe(s). When comparing tenotomies of the first toe to the rest of the population, recurrence was 27.3% in the hallux group against 2.8% in the rest of the population (not statistically significant), and mean time to healing in days was 29.8 in the hallux group against 27.1 in the rest of the population (not statistically significant). In conclusion, treatment of ulcers associated with hammer or claw toe deformity of the first toe of diabetic patients with flexor tenotomy, showed a tendency to higher rates of ulcer recurrence compared to the other toes. We propose that tenotomies for hammer and claw toe of the hallux is a safe and simple procedure that can be offered to patients with an ulcer associated with hammer or claw toe deformities of the hallux. However, there is possible risk of recurrence of the ulcer compared to tenotomies of the lesser toes.

P11.02

"Is Transfer Complications in Association with Flexor Tenotomies of the Foot an Easy Fix?"

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Aim: The aim of this study was to evaluate the complication transfer in association with flexor tenotomies of the foot, and whether there is an "easy" solution.
Methods: Over a 24-month period 82 patients underwent percutaneous needle flexor tenotomy due to hammer, mallet or claw toe deformities with an associated or impending ulcer. 36 patients had an ulcer and the remaning 46 had an impending ulcer. The tenotomy was performed with a needle (diameter=1.2 mm, length= 40mm). The needle was introduced through the skin proximal to the web level in the toes chosen for tenotomy, corresponding to the placement of the flexor tendons.
Results: The mean follow up was 92.7 weeks. In the follow up period, 99.1% (one lost to follow up) surgical incisions healed uneventfully. Among the 36 patients with ulcers, 94.4% ulcers healed (one lost to follow up, one toe amputated), in a median time of 28.0 days, 5 (13.9%) of the treated ulcers recurred during the follow up period and there were no infections or amputations related to the procedure (the above mentioned amputation was eminent at time of tenotomy). Of the 82 treated patients 27(32.9%) had transfer complications requiring additional tenotomies. Out of the patients were tenotomies were performed on all toes of one or both feet none had transfer complications.
Conclusion: Transfer is a relatively common complication, in our study 32.9% had either transfer ulcers, or an impending ulcer resulting from transfer pressure. The patients that underwent tenotomy on all toes of a foot in the primary procedure had no increase in complications such as infections, amputations or bleeding, but avoided further procedures and transfer ulcers, which pose a risk of infection. Further research is needed an under way at our institute, but a possible fix to the transfer "problem" is to perform tenotomy on all toes of an affected foot in the primary procedure.

P11.03

Outpatient Percutaneous Needle Flexor Tenotomy In Diabetic Foot Patients For Healing And Prevention Of Ulcers In Claw Toe Deformity

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Background: Ulcers caused by claw toe deformity are a common problem in the diabetic foot patient leading to significant patient morbidity. Percutaneous needle flexor tenotomy is a safe and effective treatment that can be carried out in the outpatient setting.
Objectives: To evaluate the healing rates and patient satisfaction of percutaneous flexor tenotomy in the outpatient setting for diabetic foot patients.
Study design and methods: This was a prospective study. All consecutive patients who underwent a percutaneous needle flexor tenotomy in our diabetic foot clinic between February 2018 and June 2018 were included. All tenotomies were performed by a trained member of the diabetic foot team in the Diabetic multidisciplinary foot clinic using 19 Gram hypodermic needles and no local anaesthesia. The procedure was performed in all toes with ulceration and in toes at risk for ulceration All patients had peripheral neuropathy and multiple diabetic related co-morbidities and 1/18 had had leg artery stenting for ischaemia. There was a mean follow-up of 6 weeks. We analysed the results of the procedure based on patient satisfaction and ulcer healing rates. We used a scale of 1-10 for satisfaction with the procedure, as well as patient's satisfaction with the outcome.
Results: A total of 57 percutaneous needle tenotomies were performed. Of the 18 patients, 15/18 were type 2 diabetic and ratio of male:female was 14:4 with a mean age of 61.2years. The average score on rating the procedure was 10/10 and rating the outcome was 9/10. Healing rate was 100% within a time period of 40.5±27days.
Conclusions: Percutaneous needle flexor tenotomy is a highly effective, safe and minimally invasive procedure for the treatment and prevention of ulcers secondary to claw toe deformity in the diabetic foot population. In addition it can be performed safely in the outpatient setting in this patient group with excellent patient satisfaction and cost effectiveness.

P11.04

Novel Technique: Percutaneous Medial Fascial Band Release for Hallux Interphalangeal Joint Pressure Ulcerations

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Aim: Percutaneous procedures in the diabetic patient have become increasing popular as they limit major incisions that could lead to wound healing complications in high risk patients. Percutaneous flexor tenotomy and achilles tendon lengthening have been successful procedures to reduce plantar pressures. Kim et al in 2012 have the only known publication evaluating plantar fascia release for non-healing diabetic plantar ulcerations. Kim et al evaluated sixty patients and found all patients with preoperative dorsiflexion between 5° and 30° of the affected metatarsophalangeal joint and an increase of greater than 13° range of motion after the procedure experienced healing of the ulceration. However, the procedure in this study was open fascial release. The primary aim of this report is to describe a novel technique of percutaneous medial fascial band release for offloading the hallux interphalangeal joint (IPJ).
Methods: Diabetic patients with neuropathy and/or peripheral arterial disease with hallux IPJ wounds should be considered candidates for percutaneous medial fascial band release. No local anesthesia is required. The plantar foot should be prepped with betadine. Dorsiflex the hallux to provide tension to the plantar fascia. Palpate the plantar foot to ensure proper location of medial fascial band prior to release. With the hallux dorsiflexed, an 18-gauge needle is used to penetrate the skin and incise the fascia with a swiping motion; the physician will feel and hear the release of the medial band. There are two approaches: medial or plantar approach. Both approaches have been successful at our institution. The patient will be full weight bearing and complete a five day course of doxycycline.
Conclusions: A percutaneous medial fascial band release is a novel technique with many benefits and minimal risk. The procedure is easy to perform, does not require an incision, and can be done in-office. This provides high risk patients, especially with neuropathy or poor perfusion, with a minimally invasive approach to decreasing plantar hallux IPJ pressures for chronic wounds that are putting the patient at risk for amputation.

Kim JY. J Bone Joint Surg Am. 2012 Jul 18;94(14):1297-302

Percutaneous Medial Fascial Band Release: Pre Procedure, Performing Procedure, Post Procedure

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P11.05

Percutaneous Digital Flexor Tenotomy: an Effective Procedure for Treatment of Digital Wounds in Reducible Flexion Deformities

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Aim: A complication of diabetes mellitus is atrophy of intrinsic musculature and tendon contractures which lead to digital deformities of the lower extremity. The presence of these deformities in the diabetic neuropathic patient sustaining repetitive microtrauma caused by ambulation can lead to eventual soft tissue or osseous infection requiring surgical intervention or amputation. We describe a procedure that may be performed in the operating room or office setting to assist in healing distal digital wounds in reducible digital flexion deformities.
Methods: A retrospective review was conducted of 35 patients who underwent flexor digitorum longus (FDL) tenotomy procedures performed by multiple surgeons from a limb salvage team at a single institution. Inclusion criteria included presence of distal digital wound with a reducible digital flexion contracture. Exclu-

sion criteria included patients without postoperative follow up or absence of wound. All procedures were performed under aseptic technique. The digit was hyperextended as the FDL tendon was percutaneously released with an #15 blade or 18 gauge needle at the distal interphalangeal joint (DIPJ) via a plantar approach. If performed in office, the patient attempted plantarflexion of the digit while the surgeon simultaneously hyperextended the DIPJ when performing the tenotomy. Primary closure was optional, although performed in 24/35 patients.The procedure site was dressed with topical antimicrobial ointment and gauze dressing. Oral antibiotic was prescribed at the surgeon's discretion.
Results: Of 35 patients that underwent percutaneous FDL tenotomy, one patient was lost to follow up and six patients underwent the procedure without the presence of a wound. Out of 28 patients that met inclusion criteria, the incidence of healing was 89.3% (25/28). Incidence of recurrence of wound and proximal amputation were 0.04% (1/28) and 0.07% (2/28), respectively.
Conclusion: Distal digital wounds, a sequelae of the musculoskeletal deformities present in the diabetic limb, can lead to infection and amputation if left untreated. Due to the complex medical history of this patient population, percutaneous flexor tenotomy is a minimally invasive procedure that may provide successful outcomes in healing distal digital wounds in reducible flexion deformities that may be performed in an operating room or office setting.

P11.06

Inflammation of the Nailbed's Sulcus are Often Caused by Clawing of Toes and Curable by Interventions on Tendons

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Aim: Ulcers at the nail account for 12.1% of all diabetic foot ulcers, 5.5% are in the region of the sulcus of the 1st toe. Pressure exerted by shoes and errors in cutting the nail leading to an ingrowing part of the nail are considered to be the major driving forces behind the development of these ulcers. Recently, we have shown that clawing can be the cause of damage offering a possible cure by tendon interventions instead of partial nail resections. We analysed data and photos from the German DFS Register to determine the side of these sulcus lesions at the 1st toe and to establish the frequency of clawing of the first two toes to establish the possible role of tendon interventions.
Methods: Nailbed lesions at the sulcus of the 1st toe were divided into lateral and medial. At the lateral sulcus, clawing of the 2nd toe was considered as a possible cause if present. At the medial sulcus, there had to be some sign of clawing of the 1st toe such as hallux valgus interphalangeus, flexion of the distal phalanx, torsion or signs of pressure at the medial part of the tip near to the sulcus. Photos were considered possible to evaluate, if they showed at least the entire toes in consideration.
Results: 453 out of 558 photos were eligible. At the medial sulcus, 162 of 285 showed signs of clawing (56,8%), at the lateral sulcus 88 of 168 (52,4%).
Conclusions: Most diabetic foot episodes due to lesions of the sulcus of the first toe are associated with signs of pathogenetically connected clawing. They are often interpreted by default as ingrown toenails and cutting off part of the nail seems to be the natural treatment. In many cases, this is not necessarily the case, but clawing might have compressed the nailbed transversally, causing inflammation and a reduction of the space needed for the nail. Minimally invasive interventions such as a needle tenotomies could be a treatment option in many cases.

P12.01

Treatment Outcomes of Surgical Debridement and Antibiotic-Loaded Calcium Sulphate-Hydroxyapatite Bone Void Filling in Patients with Diabetic Foot Osteomyelitis

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Aim: Antibiotic-loaded calcium sulphate-hydroxyapatite (CaS-HA) biodegradable bone graft substitute has been registered for treatment of osteomyelitis, but has hardly been studied for its effectiveness in diabetic foot patients. In the clinic, surgical debridement and antibiotic-loaded CaS-HA bone void filling is sometimes performed in patients unresponsive to standard-of-care treatment as a last-resort alternative to amputation. We aimed to assess the outcomes of this treatment.
Methods: A multicentre, retrospective cohort study is currently ongoing regarding patients with diabetic foot osteomyelitis (DFO) who have been treated by surgical debridement and bone void filling with gentamicin-loaded CaS-HA since May 2017. Primary outcome is the rate of ulcer healing with resolution of DFO on imaging during a follow-up of at least 3 months. Secondary outcomes are duration until healing, duration of surgery, postoperative use of systemic antibiotics, functional outcome, complications and adverse events including recurrent ulcers with or without DFO.
Results: So far, 13 patients (10 male; mean age 61 years; 12 type 2 diabetes) with 13 plantar foot ulcers (University of Texas classification 2A (3), 3A (10)) underlying the midfoot (1), metatarsals (9) and hallux (3) have been included. DFO was confirmed by preoperative bone cultures (3) or imaging (Magnetic Resonance Imaging (5) or radiography (5)). Mean follow-up was 47 weeks (range: 13-89). Complete wound healing was observed in 12 patients (92,3%) (mean duration: 17 weeks, range: 2-31). Imaging showed resolution of DFO in7 patients (53,8%) (mean duration: 28 weeks, range: 8-67). Mean duration of surgery was 46 minutes (range: 20-76). Postoperatively, systemic antibiotics were continued in 4 of 13 patients (mean duration: 6 weeks, range: 1-18). At final follow-up, weight-bearing mobilisation with custom-made orthopaedic footwear was possible in 11 patients. No complications and 5 adverse events (recurrent ulcer without DFO (1), recurrent ulcer with DFO (1), new-onset ulcer without DFO (2), Charcot neuroarthropathy (2), and severe foot deformity (1)) occurred without amputations.
Conclusions: Surgical debridement and antibiotic-loaded CaS-HA

bone void filling can heal DFO. Diabetic foot care units should consider this treatment for patients who are unresponsive to standard-of-care treatment in order to reduce amputations in DFO patients.

P12.02

Percutaneous Bone Biopsies Carried Out Safely and Efficiently in the Out-Patient Diabetic Foot Clinic Significantly Helps Manage Diabetic Foot Osteomyelitis.

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Aim: International guidelines on the evaluation of diabetic foot osteomyelitis (DFO) recommend using bone biopsy for definitive diagnostic assessment and guiding antibiotic therapy. Percutaneous bone biopsy (PBB), is a simple technique; however, it is traditionally carried out under fluoroscopic or CT guidance, which requires access to specialist services. This has limited the uptake of the procedure. We report on our experience of undertaking PBB in the outpatient diabetes clinic using a dedicated protocol.
Methods: Patients with diabetic foot ulceration (DFU) with clinical and radiological features consistent with DFO were included in this review. After clinical examination, available imaging (plain radiography and MRI) was reviewed by the multidisciplinary team to plan the percutaneous access site location and biopsy angle. Using aseptic technique, a stab-incision was made through uninvolved skin and bone specimens were obtained using a Rocket Medical Trephine 7G x 100mm needle. Patients included in the analysis represented a mixed cohort of those referred with chronic DFO or newly suspected DFO and those completing a treatment regime for DFO. Antibiotic therapy was stopped for a minimum of 7 days pre-procedure except in those presenting with acute osteomyelitis.
Results: A total of 43 patients were included, median age was 57.2±10.7 years, CRP 36.6±49.8 mg/L and WBC 8.4±2.5 × 109/L. Duration of DFU was >1year in 35/43(81%). All PBB procedures (100%) successfully yielded a core sample. Pain was reported in 3/43(7%) and 2/43(5%) developed a localised soft-tissue infection post- procedure; no other complications were reported. Overall, 25/43(58%) had positive PBB microbiology. Of these, S aureus (64%) and Gram-negative organisms (30%), were the most common. Following on, 22/43(51%) had reconstructive surgery and 8/43(19%) had exosectomy - all of whom went to achieve DFU healing. 4/43(9%) healed with culture-guided antibiotic therapy and 8/43(19%) remain unhealed.
Conclusions: Percutaneous bone biopsy in the evaluation DFO can be safely, effectively and efficiently performed in the outpatient diabetic foot clinic using the dedicated protocol under strict sterile conditions. It requires minimal administrative planning and can be undertaken at short notice. Furthermore, dependency on specialised theatre, imaging equipment and personnel is removed.

P12.03

The Infected Diabetic Foot: Clinical Outcomes of Osteomyelitis and Soft Tissue Infection

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Aim: To evaluate risk factors, surgical procedures, outcomes and complications in patients with of diabetic foot soft tissue and bone infections.
Methods: Two hundred and ninety four patients were included in this retrospective cohort study of moderate and severe diabetic foot infections that required hospitalization. Diabetic foot osteomyelitis (DFO) was confirmed by bone culture or histopathology. Soft tissue infection was based on negative bone culture, MRI or WBC SPECT CT. Patient outcomes were recorded up to 1 year after admission.
Results: Clinical outcomes were worse in patients with DFO. DFO patients required surgery more often (99.4 vs. 50.6, p<0.001), had more surgeries (3.3 vs. 1.1, p<0.00001), and had more amputations (83.4% vs. 26.3%, 0.001) than STI patients. In addition, DFO patients had longer hospital stays (22.6 ± 19.0 vs. 14.8 ± 15.2, p<0.001), and required a longer course of IV and oral antibiotics (50.5±46.9 vs. 23.8±32.6 days, p<0.001).
During the one year follow up, patients with osteomyelitis had more re-infections and re-admissions to hospital than patients with soft tissue infections. DFO patients had longer times to heal (94.6 ± 151 vs. 58.9 ± 139.0 days, p<0.034), a higher rate of re-infection (56.7% vs. 40.0%, p=0.001) and a higher rate of foot related re-admissions (53.5% vs. 39.4%, p=0.008) than STI patients.
Conclusions: DFO patients had more aggressive treatments and more complications after discharge from hospital related to their index infection.

TABLE. Outcomes during initial hospitalization and during 1-year follow-up period in diabetic patients with STI or OM of the foot

	STI N = 137		OM N = 157			
Outcome[a]	**Value**	**(%)**	**Value**	**(%)**	**P-value[b]**	**Odds Ratio[b]**
Surgical intervention[c]	74	(50.6)	156	(99.4)	**<.001**	132.8 (18.1-976.2)
No. of surgeries	1.1	(1.4)	3.3	(2.3)	**<.001**	
Lower limb amputation	36	(26.3)	131	(83.4)	**<.001**	16.9 (9.7-29.7)
Foot	26	(19.0)	113	(72.0)	**<.001**	11.5 (6.91-20.67)
BKA & AKA	10	(7.3)	15	(23.6)	**<.001**	1.65 (0.73-3.70)
Revascularization	12	(8.8)	18	(11.5)	0.43	1.4 (0.6-2.9)
Healed within 1 year[d]	92	(67.2)	114	(72.6)	0.41	1.3 (0.80-2.1)
Days to healing	58.9	(139.0)	94.6	(151.7)	**0.03**	
Reinfection[d]	52	(40.0)	89	(56.7)	**0.001**	2.1 (1.3-3.4)
Readmission[d]	80	(58.4)	105	(66.9)	0.058	1.4 (0.9-2.1)
Related to initial diagnosis	54	(39.4)	84	(53.5)	**0.008**	1.8 (1.11-2.81)
Related hospital LOS, days	14.8	(15.2)	22.6	(19.0)	**<.001**	
Acute Kidney Injury[c]	65	(47.4)	76	(48.4)	0.87	0.9 (0.2-3.5)
1-year mortality	4	(2.9)	5	(3.2)	1.000	1.1 (0.7-1.7)
Duration of Antibiotics	10.2	(0.0-14.0)	16.3	(12.0-28.0)	**0.001**	

STI = Soft-Tissue Infection; OM = Osteomyelitis; LOS = Length of Stay
[a]Mean and standard deviation (SD) presented for continuous variables.
[b]Determined using appropriate statistical analyses–Mann-Whitney U-test for continuous variables. Chi-squared test of homogeneity and Fisher exact test for categorical variables. Significant values are bolded.
[c]During initial hospitalization for STI or OM.
[d]After initial discharge from hospital.

Outcomes of patients with foot soft-tissue infection and osteomyelitis

P12.04

Determining the Causative Agent and Optimal Duration of Antibiotic Therapy in Patients with Diabetes and Foot Osteomyelitis: BonE BiOPsy (BeBoP)-Trial

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Aim: The optimal strategy to determine the causative organism and the optimal empiric duration of antibiotic therapy in persons with diabetic foot osteomyelitis (DFO) are currently unknown. The primary objective of this study is to compare outcomes of subjects with DFO treated with antibiotics targeted on organisms from culture results of bone biopsy with outcomes of subjects treated with antibiotics aimed at organisms from deep wound soft tissue sampling. Secondary objectives are to attempt to determine an optimal empiric duration of antibiotic treatment of DFO and to compare different techniques of microbiological identification.
Methods: We will enrol eighty subjects with DFO in a double-blind randomized controlled trial. Subjects will undergo plain X-rays, MRI, deep wound tissue biopsy and percutaneous bone biopsy, before initiation of empiric antibiotic therapy. We will treat forty subjects with antimicrobial therapy based on culture results of the bone biopsy specimen, another forty based on culture results of a deep wound specimen. In an observational arm of the study, ten subjects in each treatment group will undergo a FDG-PET/CT and repeated bone biopsy for culture, 16S-sequencing and histology after 3 weeks, ten subjects in each group will undergo these procedures after 6 weeks. We will continue treatment if either FDG-PET/CT, bone culture results or bone histology are positive at follow up for a maximum of 6 weeks in all cases.
Results: The primary outcome measure will be remission of osteomyelitis at 12 months after diagnosis, i.e. clinical cure of infection without need for additional surgery or antibiotic therapy. Other outcomes will include: (time to) ulcer healing, ulcer or infection relapse, biomarkers of systemic inflammation, adverse events of antimicrobial treatment, survival, change in gut microbiota and quality of life at 6 and 12 months. The observational part of the study will focus on signs of inflammation on follow-up imaging and bone biopsy for culture, molecular microbiology, and histology.
Conclusions: We hypothesize that antimicrobial therapy of DFO based on bone biopsy culture results will lead to a higher rate of remission than therapy based on deep wound culture.
Funding: Dutch Diabetes Research Foundation.

P12.05

Bioactive Glass S53P4 : a New Treatment for Diabetic Foot Osteomyelitis

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Aim: Diabetes mellitus is one of the most worrying health problems in the world today and foot problems are the most serious and costly complications of the disease. Osteomyelitis represents a particularly challenging condition in the diabetic foot with an associated high risk of major amputation, requiring a multidisciplinary team approach in its treatment. Bioactive glass (1) is an antibacterial synthetic bone substitute used in orthopedic and cranio-maxillofacial surgery.
Methods: From 2016 to 2018, 44 diabetic patients affected by osteomyelitis of the foot (16 forefoot, 21 midfoot and 7 hindfoot), aged 68.0 ± 10.2 years, underwent surgical debridement and were followed up until October 31, 2018 (mean follow-up 15 ± 6 months). Of the 44 patients, 31.8% were female, 70.5% requiring insulin, 47.7% had renal insufficiency, 9% underwent hemodialysis, 88.6% had hypertension, 47.7% had a history of cardiac disease, 6.8% had a history of strokes. They were divided into two groups, each of 22 patients: group A was treated with surgical debridement and a local application of bioactive glass S53P4, group B was treated with surgical debridement only. Systemic antibiotics were also used in both groups. Revascularization was performed before surgical procedure in 70.5 % of patients.
Results: Resolution of osteomyelitis was significantly increased in group A treated with bioactive glass when compared to group B (90 % vs. 61.9 %, respectively p = 0.03). The odds of bioactive glass achieving osteomyelitis resolution were 5.54 times higher than for traditional treatment (OR 5.54, 95% CI 1.10-30.5). The use of bioactive glass was associated with 81% lower probability of needing antibiotic therapy compared to group B treated only with surgical debridement (OR 0.19, 95% CI 0.04-0.87).
Conclusions: Our results show that debridement of the osteomyelitis followed by application of bioactive glass can be considered a valid option and a new efficacious treatment for diabetic foot osteomyelitis.
Reference: 1) Bonalive Biomaterials Ltd ® (20750 Turku – Finland)

P12.06

Early Diagnosis of Osteomyelitis in Diabetic Toe Ulcers and Specific Antibiotic Therapy: Can be a Toe-Salvage Opportunity?

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Aim: The purpose of this study was to describe the diagnosis of osteomyelitis in Wagner grade I or II digital ulcers with evolution time at least 3 weeks in diabetic patients, with bone edema in MRI and bone biopsy puncture, comparing the empiric and specific antibiotic therapy, the healing time and the progression to amputation.
Material and method:
This is a retrospective study. Clinical records between January 2013 and December 2015 with a minimum follow–up of a year were analyzed.
Laboratory standards were evaluated preoperative and during antibiotic therapy. The surgical bone biopsy was performed by a foot and ankle surgeon experienced in Diabetic foot pathologies. Microbiological and histological studies were analyzed. Demographic data and previous empiric antibiotic therapy were recorded.
Results: Thirty patients were included: eleven with grade I ulcers and 19 with grade II. Twenty-two patients (73.3%) got bone biopsies with positive cultures and 14 (63,3%) had a positive pathological anatomy. Eight patients got negative cultures and pathology.
Six patients that did not receive empiric antibiotic and 19, who had received empiric antibiotics, had positive cultures.
Mean healing time for patients who did not have antibiotics was 4 weeks (3-12) and for the group who received empiric antibiotics was 6 weeks (4-10).
Four patients with Wagner II ulcers had the toe amputated. Three of them had received empiric antibiotic and 3 of them had positive cultures.
Conclusion: A diagnosis of the germ was obtained in 73.3% of the patients and specific antibiotic treatment was completed. Despite empiric antibiotic therapy, 19 out of 24 patients had positive bone cultures and healing time was longer.
Amputation index was 13%, all of them were grade II. There were no major amputations.
We consider that in these groups of ulcers MRI can show bone edema. Surgical bone biopsy should be done to begin specific antibiotic therapy and improve healing time.
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P13.01

Pilot Study to Explore Plantar Pressures in the Contralateral Foot when Using Removable Cast Walker and Total Contact Cast

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Aim: International guidance for active diabetic foot pathology recommends the use of a knee high non-removable device. In practice, removable cast walkers (RCW) and total contact casts (TCC) are frequently used. Previous studies suggest that such devices do not elevate contralateral foot pressures but clinical experience suggests that this can occur.
Methods: 10 healthy volunteers were assessed using the TekScan MatScan system (Boston, MA, USA). Participants were randomised to wear devices on the left or right foot and bare foot pressures were measured on the contralateral foot in static stance for 30 seconds. Each volunteer was asked in a random order for 3 measurements - barefoot (control), TCC and RCW (XLR8 Pneumatic Walker, Thuasne). The primary outcome was the change in contralateral foot peak plantar pressures (PPP) when wearing the devices compared to barefoot. Secondary outcome was change in PPP location.
Results: 10 Participants (7 female, 3 male), median age 39 years (range 24-77), were randomised to wear device; 5 left, 5 right feet. In both devices PPP decreased in 3 and increased in 7 feet. However median contralateral PPP increased in both offloading devices when compared to the control: RCW 32 kPa (-129 to +188), p=0.185*; TCC 98 kPa (-65 to +314), p= 0.037.
When wearing the RCW PPP location stayed the same for 9 participants, in 1 participant it moved from forefoot to heel. The TCC PPP location stayed the same for 7 participants, 2 moved from forefoot to heel and 1 from heel to forefoot.
Conclusion: This small volunteer study showed that, when wearing a RCW or TCC, the barefoot contralateral foot can be exposed to higher plantar pressures and even in this small sample this was statistically significant for the TCC. It is acknowledged that patients will spend some of their time barefoot (against advice) whilst using an offloading device. These results suggest that the foot is placed at additional risk due to increases in pressure. In practice clinicians should continually reinforce contralateral foot awareness and promote suitable footwear for this at risk foot.

*Wilcoxon signed-rank test (IBM SPSS Statistics)

P13.02

Effect of Different Casting Design Characteristics on Offloading the Diabetic Foot

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Aim: Diabetic foot ulcers are a major clinical problem. Non-removable knee-high devices, such as a total contact cast (TCC), are recommended for offloading diabetic plantar forefoot ulcers. However, it is insufficiently known how each of the different design characteristics of these devices contribute to offloading the diabetic foot. The aim of this study was to assess the offloading effect of the different design characteristics that make up a non-removable knee-high cast for people with diabetes and active or previous plantar forefoot ulcers.
Methods: Sixteen persons with diabetes, peripheral neuropathy and a healed or active plantar forefoot ulcer had their plantar pressures measured during walking in a non-removable knee-high device (TCC), in that device made removable (bivalved-TCC; BTCC), in that device made below-ankle (cast shoe), in that cast shoe worn with a different walking sole and in a newly made cast shoe without a custom-moulded foot-device interface. Peak pressures, force-time integral, and perceived walking comfort were assessed.
Results: Compared with the BTCC, peak pressures in the TCC were 47% (P = 0.028), 26% (P = 0.003) and 15% (P = 0.050) lower at the hallux, midfoot and (previous) ulcer location, respectively. Compared to the cast shoe, peak pressures in the BTCC were 39-43% and 47% (both P < 0.001) lower in the forefoot regions and (previous) ulcer location, respectively. The total force-time integral was 21% and 11% (P < 0.007) lower in the TCC and BTCC compared to the cast shoe. Perceived walking comfort was 5.6 in the TCC and 6.5 in the BTCC (P = 0.037). Effects of the other design characteristics (i.e. walking sole and plantar moulding) were non-significant.
Conclusions: The TCC gives superior offloading, mostly because of being a knee-high and non-removable device, providing an optimal 'shaft effect'. The TCC does, however, negatively affect walking comfort. These results aid decision-making in offloading diabetic plantar forefoot ulcers.

P13.04

Diabetic Patients with Charcot Foot: Total Contact Cast and Supervised Controlled Ankle Motion Reloading Enhances Early Quiescence

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Aim: To evaluate a treatment protocol of gradual supervised reloading of Charcot foot to enhance early quiescence.
Methods: This study was conducted between April 2012 and April 2017 in Jabir AbuEliz Diabetic Centre; Khartoum; Sudan. 98 diabetic patients with Charcot foot were included.
All patients had clinical examination and findings documented. The local skin temperature was measured using infrared thermometry. 128 Hz Vibrating tuning fork and 10g Semmes Weinstein monofilament were used to asses for peripheral neuropathy. Vascular assessment was done by clinical examination, hand held Doppler, and ABPI. Imaging included plain radiographs and magnetic Resonance imaging was used selectively. Charcot foot was classified according to a modified Sella and Barrett staging system including osteomyelitis (OST).
All patients had Total Contact Cast which was checked every 2 weeks. Casting was discontinued on the basis of clinical, radiological and dermal thermometric signs of quiescence. The patients were then mobilized and gradual reloading of the affected limb in a CAM walker was followed up.
Results: Male to female ratio is 1.8:1. The majority of patients had NIDDM 84 (85.7%). The duration of diabetes range between 11-20 years in 47.4%. The presentation was swelling in 88 of patients(89.8%) and pain in 47 (48%). The temperature deference between Charcot foot and normal limb was more than 2 degrees in 72 (75.8%) of patients.
Only 7 patients has a peripheral vascular disease. Peripheral neuropathy was documented in 65 patients (63.7%) and in 70 patients (68.6%) by 128 Hz and 10 g monofilament respectively.
Only 16 patients (15.7%) presented with stage 0 modified Sella and Barrett.There were 33 patients (32.3%) with stage 3 and 17 patients (17.9%) had osteomyelitis. The time duration of total contact casting ranged between 3-6 months in the majority of patients. 81 (79.4%) of the patients had quiescence of disease without complication. There were 13 patients (12.7%) who developed a new foot deformity during the course of treatment.
Conclusion: Supervised mobilization of patients after resolution of acute Charcot's foot by Controlled Ankle Motion (CAM) walker reduces the risk of disuse atrophy that occurs with long duration casting. This protocol enhances early quiescence.

P13.05

The Use of Total Contact Casting in Suspected Acute Charcot Foot

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Aim: To see whether early total contact casting (TCC) for suspected clinical diagnosis of Charcot foot defined as Eichenholtz stage zero is effective in preserving a plantigrade foot type .
Method: Patients presenting with clinical suspicion of acute Charcot foot such as erythema, oedema, and heat were diagnosed with acute Charcot at Eichenholtz stage zero. This diagnosis was made only in the absence of infection or ulceration. Weightbearing x rays were ordered to rule out further advanced disease. Patients were recruited from the joint orthopaedic diabetic foot clinic where the clinical diagnosis was made by a minimum of 2 members of the multidisciplinary team. Patients were treated with TCC of the foot until clinical signs and symptoms resolved. Casts were changed at weekly intervals.
Results: 7 patients were recruited with a strong suspicion of Charcot foot between 2016 and 2018. In all cases patients consented to TCC for the management of the condition. In all cases the foot

architecture was preserved. In all cases no subsequent ulceration has been noted in relation to Charcot and patients were satisfied with the outcome up to the time of manuscript preparation. No iatrogenic lesions were noted in this cohort. In addition no surgical procedures were performed in this group of patients.
Our results support those of Chanteleau (2005) who found that early use of TCC prevented further bony destruction of the foot. In the absence of a definitive test for the diagnosis of early acute charcot foot, any diagnosis and treatment plan is made on clinical parameters alone.
Conclusion: Early casting of suspected Charcot foot in this small cohort of patients has been successful in preserving a plantigrade foot and reducing surgical intervention.
Reference: Chantelau (2005)

P14.01

The foot-health and mortality of adult patients with diabetes in regional Australia: findings from an epidemiological study with two-year follow-up

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Aim: There is limited epidemiological research that reports on the foot-health of people with diabetes within Australian regional settings. The objective of this two-year cohort study was to explore the incidence of diabetes-related foot morbidity and mortality in people residing in regional Australia.
Methods: Adults with diabetes were recruited from predominately community-based, publicly-funded podiatric services in regional Australia. The primary variables of interest were the incidence of foot ulceration, major or minor limb amputation and death. Other variables of interest were UT Texas risk classification at baseline and subsequent visits, age, sex, rurality, socio-economic disadvantage, diabetes type and duration, knowledge of diabetes and smoking status.
Results: There were 444 patients (263 males and 181 females) who completed baseline assessments, with 212 (47.7%) having a UT Texas risk classification of 3 or above. There were 4,624 patient occasions of service in total. Mean age at baseline was 65 (SD 12.9, range 19-97). Sixty-one (13.7%) participants had type I diabetes and 383 (86.3%) had type II. Three hundred and fifty (78.8%) participants had at least one follow-up visit, with 285 (63.7%) participants still being followed-up at 12 months, 239 (53.8%) at 18 months and 182 (41.0%) at 24 months. Median number of follow-up visits was 4 (IQR 4, 13, range 1, 98). There were 165 (37.2%) participants who developed incident ulcers during the study period and 29 (6.5%) who underwent incident amputations. There were 56 deaths (12.6%).
Conclusions: Public podiatric services in regional Australia are managing patients at significant risk of serious diabetes-related foot morbidity and death. The two-year incidence of ulceration and amputation is high, and the proportion of patients who died after two years is a new and important finding in an Australian context. Patients presenting to these regional public podiatry services require multi-disciplinary health care in accordance with national and international guidelines. There is a disparity that needs to be addressed between current funding models for these services and the level of diabetes-related foot morbidity the services are managing.

P14.02

Trends in Lower Extremity Amputation in People with and Without Diabetes in Ireland 2005-2015

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Aim: The National Clinical Programme for Diabetes was introduced in 2010 in Ireland. To date, estimates for lower extremity amputations (LEAs) in people with and without diabetes were conducted prior to its introduction[1]. We aim to explore trends in the incidence rates of minor and major LEAs in people with and without diabetes from 2005 to 2015.
Methods: Data were extracted from the Hospital Inpatient Enquiry database, a source of national hospital discharge data. Incidence rates (IR) of both minor and major LEAs were calculated in adults with and without diabetes over the 11-year period. Poisson regression models, adjusted for age, were used to calculate incidence rate ratios (IRR) and estimate the population attributable fraction (PAF). Poisson regression was used to perform time trend analysis and likelihood ratio testing using Stata Version 15.
Results: The IR of minor and major LEAs in males and females with and without diabetes are shown in Table 1. Males with diabetes had an average decrease of 5% per year in incidence of major LEAs (IRR 0.95(0.93, 0.96),p<0.001) and females with diabetes a decrease of 6%(IRR 0.94(0.91, 0.97),p=0.001). In people without diabetes, males had an average decrease of 3%(IRR 0.97(0.95, 0.99),p<0.001) and females an average decrease of 6%(IRR 0.94(0.91, 0.96),p<0.001). Males with diabetes had 33.1(95% CI: 30.57, 35.88) times the risk of minor LEA and 9.6(95% CI:8.74, 10.47) times the risk of major LEA compared to males without diabetes. Females with diabetes had 11.2(95% CI: 10.17, 12.26) times the risk of minor LEA and 7.1(95% CI: 6.15, 8.12) times the risk of major LEA compared to females without diabetes. The PAF of major and minor LEA, for both males and females over the 11-year period, was 53.7%(95% CI 52.4, 54.9).
Conclusions: This study provides updated estimates of the incidence of LEAs in Ireland. Diabetes continues to confer a significantly increased risk of LEA. However, for the first time, a significant decrease of major LEAs in males and females with and without diabetes is seen. This may reflect improved patient and population interventions in this time period in Ireland.
References: 1.Buckley CM. PLoS One. 2012;7(7).

	Males without diabetes per 100,000 population (95% CI)	Males with diabetes per 100,000 population (95% CI)	Females without diabetes per 100,000 population (95% CI)	Females with diabetes per 100,000 population (95% CI)
Minor	8.59 (7.97, 9.21)**	300.76 (288.57, 312.96)**	5.9 (5.52, 6.28)**	65.88 (61.33, 70.43)**
Major	13.48 (12.58, 14.39)**	129.02 (120.86, 137.18)**	7.3 (6.68, 7.92)**	51.57 (45.84, 57.29)**

*adjusted for age
**p<0.001

Table 1. Incidence of minor and major LEA in males and females with and without diabetes 2005-2015*

P14.03

Diabetic Foot Diseases in Taiwan: Trends of Prevalence, Clinical Characteristics and Amputations from Year 2007 to 2014

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Aim: The Taiwan national health insurance has a coverage rate 99.9%. Use of national health insurance research database (NHIRD) will provide nationwide statistics for patients with diabetic foot diseases (DFD) and suggest policies in the prevention and treatment of such diseases (1).
Methods: We used diagnostic code 250 for diabetes mellitus according to the International Classification of Disease, 9th revision with Clinical Modification (ICD-9-CM) diagnosis codes. De-identified data of type 2 diabetic patients with severe form of peripheral artery disease (PAD plus admission), diabetic foot infection, or diabetic foot ulcers were retrieved for year 2007 to 2014 from the NHIRD. According the aforementioned criteria, more the 60% of selected patients with DFD need in-hospital treatment. Clinical characteristics of patients and their foot diseases as well as the lower-extremity amputations (LEA) were analyzed.
Results: Patients with DFD, though increasing in number, showed a decreasing trend in annual prevalence rate (2.07% to 1.98%, P < 0.0001). This is due to the increased prevalence of patients with type 2 diabetes (T2D) (from 4.9% to 6.8%). The mean age is 66.3 years with male gender predominant (55.8%). When compared with general T2D population, patients with DFD had higher rates of diabetic comorbidities, both in micro-vascular and macro-vascular complications. For example, the dialysis rate was 11.7% in patients with DFD vs. 1.3% in general T2D population. The annual LEA rate decreased from 13.8% to 10.4%. More significantly, the major- LEA rate decreased from 7.7% to 4.9%.
Conclusions: An estimated 2% of total type 2 diabetic patients had severe DFD annually. Nevertheless, the prevalence of DFD and LEAs rates decreased.
Reference: 1. YY Huang, KD Lin, YD Jiang, CH Chang, C-H Chung, LM Chuang, TY Tai, LT Ho, SJ Shin. Diabetes-related Kidney, Eye, and Foot disease in Taiwan: An Analysis of the Nationwide Data for 2000–2009. J Formos Med Assoc 2012; 111: 637-644.

P14.04

Diabetic Foot Syndrome: Longitudinal Amputation Figures from Austria

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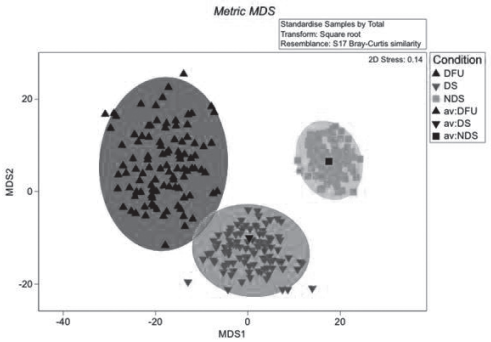
Introduction: Diabetic foot syndrome (DFS) represents a common but widely underestimated complication of diabetes mellitus. DFS requires multidisciplinary treatment in specialized healthcare centres and is associated with a high prevalence of amputations and increased mortality. Hence, treatment of DFS results in significantly increased healthcare expenses. However, longitudinal data on prevalence of DFS and amputations within Austria are lacking, but crucial for the planning of healthcare provision.
Methods: Data of the Main Association of Austrian Social Security Organizations on amputations from 2012 until 2016 in Austria were obtained and analysed. Data are presented descriptively.
Results: Overall amputations were performed in approximately 6 out of 10 000 Austrians per year, 38% of those with an amputation had diabetes mellitus. The number of amputations remains fairly stable over the years, however the distribution between subjects with and without diabetes was dependent on amputation site; forefoot amputations were performed mainly in subjects with diabetes (54-63%), while the percentage of diabetes diagnosis in in all other types of amputations was less than 50 percent.
Conclusion: Current ongoing analyses look into classification of diabetes, comorbidities and data relative to the number of subjects with diabetes mellitus. Since Austria has no nationwide diabetes registry, these data are important for the allocation of available resources to provide optimized multidisciplinary therapy in the future.



Non-metric multidimensional scaling (mMDS) plot of the NDS, DS and DFU samples using bootstrap-average analysis, showing the envelope of 100 bootstrapped samples (colored symbols) around their centroid (black symbols) for the three sample types.

P14.06

SwedeAmp – the Swedish National Quality Registry Including Data from Lower Limb Amputation to Prosthetic Supply and Follow-Up

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The Swedish Amputation and Prosthetics Registry for the lower extremity (SwedeAmp) was founded in 2011 with the intention to provide equal and best possible care for patients suffering limb loss of the lower extremity.
This paper describes SwedeAmp and presents outcome data from the first seven years of registration.
SwedeAmp includes patient-based data regarding amputation, prosthetic supply, and patient reported outcome measures (PROM) at baseline and at follow-up 6, 12, and 24 months after amputation. All data is registered on-line demanding a personal log-in. Data registration includes all levels of lower extremity amputations, from partial toe amputation to hemipelvectomy.
Until December 31th 2017, 4827 patients, 6668 amputations, 2208 prosthetic supplies, 1585 baseline and 1660 follow-up registrations have been registered.
39% of the patients were female. Mean age of all patients by the time of first registered amputation was 73 years (SD +/-16), women were older than men, and 40% were 80 years or older by the time of the primary procedure. The mortality rate was 21% within the first 6 months and 27% within the first year after the last registered amputation.
In 84% of the cases, underlying diagnosis leading to amputation was diabetes with or without vascular disease, and the majority of all patients had comorbidities such as heart disease, lung disease, neurological disease, stroke, dementia and others.
In 79% prosthetic supplies were applied for patients with transtibial amputation (TTA). The most common TTA prosthetic type had a silicone liner with vacuum suspension combined with an energy storing foot.
Time from surgery to fitting of first individual TTA prosthesis was in median 68 days (range 6 – 492) and 98 days (19 – 484) for patients with transfemoral amputation (TFA).
SwedeAmp records the complete process for patients with lower limb amputation in Sweden and includes baseline, amputation, prosthetic supply and follow-up data. The presented data are descriptive as the registry has not yet gained complete coverage over the whole country. SwedeAmp has a high future potential to identify factors leading to national guidelines for choice of amputation level, surgical technique, rehabilitation, and prosthetic devices.

P15.01

Continuous Temperature Monitoring Socks for Home Use in Patients with Diabetes

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Aim: Diabetic foot ulcers (DFU) are a serious diabetic complication that may lead to infection and amputation. Skin temperature assessment has been shown to reduce the risk of DFUs. We introduce sensor-embedded socks designed for daily wear, which perform continuous temperature monitoring of the feet of persons with diabetes. Combined with a mobile app this device informs the wearer about temperature increases to facilitate early detection of DFUs and timely intervention. The aim of the study was to evaluate the accuracy of the socks, obtain user feedback on how comfortable socks were, and examine whether observed temperatures correlated with clinical observations.
Methods: Temperature accuracy of the sensors was assessed prior to incorporation in the socks as well as in the completed sock design. A total of 35 patients with diabetic peripheral neuropathy (DPN), 18 years and older, were enrolled in a single-site study. Patients were enrolled into 3 groups based on patient-reported medical history. Group 1: subjects with no previous history of ulcers, Group 2: subjects with a previous history of ulcers, Group 3: subjects with a current pre-ulcer as determined by the investigator. The patients were instructed to wear the socks continuously for 6 hours after which the socks could be removed.
Results: The temperatures measured by the sensors were within 0.2°C of the reference standard. Patients reported that the socks were easy to use, ranking them at a median score of 9 or 10 for comfort and ease of use on a 10-point scale. We found that temperature differences observed between the feet were consistent with clinical observations.
Conclusions: We report the first use of wireless continuous temperature monitoring for daily wear and home use in patients with DPN. The wearers found the socks to be no different from standard socks. The temperature studies conducted show that the sensors used in the socks are reliable and accurate at detecting temperature, and the findings matched clinical observations. Continuous temperature monitoring is a promising approach as an early warning system for foot ulcers, Charcot foot, and re-ulceration.

This study was funded by Siren Care Inc.

P15.02

Is a Left-Right 2.2oC Difference a Valid Diagnostic to Predict Diabetic Foot Ulceration in People with Diabetic Foot Ulcer History?

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Aim: Current evidence supports using temperature monitoring to prevent diabetic foot ulceration. However, the construct validity of the measurement is yet to be established in patients with previous foot ulceration. The study aim was to investigate the construct validity of the 2.2oC contralateral temperature difference cut-off in ulcer prediction.
Method: 30 patients at high-risk of ulceration measured contralateral plantar foot skin temperatures four times a day for one week, wore a Stepwatch and kept daily activity and environmental temperature diaries. Diagnostic accuracy of the 2.2oC cut-off was calculated, and its association with activity, time of day and environmental temperature was investigated.
Results: The mean contralateral temperature difference was 0.78oC(range 0.39-1.55) at baseline, the warmer foot was consistently warmer during the week; in 29 participants the warmer foot had previously ulcerated. A left-to-right temperature difference >2.2oC was found 365 times (9.6% of measurements). Optimisation (validating increase the following day) and invididualisation (correcting for baseline temperature difference) improved to 17 times (0.4%) in 12 participants.
No ulcers developed during the study, two participants reulcerated in the month following the study (at 7 and 24 days). Skin temperature difference was not related with walking activity(r=0.0442,p=<0.001), while moderate correlation was found between absolute foot skin temperature and walking activity(r=0.534,p=<0.001). Different results were found between skin temperature differences in the group without amputation vs. the amputation group(r=0.434,p=<0.001 vs.r=0.492,p=<0.001) and absolute temperatures in the group without amputation(r=0.524,p=<0.001)vs. amputation group(r=0.563,p=<0.001).The 2.20C difference was not associated time of day(r=0.022,p =0732) and environmental temperature(r=0.015,p=0.885).
Conclusion: Singularly increased contralateral temperature differences >2.2oC occur without complications and should not be used to instigate treatment. Average foot temperatures differ between the formerly ulcerated and the contralateral foot. A 2.2oC difference should therefore be individualised based on this difference. To be used diagnostically, it must be validated the next day before any preventative action is taken. Foot temperature patterns may differ for patients +/- minor amputations; however, the results must be taken with caution due to the small sample sizes. Our findings suggest that further research is required to fully understand foot temperature patterns, before being used in daily practice to prevent foot ulcers.

P15.03

A Novel Approach for Remote Temperature Monitoring using a Single Foot

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Aim: Remote temperature monitoring (RTM) is an evidenced-based component of standard preventive diabetic foot care for high-risk patients. Home temperature can reduce incident foot ulcers 3-4 fold. Unfortunately, the most commonly-practiced approach relies on comparison of contralateral foot temperatures, thus limiting its practice in patients with history of high-level amputation and patients with wounds being treated with dressings, casts, or other footwear which should not be removed. We therefore aim to present and validate an approach for RTM that relies on temperatures from only one foot.
Methods: We addressed our aim through secondary analysis of existing data from a prospective, multicenter study in 129 participants for 34 week evaluation period. All participants had history of diabetic foot ulcer (DFU) They received standard prevention care in addition to RTM. with an in-home, daily-use, telemedicine mat. The primary outcome of interest was DFU recurrence. We considered the outcomes and thermometric data for each foot independently. Our predictive model compares temperatures among the four plantar angiosomes of the foot and between the foot and ambient. We evaluated our model's accuracy over two month intervals of participant data commensurate with a hypothesized duration between office visits for a high-risk patient.
Results: 53 DFU occurred in 37 participants. We present the accuracy of the model at three settings which we believe will be useful in clinical practice. At the most sensitive setting, the model correctly identified 91% of non-acute plantar DFU, with an average lead time of 44 days and a false-positive rate of 55%. Extrapolating over a year, we would expect 3.9 alerts/patient-year. At the second setting, the sensitivity is reduced to 80% but the false positive rate improves to 44% with 3.2 alerts/patient-year. The lead time was 36 days. At the most specific setting, the sensitivity is 53% with a corresponding specificity of 82% and lead time of 31 days.
Conclusions: Given our encouraging findings, practice of daily remote temperature monitoring using this approach may significantly reduce morbidity, mortality, and resource utilization in extremely high-risk patient populations in which practice of RTM was previously limited.

P15.05

The Application of Infrared Thermography in the Detection of Diabetic Foot Complications

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Aim: The aim of this study was to evaluate the potential of thermography as an assessment tool for the detection of foot complications by understanding the variations in temperature that occur in type 2 diabetes mellitus (T2DM).
Methods Following a detailed medical examination, participants were categorized into five groups: healthy adults, T2DM with no complications, T2DM with peripheral neuropathy, T2DM with neuroischaemia and T2DM with peripheral arterial disease (PAD) group. Thermographic imaging of the toes and forefeet was performed.
Results: 43 neuroischaemic feet, 41 neuropathic feet, 58 PAD feet, 21 DM feet without complications and 126 healthy feet were analyzed. The temperatures of the feet and toes were significantly higher in the complications group when compared to the healthy adult and DM healthy. The higher the temperature of the foot in DM, the higher the probability that it is affected by neuropathy, neuroischaemia or PAD.
Conclusions: Significant differences in mean temperatures exist between participants who were healthy and those with DM with no known complications when compared to participants with neuroischaemia, neuropathy or PAD. As foot temperature rises, so does the probability of the presence of complications of neuropathy, neuroischaemia or peripheral arterial disease.

P15.06

The Infrared Thermography and Vascular Disorders in a Diabetic Foot

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Objectives: Diabetes (DM) and specially its foot problems are a growing burden on the health care system. Peripheral arterial disease (PAD) and neuropathy are strongly related to the risk of major amputation. The presence of symmetrical distal sensory neuropathy may mask symptoms of intermittent claudication and ischemic rest pain. The ankle brachial index (ABI) is considered the gold standard of non-invasive screening in vascular disorders, but have limitations. In this study, we evaluated a novel non-invasive diagnostic method, infrared thermography (IRT), for its clinical diagnostic potential compared to conventional non-invasive measurements in PAD.
Methods: Patients were divided into 2 groups: the healthy control group and the DM group. Controls had ABI above 0.9 and no former DM or PAD diagnoses. Diabetics were divided into 3 subgroups, based on the ABI classifications, or 2 subgroups, based on the toe pressure (TP) measurements. IRT was performed with a standardized protocol. Temperature was measured in 5 areas on the plantar and dorsal sides of the foot.
Results: In generally, the diabetic's ischemic foot seems to be warmer than healthy controls. The patients who had neuroischemic feet, the mean temperature was the highest, and was the lowest on the angiopathy feet comparing to the healthy controls, or comparing to the noncomplicated diabetics without angiopathy or neuropathy. Side-to-side comparisons of temperatures showed significant differences between feet (p<.001) at all measurement sites. Unlike ABI groups, when TP was clearly abnormal (<50 mmHg), the mean temperatures were higher than with presumably more normal TP (≥50 mmHg) at all measurement sites and were statistically significant (p<.001). IRT was also capable to find differences between angiosome areas, locate subclinical infections and plantar high pressure areas.
Conclusions: The IRT provided an effective means of detecting local temperature differences. In the high risk diabetic feet with neuropathy and neuroischemia IRT showed, that the coloration was mottled and the temperature was the highest; thus, that might be a useful in clinical screening. However, normal skin surface temperature varies between individuals. Thus, we would not recommend using IRT alone for evaluating vascular disorders in diabetic feet.

infrared thermography, ABI, toe pressure

P16.01

Refocusing DFOCUS: An Update to the Diabetic Foot Online Clinic Utilization Score (DFOCUS) to Help Predict Clinic Volume

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Aim: The goal of this poster presentation is to demonstrate a useful tool for clinicians and administrative personnel to predict the clinical volume of diabetic patients to help allocate resources appropriately.
Methods: The Diabetic Foot Online Clinical Utilization Score (DFOCUS) was reviewed and updated with current epidemiological data. The online open calculator was developed based on the prevalence of diabetic patients and diabetic foot ulcer. The risk stratification score was also included to further calculate the number of diabetic patients based on the risk of developing a diabetic foot ulcer. Re-ulceration was also estimated in the calculator for patients in remission.
Results: DFOCUS v. 1 was launched in 2014. Since that time, it has received some 27,500 page visits and related queries from more than 130 nations. In October of 2018 the online open calculator was successfully launched with updated epidemiological data data from the International Working Group on the Diabetic Foot and related sources.
Conclusions: The Diabetic Foot Online Clinical Utilization Score (DFOCUS) is an online open calculator to help clinicians and administrative personnel identify and allocate resources for high risk patients with diabetes. The launch of DFOCUS v.2 suggests that further modifications and updates may be done instantly as new epidemiological data becomes available. Additionally, we intend to apply new regional cost estimates based on emerging data.

P16.02

Management Model for the Care of People with Diabetes Mellitus for the Prevention of Ulcerations in the Lower Limbs

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Introduction: the risk of amputations due to diabetes mellitus has been on the rise as a result of delayed diagnosis, poor blood glucose control, in addition to other environmental factors. The evaluation of risk factors such as neuropathy and peripheral vascular disease, deformities and ulcerations, has posed a challenge to health professionals. Objetive: to develop and validate a management model for the care of people with diabetes for the prevention of ulcerations in the lower limbs, based on the five pillars of the International Consensus on the Diabetic Foot. Method: this is a study with a methodological approach, based on the Iowa evidence-based practise method to promote qualified care, and has been developed in stages: situational diagnosis, pilot project implementation, protocol development and validation by competent experts in the field of diabetes and diabetic foot. The validation process was carried out applying the Delphis technique.
Results: the management model was developed and distributed in the form of five pillars approaching the main recommendations for handling the feet of diabetic patients, including foot examination, ulceration risk classification, diabetes education for patients and healthcare professionals, appropriate footware and treatment of pre-ulceration signs. Eleven renowned specialists took part in the validation process, who attested the management model in three stages with an individual and global content index above 0.78 e 0.90, respectively. The model has been summarized and diagrammed into a pocket guide format as information technology in health. Conclusion: this study allowed for the creation and validation of an evidence-based care management model for diabetic patients' feet, based also on the best available scientific recommendations. Special mention must be given to the recommendations for the application of pillar five, where recommendations are still scarce.

P16.03

Care Path of Patients with a Diabetic Foot Ulcer Influence Ulcer Healing: a French Multicenter Observational Study

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Aim: National and international recommendations regarding diabetic foot ulcers care are clear: patients should be addressed to a multidisciplinary foot center within 24 to 48 hours after wound occurrence. The aim of this study was to describe the care path of patients with a diabetic foot ulcer before arriving in foot centers, and study factors, influencing pathways dysfunction and ulcer outcome.
Methods: This is a multicenter, observational study including 21 french foot center. Each center included ten successive patients attending for a new foot ulcer between May and July 2015. The only exclusion criteria was "French not spoken". Patient pathway was accessed by a pre-defined questionnary. Informations regarding ulcer outcome were collected after two years. Analysis was performed by Student test, chi2 and linear regression.
Results: 207 patients were included: 133 men, 74 women, mean age 68 years; 89% had type 2 diabetes; 38% had a history of previous ulcer, 31% had peripheral arterial disease (PAD). 26% had a prescription of an offloading device before referring to the foot center. Concerning wounds 83 (40%) were infected and 94 (45%) reached joint, tendon or bone. Time between ulcer occurrence and the first GP contact was 12 (+/- 2) days, median 5 days. Patients were addressed to a foot center after an average of 83 days (+ / -15), median 26 days. Only 3% of the patient attended a foot center within 72h. 12% consulted spontaneously the foot center. Patients suffering from PAD were addressed significantly later to a foot center, this result persisted in multivariate analysis. In our study, having a non-healed ulcer 3 months after assessing a foot center was significantly dependent on ulcer infection during follow up (OR 3.93 (1,32-13,59), p= 0.0192) and initial time to attend the foot center (OR 2.92 (1,06-8,33), p=0.0406).
Conclusion: The mean delay before referring patients with a diabetic foot ulcer to a foot center in France is major and influence ulcer outcome. The prescription of an offloading device by GP is rare. Information on foot centers location and diffusion of international guidelines on diabetic foot care is urgently needed.

P16.04

Guidelines on Diabetic Foot Screening: an Evaluation of the Recommendations

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Aim: To critically evaluate the current guidelines for foot screening in patients with diabetes with a view to examine their completeness in terms of advancement in clinical practice, improvements in technology and changes in socio-cultural structure.
Method: A through search of literature was conducted within all standard scientific and clinical databases namely; Pubmed/Medline, SCOPUS, CINAHL, Google Scholar and Cochrane Register of Controlled Trials between January 2011 and January 2015 using the keywords '(Diabetes) AND (Foot Screening) AND (Guidelines)'.
Results: Ten complete diabetes foot screening guidelines were identified and selected for analysis. Six of them included the full-process guidelines recommended by the International Diabetes Federation. Evaluation of the existing diabetes foot screening

guidelines showed substantial variability in terms of different evidence-based methods and grading systems to achieve targets, making it difficult to compare the guidelines. In some of the guidelines, it is unclear how the authors have derived the recommendations, making it difficult for the users to understand them. We recommend that detailed information regarding the sources of the evidence used in each guideline should be clearly reported. This will enable new guideline developers to refer to the work performed and published by others as 'source' guidelines, and to optimize and standardize diabetes foot screening guidelines in their country. Furthermore, evidence needs to be reviewed on a regular basis as new research emerges. Limitations of currently available guidelines and lack of evidence, on which, the guidelines are based may be responsible for the current gaps between guidelines, standard clinical practice, and development of complications. Future research in diabetes foot screening should be oriented to the needs of physicians and patients to improve healthcare and should also focus on socio-cultural issues.
Conclusion: A paradigm shift on how to screen for risk factors in the high-risk population using high-quality evidence is urgently needed should the risks of foot ulceration and its devastating consequences be reduced. Large-scale, randomized trials are needed to demonstrate the benefit of various foot screening recommendations and improve outcomes.

P16.05

Toe, Flow, and Go: a Novel Program for Diabetic Limb Preservation

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Aim: The purpose of this manuscript is to describe and outline the components necessary in creating a successful interdisciplinary limb preservation program.
Methods: The four building blocks: Hot Foot Line, Wound Healing Clinic, Remission Clinic and Screening Clinic were described. These building blocks for a limb preservation program were designed based on population size and patient acuity. Specific quality measures for each clinic were also discussed in detailed to improve overall outcome of the program as well as the patients.
Results: The outcomes of each building block were measured by different outcome measures. For the 'hot foot line', in-hospital and regional amputation rate for both major and minor amputations can be monitored as well as inpatient length of stay. The wound-healing clinic can be monitored for high:low amputation ratio, time to healing, number of curative procedures, and hospitalization rates. Remission clinic data included ulcer-free days, functional activity level, or frailty level. Screening clinics can be used to gather prospective data on long-term outcomes following initial risk assessment.
Conclusions: The "Toe, Flow & Go" model that the authors proposed leverages specialists in Podiatric Surgery (Toe), Vascular Surgery (Flow) and Physical Therapy (Go) to create a successful limb preservation program. This interdisciplinary team combined with the program components outlined above helps our patients with diabetes and peripheral artery disease move through their world better.

P16.06

Decision Trees to Facilitate Risk Stratification of the Diabetic Foot

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Aim: Delays in referrals from primary care to specialist care clinics are a common issue in the clinical management of diabetic foot disease and are associated with worse clinical outcomes in terms of ulcer healing and major amputations (1-3). One reasons for the delays may be the complexity of risk stratification; a number of different risk factors, such as foot deformity, neuropathy and peripheral arterial disease, interact and influence the risk of developing diabetic foot complications. The aim was to illustrate how decision trees can be constructed to facilitate risk stratification.
Methods: A decision tree (4) was created based on the risk stratification described in the guideline document by the National Institute for Health and Care Excellence (NICE) (5).
Results: With the help of the decision tree in Figure 1, clinicians without specialised knowledge in diabetic foot disease can stratify all diabetic feet with only four decision points or less. This could facilitate accurate risk stratification and timely referral of patients.
Conclusions: Even complex risk stratifications as the one described by NICE can be transformed into simple decision trees for use in busy clinics. Future studies should investigate whether the use of decision trees lead to more accurate risk stratifications and referrals, improving the outcomes for people with diabetic foot disease.
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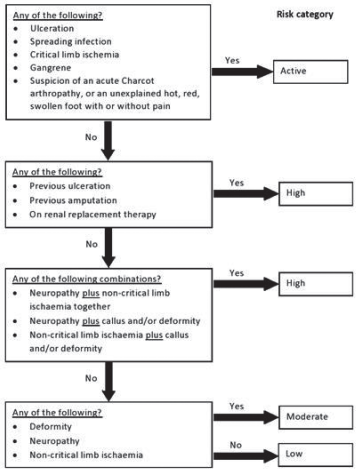
5. National Institute for Health and Care Excellence (NICE). https://www.nice.org.uk/guidance/ng19.

Figure 1. Decision tree for risk stratification according to NICE.



P17.01

Anti-Staphylococcus Aureus mAb Combination, MEDI6389, Accelerates Wound Healing in a Polymicrobial Dermonecrosis Model in Diabetic Mice

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Aim: Diabetic foot infections are often polymicrobial, and the presence of Staphylococcus aureus (SA) has been associated with delayed healing and worse clinical outcome. We developed a polymicrobial skin infection model in diabetic mice to test the hypothesis that targeting SA alone with monoclonal antibodies (mAbs) will accelerate wound healing.
Methods: Type 2 diabetic (db/db-/-) or non-diabetic (db/db-/+) mice were passively immunized with control IgG (c-IgG) or MEDI6389, a 3 mAb combination targeting alpha toxin, 4 secreted leukotoxins, and the cell surface adhesin clumping factor A (ClfA). By binding and neutralizing multiple virulence factors, MEDI6389 effectively blocks bacterial agglutination and SA-mediated cell killing, abrogates SA-mediated immune evasion and targets the bacteria for opsonophagocytic killing. Twenty-four hours following passive immunization the mice were intra-dermally infected with SA (5e7CFU), Pseudomonas aeruginosa (PA) (1e5CFU) and Streptococcus pyogenes (SP) (10CFU) and bacterial burden, pro-inflammatory mediators, lesion size and wound healing were monitored for 40 days.
Results: Infection of diabetic mice with SA/PA/SP resulted in rapid bacterial proliferation, a prolonged pro-inflammatory response and large dermonecrotic lesions that were not healed 40 days post-infection. In contrast, the mixed infection resulted in superficial lesions in non-diabetic mice with complete wound closure in 7 days. This illustrated an increased susceptibility of diabetic mice to a polymicrobial infection. Passive immunization of diabetic mice with MEDI6389 significantly reduced lesion sizes compared to c-IgG and resulted in complete wound closure in 14 days versus more than 45 days in c-IgG immunized mice. Targeting a single pathogen with MEDI6389 not only accelerated SA clearance from the wound, but resulted in a significant reduction in both SP and PA CFU along with significant decreases in multiple pro-inflammatory mediators compared to c-IgG.
Conclusion: Collectively our data suggest that targeting SA with a specific multi-mechanistic mAb combination decreases disease severity and accelerates time to healing in a polymicrobial diabetic skin infection model. MEDI6389 therefore holds promise as an immunotherapeutic approach against DFU complications.

P17.02

Molecular Profile of Healed and Non-Healed Diabetic Foot Ulcers

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The Aim: to reveal the differences in molecular profile of healed and non-healed diabetic foot ulcers.
Materials: 19 type 2 diabetic patients with mean age 59 ± 11 years and known diabetes duration as for 14 ± 8.0 years took part in this study. All patients had the signs of severe peripheral neuropathy: vibration perception (VPT) = 49.4 ± 10.2 V and Neuropathy Disability Score (NDS) = 14.0 ± 4.2 scores (M ± SD).
Methods: Biopsies were performed from the margin and central part of the lesion at the beginning of treatment period. Step paraffin slides were stained with hematoxylin and eosin. Immunohistochemistry was done with antibodies to pancytokeratin (pCKW-marker of epithelial cells), smooth muscle actin (SMA- marker of fibrobolasts), markers of stemness cells: CD34, ALDH 1. After 6 months all patients were divided into 2 groups: group 1 (n= 9) was patients with healed ulcers during 6 months or less, group 2 (n=10) was patients with non-healed ulcers in 6 months. Kruskall-Wallis test and bivariate correlation analysis were used for statistics.
Results: There were no differences in age and ulcer duration between groups (p=0,417 and p=0,52 respectively). There was no difference in CD 34 between groups (p= 0.36). Groups differed significantly in pCKW (p=0.015), SMA (p=0.015) and ALDH1 (p=0.024). Significant high bivariate correlations were found between ALDH1 and pCKW (r=0.8, p<0.000), ALDH1 and SMA (r=0.9, p<0.000).
Conclusion: The molecular profile of ulcers healed in 6 months or less is characterized by presence of stemness cell marker ALDH1, markers of epithelial cells and fibroblasts. In accordance with these findings we can assume that presence of stemness cells define by ALDH1 but not CD34 is key factor for ulcer healing.

P17.03

Effect of ADM on the Expression of SDF-1 and Wnt3a/β-Catenin in Mouse Hair Follicle Regeneration

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Aim: When the skin is damaged in a large area, autologous skin flap or flap transplantation has the disadvantages of limited skin source. With the development of tissue engineering, tissue engineering dermal substitutes have become an important way to repair defects. In the accident of an experiment, we used imported porcine tendon tissue engineering products in C57BL/6J mouse wounds to find that the wounds healed and showed signs of white hair growth, which made us have the effect of promoting similar hair growth in domestically produced tissue engineering materials. curious. Studies have shown that , the porous three-dimensional structure of ADM surface can significantly promote the attachment, proliferation, migration and differentiation of inoculated cells. The extracellular matrix-like ultrastructure of the ADM scaffold can provide the ligands required for cell attachment, and promote the communication between adjacent cells.
Methods: A mouse full-thickness skin defect model was made with the spine as the midline. 6 mm diameter defects were made

on the left and right sides. Left and right sides were covered with gauze and ADM, respectively. 7 days after operation, wound and its surrounding 2 mm tissue were taken for western blot test protein expressions of TNFα, β-catenin, TGFβ1, Wnt3a, VEGF, SDF-1, FGF2, FGF9, AKT. Some tissues were taken for Immunohistochemistry for detection of Wnt3a, SDF-1, FGF2, FGF9. Data were analyzed with the sudent't test.
Results: The protein expression of TNFα and TGFβ1 in the 7-days wound of mice was higher in the gauze group than in the ADM group, while the protein expression of β-catenin, Wnt3a, VEGF, SDF-1, FGF2, FGF9, and AKT was higher in the ADM group than in the gauze group.Immunohistochemistry results showed that Wnt3a, SDF-1, FGF2, and FGF9 were higher in the ADM group than that in the gauze group, and the positive cells are mainly distributed in the cytoplasm of hair follicle cells.
Conclusions: In the wound repair process, ADM may promotes the regeneration of hair follicles by up-regulating the expression of SDF-1 and Wnt3a/β-catenin signaling pathway.

P17.04

Levels of Growth Factors in the PRP of People with Diabetes

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This study aimed to measure the concentrations of specific intrinsic growth factors in the Platelet Rich Plasma (PRP) obtained from the blood samples drawn from 40 study participants. The participants consisted of 3 groups. Healthy diabetics and healthy age, gender matched (n=13) and a discreet group of 14 participants with a non-healing diabetic foot ulcer. Ethical approval was obtained from ORECNI (10/NIRO2/30).
A sample of 24ml of whole venous blood was drawn from each participant and prepared as per the manufacturer's instructions to produce PRP.
Growth factor specific Enzyme-linked Immunosorbent Assays (ELISAs - Quantikine®, R&D systems) were used to determine the concentrations of growth factors PDGF- AB and PDGF -BB, TGFb, and VEGF of the PRP of the study participants.
A one-way ANOVA was used to determine whether there were significant differences between the levels of the different growth factors present in the samples of PRP. For significant interaction effects, post hoc analysis using Tukey's multiple comparison test was employed.
Results: The mean levels of PDGF-BB, VEGF and TGF-β1 were higher in the groups of participants with diabetes and a foot ulcer than the healthy participants. When comparisons were made between Groups 1 and 2, and Groups 1 and 3 using Tukey's Multiple Comparison Test there were some significant differences between some of the concentrations of growth factors.
There was a trend for the levels of VEGF, TGF-β and PDGF- BB to be higher in the participants with diabetes than in either of the other groups. The levels of PDGF-AB were found to be higher in the healthy participants, than either of the groups with diabetes.
The bioavailability of growth factors is key to PRP being an effective adjunct to the management of diabetic foot wounds; however, the varying kinetics of their bioavailability, as identified by Mazzucco et al. (2009), requires more work to help identify the appropriateness of the application to the different types of tissue in the wound.
This study is the first to investigate the levels of VEGF, TGF-β and PDGF- BB and PDGF-AB in the PRP of participants with diabetes and diabetes and a foot ulcer.

P17.05

Association Between Interleukin-1β (+3953) C>T Polymorphism and Foot Ulcer in Patients with Type-2 Diabetes Mellitus

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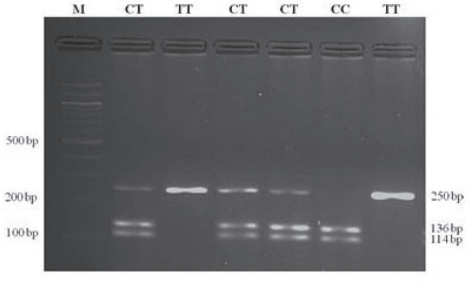
Aim: To study the association between IL-1β (+3953) C>T polymorphism and foot ulcer in patients with T2DM.
Methods: Non-randomized case control study. The study subjects were enrolled in 3 groups, with 100 participants in each group. Group 1 (case) included subjects with T2DM and foot ulcer, Group 2 (case) included subjects with T2DM and no foot ulcer; Group 3 (controls) included healthy subjects.The inclusion criteria were all patients with T2DM and foot ulcer more than 4 weeks duration, and T2DM patients without ulcer. Exclusion criteria were thyroid dysfunction, tuberculosis and other chronic inflammatory disorders.
Results: The wild genotype was CC, heterozygous was CT and homozygous was TT. In all 3 groups the commonest genotype and allele was CC and C respectively. The distribution of CC, CT, TT genotypes in group 1 was 65%, 25%, and 10% and in group 3 was 65%, 27%, 08% respectively. The odds ratio (OR) for genotypes CT and TT were 0.92 and 1.24 respectively. The T allele was present in 22.5% (n=45/200) of cases and in 21.5% (n=43/200) controls (OR-1.05, p=0.8). The difference was not statistically significant.
The distribution of CC, CT, TT genotypes in group2 was 62%, 26% and 12% respectively. An analysis between group 2 and group 3 showed an odds ratio of 1.0 for CT genotype and 1.5 for TT genotype. The frequency of T allele in group 2 and group 3 was 25.0% (n=50/200) and 21.5% (n=43/200) respectively (OR-1.21, p=0.4). The difference was not statistically significant



Gel electrophoresis- The 250 bp PCR product was digested with Taq1 restriction enzyme. The C allele gets cut and yields 136 bp and 114 bp product and T allele remains uncut. Lane 1 shows 100 bp marker, Lane 2,4,5: CT heterozygous, Lane 3,7: TT homozygous (recessive) and lane 6: CC homogygous (wild type).

In another subset analysis, 108 subjects with diabetic neuropathy and 92 without neuropathy were analyzed for the polymorphism, but was not significant.
In a subset analysis of 91 subjects with Diabetic Nephropathy (DN) and 109 without DN showed non-significant association with this polymorphism.
In a subset analysis, 107 cases with diabetic retinopathy (DR) and 93 controls without DR were analyzed for IL-1 β (+3953) polymorphism,CT and TT genotype showed an increased odds for DR,T allele showed an OR-4.01 (P<.001) .
Conclusion: Interleukin-1 β (+3953) C > T polymorphism did not show any significant association with diabetic foot ulcer, but significatnly increased risk for retinopathy.

P17.06

Importance of Xa Factor Correction for Diabetic Foot Patients Management

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Aim: Targeting of Xa coagulation factor and its clinical importance in diabetic foot treatment outcomes, mortality and morbidity rates besides standard guidelines.
Methods: 34 patients between ages 47-76 were observed with diabetic foot neuro-ischemic infected ulcers during January-December 2018. 12 patients received systemic hypocoagulation starting with i/v and s/c heparin in early perioperative period followed by rivaroxaban for next 30 days and more besides standard local and complex treatment including metabolic disorders correction, antibacterial adequate treatment, appropriate revascularization, vital functions improvement and local edema decompression, debridement, negative pressure treatment and offloading. Doses of rivaroxaban started with 20mg and tending to decline up to 10 mg per day in single dosage. No major bleeding developed. Patients who developed gastrointestinal discomfort immediately recommended to cancel the medication.
Results: The group of patients with Xa factor correction revealed preserved weight bearing foot with initial only 1 to 3 toe amputation in 7 cases, trans-metatarsal amputation 3, heel necrectomies with full healing of soft tissue defect followed by skin grafting in 2 cases. No major bleeding or cardio-cerebral event was registered.
In parallel similar group of 12 patients received only heparin in the perioperative period followed with administration of disaggregants. 2 patients developed re-occlusion of popliteal artery after thromb-endarterectomy in 2 months with relapse of critical ischemia and underwent femoro-tibial auto-venous bypass grafting, repetitive toe minor amputations in 5 cases and 2 trans-metatarsal amputations after 2-4 months later first discharge from the hospital. 1 patient developed fatal stroke 1 month later, 1 patient developed non-fatal myocardial infarction followed by coronary artery stenting in 3 months. One disabled institutional patient underwent over knee amputation in early perioperative period. 1 patient developed peripheral pulmonary minor right side non-fatal thromboembolism.
Conclusions: Our observation underlines the importance of factor Xa regulation as an important milestone in prevention and treatment of local perfusion disorders in the lower limbs of diabetic foot patients with foot ulcers in peri- and postoperative period as well as other macro-vascular fatal and non-fatal events prevention and life quality improvement. Patients with local septic edema also benefit from the inactivation of Xa factor.

P18.01

The Use of Methylene Blue Dye as a Guide for Precise Surgical Debridement in Patients with Diabetic Foot Ulcerations

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Aim: The purpose of this poster is to discuss the novel technique of utilizing topical methylene blue dye as a way to guide precise and minimalistic surgical debridement in diabetic foot ulcerations. While, surgical debridement is the most important step in treating wounds and involves resection of all nonviable tissue. We propose the use of this technique to better help identify nonviable tissue for debridement, which provides a healthier wound bed for the proper phases of wound healing to occur.
Methods: Topically apply methylene blue to wounds prior to surgical debridement. While healthy epithelial tissue is wiped clean and is unstained by the dye. Biofilm, eschar, nonviable and granular tissue remains stained. This visual distinguishment allows for a more precise, less redundant and complete surgical debridement. We utilize an atraumatic surgical debridement of diabetic foot wounds with the application of topical methylene blue dye prior to sharp resection of all non-viable tissue.
Results: In acute or chronic diabetic foot wounds, methylene blue will stain all nonepithelial tissue, which indicated all soft tissue needing debridement. This technique works well with identifying epithelialization and appropriately preparing a wound bed by removing the blue stained layer of tissue. Using this visual marker we are able to better identify what requires surgical resection, and gives us a healthy wound base.
Conclusion: Topical methylene blue is an effective and creative way for safely assisting surgeons in their debridement of diabetic foot ulcerations. It helps delineate between unstained epithelialization tissue and the tangential layer of biofilm and exposed soft tissue requiring surgical debridement. The dye provides a visual cue for the provider to identity all the surface areas that need or has undergone surgical debridement, and prevents loss of healthy tissue.

Disclosure: None

P18.02

Biomarker Discovery for Prediction of Healing vs. Non-Healing Chronic Diabetic Foot Ulcers

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Aim: This pilot translational study seeks to identify proteomic and genomic biomarkers to aid in the diagnosis, prognosis, and treatment of chronic diabetic foot ulcers (DFU).
Methods: 32 consecutive patients with chronic DFUs (>1cm2 for >4 weeks) were recruited (81% male; aged: 57.4 ± 12.7yrs). On Day 0, serum samples were collected from the wound bed during debridement and processed. Serum inflammatory protein levels were quantified using multiplex assays for 18 human cytokines with additional global proteomic assessment conducted via mass spectrometry. Quantitative PCR via genomic array panel with 84 genes associated with wound pathways and tissue repair was used to assess genetic expression. Subjects were treated with standard of care and categorized into a healing or non-healing wound group based on wound appearance at a 12-week follow-up visit. Proteomic and genomic expression was then compared between patients with healing and non-healing DFUs.
Results: The study cohort consisted of 13 healing and 19 non-healing DFUs. There were no significant differences in patient characteristics between the two groups, including age, sex, race, BMI, vascularity, insulin dependency, HbA1C, and tobacco use. Non-healing DFUs had a 5.1-, 3.8-, and 3.1-fold decrease in C4b-binding protein (C4BP), neutrophil gelatinase-associated lipocalin (NGAL), and annexin A1, respectively, and a 12-fold increase in transketolase compared to healing DFUs. Cytokine analysis showed non-healing DFUs had just over half the amount of interleukin-1β (IL-1β) and interleukin-6 (IL-6) compared to healing DFUs. Non-healing DFUs also had more than a 4-fold increase in actin cytoplasmic 1 (ACTB), beta-2-microglobulin (B2M), and collagen alpha-1 (III) chain (COL3A1) gene expression, as well as a 2-fold decrease in expression of the granulocyte-macrophage colony-stimulating factor (CSF2) gene.
Conclusions: Findings from this initial translational study identified serum C4BP, NGAL, annexin A1, and transketolase as the leading candidate biomarkers for predicting healing and non-healing chronic DFUs.
Acknowledgements: The project was supported by National Institute of Health (NIH) grants T35DK074390 (National Institute of Diabetes and Digestive and Kidney Diseases) and S10 OD010662 (Office of the Director). The content is solely the responsibility of the authors and does not necessarily represent the official views of the NIDDK or NIH.

P18.03

Randomized Clinical Trial to Compare Negative Pressure Wound Therapy with and Without Simultaneous Irrigation in the Infected Diabetic Foot

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Aim: To compare the effectiveness of traditional Negative Pressure Wound Therapy (NPWT) and Negative Pressure Wound Therapy with continuous irrigation (NPWTi) to heal complex wounds in patients with diabetic foot infections (DFI) that require surgery.
Methods: We enrolled 150 patients in a randomized clinical trial with moderate and severe DFI based on IDSA/ IWGDF infection criteria in a 16-week randomized clinical trial. Inclusion criteria: diabetes per ADA criteria, and a surgical wound >5cm2, ABI>0.7. Patients received either traditional NPWT 125 mm/Hg or NPWTi with 125 mm/Hg with continuous irrigation with 30 cc/hour of betanie-polyhexanide, as part of standard surgical care. Co-morbidities were evaluated with a modified Kaplan scale. Vascular status was evaluated with ABI, systolic ankle and toe pressures, and skin perfusion pressure, and sensory neuropathy was evaluated with 10-gram monofilament and vibration perception threshold testing. The proportion of wounds that were covered with Integra or skin grafts or surgical closed and the time to closure, as well as the proportion of healed wounds and the time to healing were recorded over a 16-week evaluation period. Patients that did not have surgical closure could continue NPWT at home. All patients receive local wound care, off-loading and parenteral antibiotics as part of standard care.
Results: There was no difference in patient demographics or wound characteristics among the treatment groups. There was no difference in the proportion of wounds that were surgically closed or covered before discharge from the hospital (NPWT vs NPWTi 90.7% vs 90.8, P=0.60). There was a high rate of wound dehiscence after closure in both groups. The proportion of healed wounds within 16 weeks was (58.7% vs 60.0%, P=0.54), and time to healing (62.2 +/- 43.8 vs. 53.2 +/- 28.5 days, P=0.26). There was no difference in length of stay (13.6 +/- 6.3 vs. 14.1 +/- 10.7, P=0.73).
Conclusion: There was no advantage identified when continuous irrigation was used in conjunction with NPWT compared to traditional NPWT without irrigation.

P18.04

Clinical Outcome and Costs of Domiciliary Delivery of Negative Pressure Wound Therapy in Post-Surgical Diabetic Foot Patients Compared with In-Patients.

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Aim: to evaluate costs and resource utilization of a domiciliary service of negative pressure wound therapy (NPWT) placement for diabetic foot ulcers (DFU) managed by visiting nurses (VN) of National Health Service.
Methods: We retrospectively analyzed the databases of a local Health Authority Service and of the University Hospital in which all the DFU cases of the area are admitted for surgical procedures, for the year 2015. All the patients to which NPWT was prescribed during admission and to which it was then applied and managed by VNs at their home were traced and healing rates (HR) and times

(HT), number of days of NPWT, costs and days of in-hospital stay were sorted out and compared to those of 2012, when the service was not active.
Results: 52 DFUs patients among those admitted in 2015 were managed for NPWT by VNs. Their HR (87.5%) and HT (143.6 ± 38.2 days) didn't significantly differ from controls, while the length of NPWT was considerably shorter (14.1±5.4 vs 20.7±11.3 days, p<0.01). The costs, calculated as number of days of therapy and days of in-hospital stay were significantly lower in 2015, when normalized for the number of patients and days of NPWT (31.2 € vs 450 € per day of therapy, respectively, p<0.001), when compared to those presented in 2012.
Conclusions: the implementation of a domiciliary service for the delivering of NPWT to DFU patients after surgical intervention proved not only to be as safe and effective than the in-hospital management, but also was associated to a significant reduction of costs and resource utilization.

P18.05

Manipulating Wound Tension and Geometry to Accelerate Healing

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The purpose of this quality assurance case series is to evaluate the positive effects of wound tension relief in wound healing. Reducing wound edge tension seems to facilitate wound closure. In theory, linear shaped wounds epithelialize faster compared to ones that are circular in nature. The application of skin tension towards the wound, has the potential to transform a circular wound to one that is more linear. Relieving tension around the periwound, which ultimately reduces the distance between wound edges and promotes epithelial cell migration, can accelerate this evolution in shape geometry. This particular case series used the PreLoc Wound Closure Device manufactured by ZipLine Medical which is designed to provide gentle, constant force across the wound using micro-adjustable ratcheting straps. With this periwound tension relaxation, the skin edges at the most extreme ends become closer approximated which encourages epithelial cell migration to facilitate wound closure. Additionally, applying skin tension towards the wound from opposite directions using PreLoc further relaxes the wound edges and acts as a wound splint to limit skin edge movement, frictional forces and potential damage to the newly formed epithelial cells. PreLoc consists of applying uniform bidirectional opposing tension towards the wound which allows the wound edges to rest in closer proximity. Reducing wound tension relief demonstrated positive effects in wound healing based on the presented reviewed case studies. PreLoc Wound Closure Device promoted wound edge relaxation and wound geometry manipulation. Opposing tension application towards the wound using PreLoc further relaxed the wound edges and limited wound edge motion. Both the wound edge tension relaxation and limitation of movement showed weekly measurement improvement and promoted integumental bridging within the wound itself compared to wounds where tension relaxation was not considered. All subjects showed significant improvement in wound dimensions. These techniques can be used in conjunction with skin substitutes, wound care products and casting techniques. The use of wound tension relief has the power to expedite wound healing. Accelerating the healing time of wounds, decreases the risks of further complications including infection and amputation, decreases hospital costs and most importantly promotes a better patient quality of life.

P18.06

Application of Noninvasive Skin-Stretching Device in Wound Healing of Diabetic Foot

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Objective: To evaluate the clinical value of noninvasive skin-stretching device in the healing of diabetic foot
Methods: A total of 51 diabetic patients with diabetic foot gangrene at Wagner stage 4 after toe amputation or debridement were recruited in the study from May 2017 to March 2018 by using a prospective cohort design. The patients were assigned into trial group (n=17) and control group (n=34) and matched by 1::2 ratio. All patients underwent basic treatment and vacuum sealing drainage therapy until exposing bones were covered by fresh granulation tissues and wound inflammation disappeared. The wounds of control group were received regular dressing change, and adhesive non-invasive skin- stretching devices were applied to the wounds of trial group. The wounds were observed from the 1st day to the day of wound healing or 3 months after surgery. Healing rates were compared, and Kaplan-Meier survival analysis was used for comparing cumulative wound healing rate over time between two groups.
Results: The healing rate of trial group was significantly higher than that of control group (94.1% vs 58.8%, $\chi 2=5.206$, P<0.05). The differences of Kaplan-Meier healing time curve between two groups were statistically significant (P<0.01). Median of healing time in trial group was significantly shorter than that in control group [42 (41, 59) vs. 78 (50, 90) d, Z=3.30, P<0.01]. Taking the end of the last vacuum sealing drainage therapy as the starting point of time, the differences of Kaplan-Meier healing time curve between two groups were statistically significant (P<0.01), and the median of healing time in trial group was significantly shorter than that in control group [13 (8, 14) vs. 42 (26, 42) d, Z=4.845, P<0.01].
Conclusions: The application of noninvasive skin-stretching device in diabetic foot gangrene in the repairation stage after surgery can reduce wound healing time and increase wound healing rate.

P19.01

Validation of the Ipswich Touch Test in Persons with Diabetes

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Background: Loss of protective sensation (LOPS) is associated with diabetes and causes foot ulceration, infection & amputation. Identifying those with LOPS requires the use of a screening test such as the standard monofilament test (SMT). The Ipswich Touch Test (ITT), developed by Dr. Gerry Rayman in the United Kingdom, tests for LOPS using a finger to lightly touch the toes on patient's feet in a particular order.
Aim: The aim of this study was to validate the SMT (criterion) compared to the ITT (new test) with a group of 16 healthcare practitioners and 8 patient participants.
Methods: The investigators recruited and tested each participant in random order using SMT, ITT and Neuropathy Disability Score to determine LOPS. Information was blinded to the participant and other practitioners. All practitioners were trained on how to conduct the SMT and ITT. Each practitioner assessed all of the participants in a randomized order using a specific protocol on the same day. A blind observer collected and de-anonymized data onto spreadsheets.
Results: The ITT compared to the SMT demonstrated specificity of 100% for all raters and a mean sensitivity of 93.8% for LOPS. There was some disagreement between the SMT and the ITT between different practitioners and participants. The Kappa coefficient was 0.97 and 0.83 for SMT and ITT respectively.
Conclusions: This study demonstrated the validation and cost-effectiveness of ITT compared to the SMT in identifying LOPS. ITT can be used by healthcare professionals as an effective tool for screening for LOPS in people with diabetes.

P19.02

Accuracy of Vibration Perception Threshold Measurements for Diagnosing Diabetic Polyneuropathy: a Diagnostic Test Accuracy Study

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Aim: Among several methods of diagnosing and classifying diabetic polyneuropathy (DPN), vibration perception threshold (128Hz, VPT) is a commonly accepted assessment. Although, because it considers only one sensitivity modality, it could overlook and misclassify the DPN presence and severity. A new approach that considers uncertainty in predicting and quantifying the presence of DPN was developed on a rule-based Fuzzy expert system[1], including as input, pressure (monofilaments) and vibration sensitivity, and DPN symptoms (MNSI questionnaire). Usually, VPT assessment uses a 128Hz tuning fork. However, this tool constantly decreases amplitude of vibration during its application[2]. To overcome this drawback, we used a shaker vibration exciter to control the amplitude and frequency of VPT[3]. Our aim was to (i)investigate the relationship between the shaker measures and the Fuzzy classification tool to detect DPN; and (ii)validate the diagnostic accuracy of the shaker for detecting DPN against the Fuzzy tool as a clinical reference.
Methods: In 66 participants [33 health controls (56.3±9.9yrs) and 33 diabetic (55.6±15.4yrs)] VPT was measured at the first metatarsal head(MTH) and the heel at 30 and 200Hz. The Fuzzy score was obtained and sorted into 2 classes: absent and present DPN. Accuracy was evaluated by ROC curve analysis, and correlations by Spearman coefficients.
Results: The greater ROC curve area was obtained when 30Hz @ MTH was compared with the fuzzy (ROC=0.816), demonstrating a very good accuracy in detecting patients with DPN, based on the Fuzzy scores. The correlation between the Fuzzy and VPT was significant and positive (r=0.67;p<.001), indicating that the higher the fuzzy score, the higher the VPT.
Conclusions: The results of the shaker presented good accuracy and correlation with the Fuzzy score to detect DPN, thus the shaker can accurately assess patient's condition through the quantification of DPN severity by VPT.
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P19.03

The Combination of Low-Frequency and High-Frequency Vibration Perception Thresholds Could Contribute to a More Sensitive Diagnosis of Diabetic Polyneuropathy

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Aim: Vibration sensitivity is fundamental to estimate the risk of developing ulcers [1]. At higher frequencies, changes in vibration perception threshold (VPT) due to diabetic polyneuropathy (DPN) can be observed [2]. In this study, we compared VPT at low and high frequencies in diabetic patients to identify potential advantages of its usage over the established high-frequency diagnostics.
Methods: 33 healthy controls (CG: 56.3±9.9yrs) and 33 patients with Diabetes mellitus (DM: 55.6±15.4yrs) participated in this study. VPTs were measured at the foot sole at two different frequencies (30Hz & 200Hz) and locations (first metatarsal head (MTH) & heel).
Results: At 30Hz, DM showed ~3.5 times higher VPTs at the heel and ~5.0 times higher VPTs at the MTH compared to CG (both p<0.001). At 200Hz, VPTs in DM were ~2.5 times higher and showed no significant differences for either location. In addition, positive significant correlations were observed between the duration of DM, the two locations and frequencies (r ranges from 0.38 - 0.43).
Conclusions: In patients with DM, epidermal denervation starts earlier than in deeper dermal layers [3]. Consequently, sensitivity

changes in superficial fast adapting Meissner corpuscles (FAI) may occur earlier than in Pacinian corpuscles of deeper tissues (FAII). FAI respond optimally to lower frequencies (~30Hz). As shown in our data, VPTs at 30Hz show larger differences between DM and CG. Thus, FAII and their pathways seem to be influenced less than FAI and their pathways. Nevertheless, different clinical diagnostic tools for DPN concentrate on changes in VPT of FAII (~128Hz vibrations) [1]. Therefore, additional low frequency VPT measurements could be an additional test to improve sensitivity in diagnosing DPN, which is supported by the positive correlations to duration of the disease.

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P19.04

Hidden Dangers Revealed by Misdiagnosed Diabetic Neuropathy: a Comparison of Clinical Tests for the Detection of Vibration Perception Threshold

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Aim: Diabetic Peripheral Neuropathy [DPN] is an important complication and contributes to the morbidity of diabetes mellitus. Evidence indicates early detection of DPN results in fewer foot ulcers and amputations. The aim of this study was to compare different screening modalities in the detection of DPN in a primary care setting.
Methods: A prospective non-experimental comparative multi-centre cross sectional study was conducted in various Primary Health Centres. One hundred participants living with Type 2 diabetes for at least 10 years were recruited using a convenience sampling method. The Vibratip, 128Hz Tuning Fork and Neurothesiometer were compared for sensitivity and specificity in the detection of vibration perception.
Results: This study showed different results of DPN screening tests, even in the same group of participants. This study has shown that the percentage of participants who did not perceive vibrations was highest when using the VibraTip (28.5%). This was followed by the neurothesiometer (21%) and the 128 Hz Tuning Fork (12%) ($p< 0.001$).
Conclusion: Correct diagnosis and treatment of neuropathy in patients with diabetes is crucial. This study demonstrates that some instruments are more sensitive to vibration perception than others. We recommend that different modalities should be used in patients with diabetes and when results do not concur, further neurological evaluation should be performed. This would significantly reduce the proportion of patients with diabetes who would be falsely identified as having no peripheral neuropathy and subsequently denied the benefit of beneficial and effective secondary risk factor control.

P19.05

When Time is Limited, Which Vibratory Test Should be Selected for Peripheral Neuropathy Screening?

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Aim: Numerous guidelines recommend pairing Semmes-Weinstein monofilament (SWM) testing with a secondary clinical test when screening for diabetic peripheral neuropathy, yet time is very limited in clinical practice. This study compared the time to complete and the diagnostic agreement of three vibratory sensation tests.
Methods: Sixty-five individuals (42% male; aged: 61±12yrs) were recruited. A single investigator administered the following tests bilaterally: 10-site SWM, traditional tuning fork (TTF), electronic tuning fork (ETF), and vibration perception threshold (VPT) via biothesiometer. Administration times were compared with a one-way repeated measures ANOVA. Cochrran's Q test was used to compare the varied tests' diagnostic agreement. In recognition of the varied administration/interpretation techniques associated with the varied tests, a liberal and a conservative means of diagnosing peripheral neuropathy was utilized with the SWM, ETF and TTF tests.
Results: The ANOVA indicated there were significant ($p<.001$, partial eta squared= .442) differences in time to complete the varied tests. Sidak post-hoc comparisons indicated the VPT testing took an intermediate time to complete, while the ETF and TTF tests took the least amount of time, and the SWM test took the longest time. There were significant differences between the different tests in regards to neuropathy diagnoses (Table 1).
Conclusion: Tuning fork methods required 11sec less to administer than VPT testing. Although that may seem trivial, it is worth noting peripheral neuropathy screening often fails to occur in the precious few minutes clinicians are allotted per patient. Clinicians should also be mindful that different tests yield different diagnostic conclusions.

	ETF liberal	TTF liberal	VPT	SWM conservative	TTF Conservative	ETF Conservative
SWM liberal	0.093	**<.001**	**0.001**	**<.001**	**<.001**	**<.001**
ETF liberal		1.000	1.000	**<.001**	**<0.001**	**<.001**
TTF liberal			1.000	0.093	**0.009**	**<.001**
VPT				0.055	**0.005**	**<.001**
SWM conservative					1.000	1.000
TTF Conservative						1.000

SWM liberal= failure to detect Semmes Weinstein Monofilament at ≤9/10 sites, ETF liberal= inability to feel electronic tuning fork vibration for at least 9sec, TTF liberal= inability to feel traditional tuning fork for at least 9sec, VPT= vibration perception threshold, SWM conservative= failure to detect Semmes Weinstein Monofilament at ≤6/10 sites, TTF conservative= failure to sense any vibration stimulus at initial application of traditional tuning fork, ETF conservative= failure to sense any vibration stimulus at initial application of electronic tuning fork

Table 1. P-values for pairwise comparisons of neuropathy diagnosis by varied tests and varied diagnosis cut points

P19.06

The Rotterdam Diabetic Foot Study Test Battery: In All Disorder a Secret Order.

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Aim: Loss of sensation due to diabetes related neuropathy often leads to diabetic foot ulceration. To assess sensation, several test instruments are advised, like static- and moving two-point discrimination (S2PD, M2PD), monofilaments (S1PD) and tuning fork.
Methods: Mokken Scale Analysis was applied on Rotterdam Diabetic Foot Study data to select hierarchies of tests to construct measurement scales.
Results: 39-item and 31-item scales were developed for measuring loss of sensation for research purposes and a 13-item scale for clinical practice. All instruments were strongly scalable and reliable. In addition, the 39 items can be classified into five hierarchically ordered core clusters: S2PD, M2PD, vibration sense, S1PD, and prior ulcer or amputation.
Conclusions: Based on the presented scales, clinicians may be able to better categorize patients in their sensory loss at the feet. Therefore, a more precise medical decision making is possible, with consequent recommendations regarding intervention strategies and patient information.

P20.01

What is the Increased Attributable Risk Due to Diabetes in People Hospitalized for Foot Infections?

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Aim: To compare clinical outcomes in people with and without diabetes admitted to the hospital for a foot infection
Methods: Foot infection in people without diabetes is uncommon. A common mechanism for foot infection in people with and without diabetes involves puncture wounds. We evaluated 105 consecutive patients between June 2011 and December 2018 with foot infection resulting from a puncture injury, 85 had diabetes (DM) and 20 did not have diabetes (NDM), based on American Diabetes Association criteria. We evaluated peripheral arterial disease based on toe pressure, TBI, and ABI's, sensory neuropathy, the need for surgery and amputation, length of stay (LOS), bacterial pathogens, and the type of infection [osteomyelitis (OM) versus soft tissue infection].
Results: DM patients took significantly longer before they presented to hospital (mean 21.5± 7.8 vs 8.9± 9.2days p= 0.01) than NDM;DM patients had neuropathy 44.6 times more frequently (91.8% vs 20.0%, p<0.001) DM had osteomyelitis more frequently (36.5% vs 5.0%, p<0.001). DM required more surgeries (2.7±1.2 vs 1.5±0.76, p=0.005) and more amputations (50.6% vs 0, p<0.001). Length of hospitalization was also significantly longer in DM patients (16.4± 10.62 vs vs. 8.4±10.7 days, p=0.001). The most common soft tissue organism in DM is staphylococcus aureu, and in NDM are methicillin-resistant staphylococcus aureus, pseudomonas aeruginosa, and Pantoea agglomerans. The most common OM organism in DM is staphylococcus aureus.
Conclusions: DM patients have more severe outcomes when admitted to hospital for foot infection compared to patients without diabetes. DM patients wait 3 x longer to seek medical care. They have sensory neuropathy 44.6 times more frequently. The risk of osteomyelitis and amputation is 10.9 and 20.5 times higher than people without diabetes. Length of hospitalization was twice as long.

P20.02

Neuropathic vs Neuroischaemic Infected Foot Ulcers

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Introduction and Aim: Foot infections are a common problem in diabetic patients and are an important risk factor for limb amputation. The aim of this work was to compare baseline characteristics and outcomes of infected diabetic foot ulcers (DFU) between patients with purely neuropathy ulcers and patients with both neuropathic and ischemic disease.
Methods: Retrospective observational study of diabetic patients admitted to a Tertiary Diabetic Foot Unit with PEDIS 3 or 4 infections, between January 2010 and December 2017. Only the first admission was analyzed. The main outcomes evaluated were lower limb amputations (LLA), readmission due to DFU and death, and were accessed at 6 months follow up. IBM SPSS Statistics® software was used for statistical analysis, p level <0.05 was considered statistically significant.
Results: A total of 408 patients were included; 40.9% (n=167) had a neuropathic ulcer and the remainder 59.1% (n=241) presented with a neuroischemic ulcer. Patients with neuropathic ulcers, compared to those with neuroischemic ones, were younger (57.3±11.1 vs 67.2±11.8 years, p <0.001), had a shorter duration of diabetes mellitus [median 15 (IQR 10-22) vs 20 years [IQR 15-25], p=0.001) with a higher prevalence of type 1 diabetes (18.0% vs 9.5%, p=0.021) and had a worse median HbA1c (8.5% vs 8.0%, p=0.001). In the neuroischaemic group there was a higher prevalence of retinopathy (72.6% vs 60.2%, p=0.006), nephropathy (62.7% vs 45.8%, p=0.001), ischemic cardiac disease (39.0% vs 10.8%, p<0.001) and cerebrovascular disease (32.4% vs 8.4%, p<0.001). Regarding the microbiological isolates, Staphylococcus aureus was the most common agent isolated in both groups. There was a higher prevalence of Pseudomonas aeruginosa in the neuroischemic group (22.8% vs 13.4%, p=0.039) and of Beta-hemolytic streptococcal infections in

pure neuropathic ulcers (20.0% vs 3.0%, p<0.001). At 6 months follow-up, the occurrence of LLA (55.4% vs 19.8%, p<0.001), readmission (34.2% vs 22.2%, p=0.006) and death (4.7% vs 1.2%, =0.045) was more common in the neuroischemic group.
Conclusion: Diabetic patients with DFU, especially the ones with peripheral artery disease, have a worse prognosis and should be promptly identified and managed aggressively by a multidisciplinary team.

P20.03

How to Avoid Toes Amputations in Infected Diabetic Foot

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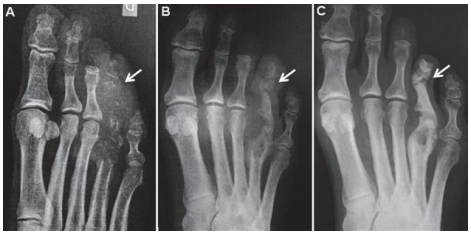
We aim to show that a low-cost Photodynamic Therapy (PDT) protocol can drastically reduce the rate of amputation in diabetic foot. Patients were grouped according to the Wagner classification. All patients presented Wagner Grade 3 classification, with osteomyelitis in one or more toes. The study included 34 patients with circulatory viability, 16 of them, in the control group receiving antibiotics and debridement and 18 treated with antibiotics and PDT.
Results shows that all 16 patients that were in the control group ended up suffering an amputation. In contrast, there was only one patient undergoing PDT treatment requiring amputation.
Statistical analysis for quantitative variables the Shapiro—Wilk test ($p < 0.05$) was used. The comparison between the control group and treated patient group with PDT was performed by the Chi-square test and the Mann—Whitney test. Kaplan—Meyer method to represent the survival curves. The statistical program used in this study was the Stat 11.0. The level of significance was set at $p < 0.05$. There were statistically significant differences between groups for incidence of amputation.
In cases of osteomyelitis, bone removal is always required, it is almost a consensus that bone infection in the diabetic foot is a strong indication for amputation. Infections by microorganisms such as bacteria, virus and fungi can be efficiently treated by PDT. This PDT protocol offers the cure of osteomyelitis (Figure 1).
In conclusion we can confidently state that PDT treatment provides a better prognosis for diabetic feet and can prevent a large number of amputations.



Typical evolution of bone structure after PDT treatment. The patient was classified as Wagner Grade 3 initially. Osteomyelitiswas confirmed after X-ray evaluation. Radiological images of the distal epiphysis of the fourth metatarsal. (A) Fracture and loss ofbone substance (29th November 2012). (B) After 48 days of the PDT treatment the fracture was healing (17th January 2013). (C)Almost seven months after PDT treatment it can be observed the consolidation of the fracture callus and consistent radiopaqueimage

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P20.04

Predictors of Major Lower Limb Amputation in Patients Admitted for Diabetic Foot Infections

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Introduction and aims: The increasing prevalence of Diabetes Mellitus has led to a high risk of diabetic foot infections (DFI). DFI may ultimately result in a major lower limb amputation (LLA). The aim of our study was to identify the comorbidities that would be predictive of major LLA among patients with DFI.
Methods: Retrospective and observational review of diabetic patients admitted to a Tertiary Diabetic Foot Unit due to DFI, between January 2010 and December 2017. Patient's re-admissions were excluded. IBM SPSS Statistics® software was used for statistical analysis, p level <0.05 was considered statistically significant.
Results: We included 408 patients (74.3% male), mean age of 63.2±12.4 years and median DM duration of 18 years (IQR 12-25 years). The majority (59.1%, n=241) had a neuroischemic ulcer, with the remainder classified as purely neuropathic ulcers. A total of 32 patients (7.8%) were submitted to major LLA. Patients who underwent major LLA were older (69.3±10.6 vs 62.6±12.5 years, p=0.003) and had a higher percentage of macrovascular disease, namely cardiac ischemic disease (CID) (53.1% vs 25.3%, p<0.001) and peripheral vascular disease (PVD) (96.9% vs 56.1%, p<0.001). The most common isolated agent in major LLA were bacteria from the Enterobacteriaceae family (55.6%). Even though 59.4% of patients who underwent major LLA were male, on univariate analysis female patients had a 2.1 higher risk of major LLA (CI95% 1.004-4.443, p=0.049). The factors associated with the incidence of major LLA were female gender, older age, macrovascular disease, CID and PVD, with patients presenting with a neuroischemic ulcer having a 24.5 higher risk for major LLA (IC95% 3.311-181.375, p=0.002). On multivariate analysis, PVD remained statistically significant. Duration of diabetes, presence of osteomyelitis, previous LLA and a positive bacterial culture result were not significant factors for major LLA. At 6-month follow-up, patients with major LLA had a higher mortality risk [OR 5.7 (IC95% 1.655-19.726, p=0.006)].
Conclusion: Older diabetic patients with established macrovascular disease and neuroischemic ulcers are at higher risk for major LLA. The early identification of these comorbidities and a more aggressive treatment of DFI in these patients may result in better outcomes.

P20.05

Timing and Risk Factors for Necrotizing Fasciitis After Surgical Treatment of Chronic Diabetic Foot Ulcers

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Aim: To describe the incidence, timing and risk factors associated with necrotizing fasciitis (NF) after initial limb-sparing surgical management of infected foot ulcers in patients with diabetes mellitus (DM).
Methods: Retrospective review of the American College of Surgeons-National Surgical Quality Improvement Program (ACS-NSQIP) database was performed. Patients with a diagnosis of foot ulcer were selected. Patients who did not have DM, underwent major amputation, or did not have evidence of infection were excluded.
Results: Out of 517 patients, 10 (1.9%) were readmitted and underwent reoperation for NF after limb-salvage surgical treatment of an infected DM foot ulcer. The median duration of initial hospital stay (4.5 vs. 6.0 days, p=.226), time from admission to surgery (0.5 vs. 1.0 day, p=.335), duration of surgery (27.5 vs. 22 minutes, p=.784) or time from surgery to discharge (3.5 vs. 4.0 days, p=.277) did not significantly differ between those who developed NF and those who did not. The median time until readmission among patients who subsequently developed NF after discharge was 7.0 days (25th to 75th interquartile range [IQR] 6.0-18.0 days), and the median time from readmission to reoperation was 1.0 day (IQR 0.0-1.0 day). After readmission, 9 out of 10 patients with NF (90.0%) underwent major amputation. Patients readmitted for NF had higher serum blood urea nitrogen (BUN) (p=.028) and creatinine levels (p=.040). In addition, patients who were readmitted for NF treated with non-insulin agents for glycemic control had greater odds of having NF than those controlled with insulin (odds ratio [OR] 3.83, 95% confidence interval [CI] 1.09-13.5, p=.048).
Discussion: Patients who developed NF had poorer renal function and were more likely to be treated with non-insulin agents for glycemic control. In addition, the median time to readmission from discharge was 7.0 days. Sooner follow-up may improve outcomes in patients with poor renal function and DM controlled with non-insulin agents. As 90% of patients who were readmitted for NF underwent major amputation, closer surveillance may lead to earlier intervention of NF in patients with DM and improve limb salvage rates.

P20.06

Outcomes After Admission with Diabetic Foot Attack Indicate High Healing Rate and Amputation-Free Survival Using a Dedicated Protocol: 18-Months Follow-Up Study

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Aim: Severe foot infection ('diabetic foot attack', DFA) is the most common diabetes-specific reason for hospitalisation in the United Kingdom. However, outcomes data in this distinct clinical phenotype is limited. This study was performed to evaluate outcomes in DFA patients after treatment with a dedicated protocol.
Methods: We prospectively recorded data on 106 consecutive patients undergoing emergency admission for DFA (TEXAS Grade 3B or 3D,IDSA Class 3) at a specialist diabetic foot unit between January 2016 and April 2017. The protocol applied consisted of initial broad-spectrum antibiotics, medical optimisation, prompt radical surgical debridement (100% of the cohort) and where required, lower limb revascularization for peripheral arterial disease(PAD). Outcomes evaluated were: 1)Healing, 2)major amputation, 3) death and 4)not healed. The first outcome reached in one of these four categories over a mean follow up period of 18.4±3.6 months was considered.
Results: 106 patients were included with mean age 60.4±12.7 years, mean HbA1c 8.9±2.2%. PAD was present in 47%, chronic kidney disease in 30% and 29% had major psychiatric comorbidities. Overall, 57.5%(n=61) healed, 5.6%(n=6) underwent major amputation, 23.5%(n=25) died without healing and 13.2%(n=14) were alive without healing. The mean time to the first outcome (months) was –healed 6.2±5, major amputation 3.3±1.3, death 7.7±6.0 and not healed 16±3.3. Key predictors of outcome were minor amputation (p=0.035), age(p=0.008) and presence of PAD (PAD+)(p=0.009). Those with PAD+ demonstrated significantly worse outcomes compared to those without PAD(PAD-) with fewer healing (OR 0.2 95% CI 0.129-0.649) higher major amputation rate(OR 2.3 95% CI 0.411-13.40) and greater mortality(3.9 95% CI 1.47-10.49). Furthermore, time to achieve healing was significantly higher (PAD- 4.6±3.8 vs PAD+ 9.2±5.6 months, p=0.0003) and time to death was significantly lower (PAD- 11.8±4.5 vs PAD+ 6.1±5.9 months, p=0.03). In 47%(n=50) a minor amputation was required but not influenced by PAD(p=0.610).
Conclusions: We report high diabetic foot healing rates and major amputation-free survival using a dedicated DFA protocol. Older age and PAD were the strongest predictors of negative outcomes. Need for minor amputation is influenced by infection, not PAD. Furthermore, and of concern, an admission with DFA was associated with high 18-month mortality, especially in those with PAD.

P21.01

Critical Factors for Wound Healing in Patients with Critical Limb Ischemia

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Aim: To determine critical factors for wound healing in patients with critical limb ischemia (CLI).

Methods: We retrospectively investigated 76 consecutive patients with CLI (45 male; 31 female) treated by revascularization and wound treatment by a multidisciplinary team at our institution between October 2013 and October 2018. Altogether, there were 94 foot ulcers in the 76 patients. We obtained data on age, sex, comorbidities including diabetes and renal failure, ambulatory status, history of amputation, infection status (C-reactive protein (CRP) levels), method (endovascular therapy or bypass surgery) and number of times of revascularization, vascular status (pre- and post-revascularization skin perfusion pressure (SPP)), duration of antibiotic administration, and existence of osteomyelitis. The wound, ischemia, and infection statuses were categorized using the Society for Vascular Surgery Lower Extremity Threatened Limb classification. Data were assessed using multivariate analysis.
Results: The mean age of the patients was 72.7±12.4 yrs, with 76.3% (n=58) having diabetes and 55.3% (n=42) having end-stage renal failure. Of the ulcers, 57 were associated with foot osteomyelitis. 76 (80.1%) healed (40 patients required minor amputation), 10 did not heal (9 patients required major amputation) and 8 patients died. Multivariate logistic regression analysis showed that CRP and post-revascularization SPP values were significantly associated with prognosis (p=0.0423, OR=0.795, 95%CI 0.636-0.992 and p=0.0205, OR=1.088, 95%CI 1.013-1.168, respectively), Multivariate linear regression analysis showed that the number of revascularizations and foot infections were significantly associated with the time to wound healing (p=0.0162, coefficient=30.864, 95%CI 5.892-55.835 and p=0.0092, coefficient=45.823, 95%CI 11.73-79.915, respectively).
Conclusions: Our results indicate that the vascular status after revascularization significantly affects wound healing in CLI patients and that infection affects both wound healing and the time to wound healing.

P21.02

Clinical Characteristics and Cardiovascular Risk Factors Analysis of Sub-LEAD in Chinese Diabetic Patients

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Aim: To analyze the clinical characteristics and macro- & microvascular risk of diabetic patients with 0.9 ≤ ABI < 1.0 (Sub-LEAD).
Methods: The study included 10804 diabetic patients patients who were treated in tertiary hospitals in China between June 2016 and December 2016. They were divided into four groups according to ABI value: ABI < 0.9 (n=1243, G1), 0.9 ≤ ABI < 1.0 (n=1691, G2), 1.0 ≤ ABI ≤ 1.3 (n=7606 cases, G3), ABI>1.3 (n=264, G4).Their clinical data, biochemical parameters, macrovascular and microvascular disease were compared and analyzed between G1, G2 and G3.
Results: The percentage of sub-LEAD (G2) was 15.65%, significantly higher than that of G1 (11.50%). There were significant differences in age, gender, difference blood pressure, fasting blood glucose, total cholesterol, low density lipoprotein cholesterol (LDL-C), urinary albumin excretion level and eGFR level among three groups (G 1 ,2, 3) (P < 0.05). The incidence of intermittent claudication in G2 group (4.4%) was lower than that in G1 group (16.7%) and higher than that in G3 group (2.9%). coronary heart disease (17.3%), cerebrovascular disease (20.8%), retinopathy (16.2%), diabetic kidney disease (21.2%) and peripheral neuropathy (48.3%) in G2 group were higher than those in G3 group, lower than those in G2 group, and there were significant differences. ABI values of G2 were correlated with age, gender, diabetic duration, BMI, systolic blood pressure, fasting blood glucose and intermittent claudication.
Conclusion: Diabetic patients with 0.9 ≤ABI < 1.0 have a higher risk of macrovascular and microvascular disease and need to pay more attention for screening and intervention as soon as possible.

Comparation of clinical data, biochemical parameters, macro-and micro-vascular between three groups

	ABI < 0.9 group (N=1243 G1)	0.9 ≤ ABI < 1.0 group (N=1691 G2)	1.0 ≤ ABI ≤ 1.3 group (N=7606 G3)
Age(yrs)	71 (64,79)	65 (58,73) *#	63(58,70)
Dur-of-DM(yrs)	12 (7,20)	8.5 (4,15) *-	8(4,14)
BMI	24.5 (22.3,26.8)	24.6 (22.5,27)	24.6(22.5,26.8)
SBP(mmHg)	140 (127.8,154)	136 (125,148) *#	134(123,146)
SBP-DBP	62 (50,76)	57 (48.25,69) *#	55(46,67)
WHR	0.946 (0.913,0.98)	0.946 (0.908,0.977)	0.951(0.91,0.98)
FBG(mmol/L)	8.2 (6.6,10.9)	8.2 (6.6,10.8) #	7.9(6.42,10.25)
HbA1c(%)	8.1 (7,9.7)	7.9 (6.8,9.7) -	7.9(6.8,9.6)
CHO(mmol/L)	4.6 (3.7,5.5)	4.7 (3.9,5.4) #	4.5(3.74,5.33)
LDL-C(mmol/L)	2.72(2.08,3.37)	2.82(2.21,3.39)#	2.64(2.03,3.27)
eGFR(ml/min/1.73m2)	100.4 (74.64,126.8)	112.98 (87.52,137.43) *#	115.87(92.3,140.66)
U-Alc(mg/g)	29.74 (12,169.55)	18.02 (6.78,56.58) *#	12.1(4.5,36)
24h-Uprotein	0.175 (0.073,0.73)	0.11 (0.06,0.3) *-	0.12(0.06,0.34)
The pulsation of dorsal pedal artery(%)	477 (38.4%)	426 (25.2%) *#	807 (10.6%)
ASCVD(%)	307 (24.7%)	292 (17.3%) *#	874(11.5%)
cerebrovascular disease(%)	368 (29.6%)	351 (20.8%) *#	940(12.4%)
DR(%)	355 (28.6%)	274 (16.2%) *-	1377(18.1%)
DKD(%)	328 (26.4%)	359 (21.2%) *#	1147 (15.1%)
DPN(%)	689 (55.4%)	817 (48.3%) *#	2946(38.7%)
Non-macrovascular complications(%)	366 (29.4%)	712 (42.1%) *#	4574 (60.1%)
3 macrovascular complications(%)	90 (7.2%)	54 (3.2%) *#	81 (1.1%)
Non-microvascular complications(%)	421 (33.9%)	699 (41.3%) *#	3852(50.6%)
2 microvascular complications(%)	286 (23%)	294 (17.4%) *#	970(12.8%)

* There was significant difference between G2 and G1 (P < 0.05). # There was significant difference between G2 and G1 (P < 0.05).

P21.03

Study the Impact of Peripheral Arterial Disease in Patients with Diabetic Foot Osteomyelitis

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Aim: Peripheral arterial disease (PAD) is common in patients with diabetic foot ulcers and is one of the risk factors associate osteomyelitis.
Methods: From 2014 to 2017, 274 patients with type 2 diabetes mellitus treated for diabetic foot osteomyelitis (DFO) at a major diabetic foot center in Taiwan were analyzed. Diagnosis of osteomyelitis was confirmed by clinical probe-to-bone test and radiographic findings. Wounds were recorded by PEDIS (perfusion, extent size, depth, infection, and sensation) scoring. Foot treatment outcomes were classified as major- lower-extremity amputation (LEA), minor-LEA, and limb-preserved.
Clinical characteristics, laboratory data, and wound classification were analyzed for foot outcome. In addition, the bacteria strains cultured from wound swab were analyzed between different perfusion grades.
Results: The median age of patients with DFO was 61.1 years and 66.4% were male. Among them, 89 had perfusion score 1, 62 had perfusion score 2, and 123 had score 3. Patients with DFO and PAD (perfusion score 2 and perfusion score 3) are older (66.38 vs 53.00 years), higher rate of major adverse cardiac event (47.0% vs 19.1%), and higher rate on dialysis (31.9 vs 9%), larger wound (15.00 vs 7.75 cm2), lower level of hemoglobulin (10.4 vs 11.5 mg/dL) and higher level of C-reactive protein (79.21 vs 43.30 mg/L)

comparing to who without PAD. Higher rate of major LEA was observed according to poor PAD perfusion (6.7%, 11.3% and 22.8% in patients with score 1, 2, and 3, respectively, P =0.004). Following multi-variables regression, patients with perfusion score 3 was the independent risk factor to predict major LEA (odds ratio 4.704, 95% confidence interval 1.691-13.086). For the 185 patients with PAD who received revascularization (n = 65), the major LEA rate was 12.3%.
The gram-positive aerobes were the predominant bacteria in DFO (67.2%). With the higher PAD scoring, lower rate of gram-positive aerobic isolates were found (76.4%, 74.2%, and 56.9% in perfusion 1, 2, and 3, respectively, P for trend = 0.002).
Conclusions: Peripheral arterial diseases have impact on clinical presentations and LEA outcomes for patients with DFO. Revascularization showed benefits on limb preservation in these patients.

P21.05

Evaluation of Peripheral Perfusion in Heel Ulcerations Status-Post Transmetatarsal Amputation with Tendo-Achilles Lengthening: The Importance of the Peroneal Artery

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Aim: The primary aim was to evaluate the peripheral perfusion in patients who developed heel ulcerations status post transmetatarsal amputation and tendo-achilles lengthening. Peripheral perfusion of the three distal vessels, anterior tibial, posterior tibial, and peroneal arteries as well as heel blushing were assessed.
Methods: A retrospective review of 55 patients who underwent a transmetatarsal amputation and tendo-achilles lengthening over a 8 year period (January 1, 2007 through December 31, 2015) was performed. Of the 55 patients, 10 patients developed heel ulcerations at a mean of 7.6 months (0.7 - 41.2 months) post-operatively. Non-pressure wounds (decubitus and dehiscence) were excluded. All 10 patients underwent vascular angiography during the perioperative period.
Results: Interventional balloon angioplasty was performed on 60% (6/10) of patients on one or more of the following vessels: superficial femoral artery (SFA), anterior tibial (AT), or posterior tibial (PT). Diagnostic angiography without intervention was performed on the remaining 40% of patients. No patients underwent peroneal intervention. In-line flow was present in 0% (0/10) of the peroneal arteries, 60% (6/10) of the anterior tibial arteries, and 70% (7/10) of the posterior tibial arteries; Heel blush was present in 60% (6/10). The incidence of vessel run-off was as follows: 70% (7/10) with 1VRO, 30% (3/10) with 2VRO, 0% (0/10) with 3VRO. The incidence of major lower extremity amputation was 30% (3/10) with a mean time of 5.2 months (3.5 - 8.3 months) from time of heel wound development.
Conclusion: The angiosomes to the heel are primarily vascularized by the posterior tibial and peroneal arteries. Current literature states that disease of the tibial peroneal trunk is a frequent finding in the diabetic limb, however there is sparse literature discussing successful intervention of the peroneal artery. Despite the presence of a posterior tibial artery or heel blush as demonstrated on angiography in this cohort, no patient had in line flow via the peroneal artery, nor did they undergo peroneal artery intervention. Our results demonstrate that intervention of the peroneal artery should be further investigated in patients with heel ulcerations to potentially increase rates of limb salvage.

P21.06

Diabetic Patients with Peripherial Arterial Disease: Associated Factors for a Successful Syme Amputation

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Aim: We recorded our experience with Syme amputation(SSA) in adult diabetic patients searching for any predictive criteria for successful results; taking into the assessment of vascular parameters (Posterior tibial artery flow), renal disease status and metabolic parameters.
Methods: We retrospectively study 17 diabetic patients who have undergone a Syme amputation between 2008-2016. The condition of the posterior tibial artery was evaluated by digital angiography and in case of occlusion it was revascularized prior to the amputation. Risk factors were evaluated.
Results: The median age was 57 years. The predominant lesion was ischemia. Ten patients had occlusion of the posterior tibial artery; 8 were revascularized, of which 4 were successful.
Nine patients evolved favorably and did not require a higher level of amputation. Eight patients required a major amputation, 7 infrapatellar and 1 supracondylar. At the time of the Syme amputation, 6 patients continued with the posterior tibial artery occluded. Permeability of the posterior tibial artery was statistically significant. (p=0.0152) For risk factors, only the dialysis gave a statistically significant result. (p=0.0034)
Conclusion: Syme amputation in diabetic patients may be an alternative in patients with preserved heel pad tissue and posterior tibial Artery permeable at the time of surgery. Patients on dialysis may be more likely to fail at this level of amputation. We found no relationship between other factors and the evolution of amputation.
References:
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Risk Factors evaluated

Risk Factors	Total	Successful	Not successful	p
	n=17	n=9	n=8	
Dialysis, n (%)	8 (47)	1 (11)	7 (87)	0,0034
Kidney-Pancreas Trasplant, n (%)	1 (5)	1 (11)	0	1
Insulin dependent Diabetes, n (%)	13 (76)	5 (55)	8 (100)	0,0824
Smoking, n (%)	8 (47)	3 (33)	5 (62)	0,3469
Dyslipidemia, n (%)	8 (47)	4 (44)	4 (50)	1
Obesity, n (%)	4 (23)	2 (22)	2 (25)	1
HbA1c Preop, gr/dL	7,4 (1,5)	7,1 (1,5)	7,7 (1,6)	0,4660
Albumin Preop, gr/dL	2,8 (2,6-3,1)	3,1 (2,6-3,3)	2,75 (2,55-2,9)	0,2096

P22.01

Safety of Tap Water for Diabetic Wounds Cleansing, Jabir Abueliz Diabetic Center (JADC), Khartoum, Sudan

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Aim: To investigate the safety of tap water for cleansing diabetic wound from bacteriological point of view.
Methods: this is cross-sectional study, carried from 25 Feb till 28 Mar in JADC, Khartoum, Sudan. Sample was water used for cleansing wounds in diabetic foot clinic. It was collected by stratified random sampling method. One hundred and twenty specimens were collected under aseptic technique from different taps and containers. They were processed immedialetly, cultured on Blood and MacConkey agars. Over night incubated at 37 C and interpreted next day.
Results: Bacterial growth for all specimens was minimum and hardly exceeded the inoculum , so considered as insignificant. This did not require any further identification.
Conclusion: the tap water which is used for cleansing wound in JADC is bacteriologically safe. The cleansing by tap water was discussed for years [1,2,3] and most of data refer to lack of adverse events; infection and slowness of healing. Putting these points in mind beside the availability of tap water in comparison with normal saline and other solutions tap water should be considered as preferable for cleansing of diabetic wounds in low income countries.
Limitation: bacterial count was not carreid as the bacterial counting chamber was not available.
References: 1. Lynne Watret, The Diabetic Foot Journal Vol 12 No 3 2009; 2. Christina Chao, August 1, 2015, Volume 92, Number 3 American Family Physician; 3. Fernandez R, Griffiths R, Cochrane Database of Systematic Reviews 2012, Issue 2. Art. No.: CD003861. DOI: 10.1002/14651858.CD003861.pub3.
Acknowledgements: GADC provides the collection tools along with the culture media and equipment.

P22.02

The Results of Diabetic Foot Syndrome Screening Among Rural Patients with Diabetes in Uzbekistan

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Diabetic foot syndrome (DFS) is currently considered the most severe of all late diabetes complications, resulting in deteriorating health outcomes, increased disability and reduced life expectancy.
Aim: To study the frequency of occurrence of DFS in rural peoples with diabetes in Uzbekistan
Methods: Upon the international project WDF08-379 "Prevention of lower limb amputations in people with diabetes in Uzbekistan", implemented by "Umid" Charity Association jointly with Ministry of Health of Uzbekistan and RSSPCE in 2010-2012, 1262 patients were screened for DFS in 6 pilot rural regions, of them 184 peoples with Type 1 Diabetes and 1078 patients with Type 2 Diabetes, in the 25-65 age-group with duration of the disease 7-15 years.The examination of patients included determination of HBA1c and hyperglycemia level, Doppler ultrasound, ECG, the tests for vibration, pain, tactile and temperature sensitivity evaluation, as well as health examinations by multidisciplinary team (endocrinologist, surgeon, cardiologist, podiatrist).
Results: Findings from the screening showed the diabetic polyneuropathy in 83,2% of peoples with T2DM и 67,4% of those with T1DM, hyperkeratosis (64,8%), trophic ulcers (17.3%); ischemia of lower limbs vessels (24.2%), Charcot's foot (9 %); gangrene (0.3%). Frequency of DFS occurrence was 55.3% (T2DM) and 31.7% (T1DM) accordingly. The greatest number of lower limb amputations (3.8%) and re-amputations (2.0%) was found in T2DM patients with disease of more than 10 years. 68% of peoples with diabetes were hypertensive. The major cause for DFS developing and further amputation was prolonged decompensation stage (HbA1c> 8.6% in 94,2% of peoples with diabetes) and a poor knowledge on rules of foot care in rural regions.
Conclusions: Frequency of DFS occurrence in Uzbekistan was 55.3% (T2DM) and 31.7% (T1DM) accordingly. The greatest number of lower limb amputations (3.8%) and re-amputations (2.0%) was found in T2DM patients with 5-10 years disease duration. Decompensation stage (HbA1c > 9.5%) in 94.2% of peoples with diabetes is one of principal causes of high frequency of DFS occurrence, a considerable number of amputations and development of other diabetes complications. That shows the necessity to improve the education quality on foot care in Diabetes Self-Management schools.

P22.03

Evaluation of an Interdisciplinary Diabetic Foot Clinic at Siriraj Hospital: a Retrospective Study

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Objectives: To study diabetic foot problems and effectiveness of interdisciplinary diabetic foot care at Siriraj Diabetic Foot clinic
Methods: Patients' records were retrospectively reviewed for 12 months after the first visit to the Siriraj Diabetic Foot clinic. Results of risk classification screening and follow up, foot ulcer healing time, new ulcer, recurrent ulcer, lower limb amputations, mortality, and risk factors of ulcer development and healing were recorded.
Results: There was the total of 317 patients, 75 low risk, 93 mod-

erate risk, and 149 high risk with foot ulcer in 59 cases. All patients received diabetic foot screening at their first visit. At 12 months follow up about 79.5% of patients underwent follow up screening, 20% loss to follow up, and 1 patient was dead due to ulcer infection. There was the total of 108 ulcers, 49% old ulcer, 51% recurrent ulcer. Result showed 58.3% of those ulcers healed with the median of ulcer healing time for 6 months, 27.8% of ulcer was not healed, and 7.4% underwent minor amputation. Significant factors for ulcer healing were proper diabetic shoes and shoes modified at the clinic which improve ulcer healing by 5-6 times.
Conclusion: This study demonstrates baseline characteristics and effectiveness of interdisciplinary diabetic foot care at Siriraj Diabetic Foot clinic. Proper shoes are a positive factor for diabetic foot ulcer healing. The result of this study will be an important database for future service and research development.

P22.05

Development of Diabetic Foot Nurse Professional in Thailand

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Aims: Diabetic foot patients need multidisciplinary care team. Major roles and responsibilities of nurses in the diabetic foot care team in developing countries where resources are limited have not been specified. The aims of this presentation are to identify major roles and responsibilities of nurses, pathway and its major obstacles to develop diabetic foot nurse professionals in Thailand.
Methods: The study was conduct at the Faculty of Medicine Siriraj Hospital because it is the biggest university hospital in Thailand providing healthcare services from primary to tertiary care levels.
Results: Major roles and responsibilities of nurses on diabetic foot care teams include patient evaluation for risk category, ABI measurement, ulcer care, and individualized patient education. They also act as the manager, and coordinator of the team. Moreover, and the same as many other developing countries, Thailand has no podiatry professionals in the healthcare system. Nurses have to take care of trimming callus and nail care.
In the current healthcare system in Thailand, there are general regulations for career path development to become a nurse professional in specific problems. The knowledge required for these positions are divided into 5 levels from K1 to K5. There are specific requirements, such as duration of work and publications, for each level. Currently there is only 1 nurse who is recognized as K3 (senior professional level) in diabetic foot care. The major problem is the time required to go from one step to the next and there is no specific training course for diabetic foot care nurses. They must take different short courses at different institutions while assuming their existing, routine nursing responsibilities.
Conclusions: Nurses have many roles and responsibilities in the diabetic foot care team in Thailand, where resources are limited. Diabetic foot problems are complicated and taking care of diabetic foot patients requires skilled personnel. Multi-tasking skills for nurses needs to be urgently developed, and specific diabetic foot training course for nurses is recommended.

P22.06

Simple, Low-Cost, Effective Ways to Provide Offloading Insoles for Low Income Regions

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Aim: As the prevalence of diabetes continues to rise in every country there is an increasing need to provide therapeutic footwear and offloading insoles for persons with diabetic peripheral neuropathy and at-risk feet in low-resource, developing countries.
Method: Literature review and case studies.
Results: Published research demonstrates that offloading via custom or customized shoe insoles is a proven method for reducing areas of elevated peak plantar pressures on the foot. There has also been exhaustive research performed comparing different materials, designs and methods of manufacture. This research reveals that there are many viable approaches to constructing an insole that could provide sufficient offloading to ulcers, pre-ulcerative calluses and plantar prominences of the foot.
Conclusions: In recent years, an international working group has spent time in West Africa developing and implementing a program to train local medical providers to measure for, fabricate and adjust custom footwear using affordable, locally-sourced materials. By all accounts, the program has shown success. This same concept can be utilized for the creation of a simple, repeatable process to fabricate custom insoles to provide offloading insoles in these same developing countries and low-income rural areas. The process would necessarily focus on simple techniques enabling custom offloading insoles to be fabricated with minimal or no specialty materials or equipment and in only one visit to the provider. This can and should be done.

Direct molded offloading insole

P23.01

Disparities in Inpatient Management and Outcomes of Diabetic Foot Infections in the United States, 2002-2015

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Aim: The purpose of this study was to evaluate the disparities in the inpatient management and outcomes among different ethnicities with the diagnosis of diabetic foot infection (DFI).
Methods: The HCUP-Nationwide Inpatient Sample (2002 to 2015) was queried to identify patients who were admitted for management of DFI using ICD-9 codes. Outcomes evaluated included minor and major amputations, open or endovascular revascularization, and hospital length of stay (LOS). Trends for amputation and open or endovascular revascularization were evaluated over the study period. Multivariable regression analyses were performed to assess the association between race/ethnicity and outcomes.
Results: There were 150,701 admissions, including 98,361 Whites, 24,583 African Americans (AAs), 24,472 Hispanics, and 1,631 Native Americans (NAs) in the study cohort. 45,278 (30%) underwent minor amputations, 9,039 (6%) underwent major amputations, 3,151 (2%) underwent open bypasses, and 8,689 (5.7%) had endovascular procedures. There was a decreasing trend in major amputations and an increasing trend of minor amputations over the study period (P<.05). The risks for major amputation were significantly higher (all p<0.05) for AA (OR 1.4, 95% CI 1.4, 1.5), Hispanic (OR 1.3, 95% CI 1.3, 1.4), and NA (OR 1.5, 95% CI 1.2, 1.8) patients with DFIs compared to Whites. Hispanics (OR 1.3, 95% CI 1.2,1.5) and AAs (OR 1.2, 95% CI 1.1,1.4) were more likely to receive endovascular intervention or open bypass than Whites (all p<0.05). NA patients with DFI were less likely to receive revascularization procedures (OR 0.6, 95% CI 0.3, 0.9, p=0.03) than Whites. The mean hospital LOS was significantly longer for AAs (9.2 days) and Hispanics (8.6 days) with DFIs compared to Whites (7.9 days, p<0.001).
Conclusions: Despite a decreasing trend in amputation over the past decade, racial and ethnic minorities including AAs, Hispanic, and NA patients with DFIs have a significantly higher risk of major amputation and longer hospital length of stay than their White counterparts. NAs were less likely to receive revascularization procedures compared to other minorities despite exhibiting an elevated risk of an amputation. Further study that investigates potential causes of disparities may help promote equity in the treatment and outcomes of these at-risk patients.

P23.02

Arterial Insufficiency, Infection, and Foot Deformity Concept in the Management of Diabetic Foot Ulcer

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Aim: There is consensus that arterial insufficiency, infection, and foot deformity with neuropathy are significantly associated with diabetic foot ulcer (DFU) healing. Although critical limb ischemia is not uncommon, traditional and new classifications do not take into account the coexistence of deformity and neuropathy, and the clinical significance of foot deformity. Thus, this study aimed to investigate the impact of foot deformity on the clinical outcomes in patients hospitalized for the treatment of DFUs.
Methods: The study involved 133 consecutive patients hospitalized because of lower-extremity wounds at Yao Tokushukai General Hospital between January 2015 and December 2016. Based on data from these patients, we analyzed the DFU cohort for the incidence of arterial insufficiency, infection, and deformity (AID) separately. Wound severity was graded from 0 to 3 using the AID score and patients with and without AID were compared.
Results: AID scores of ≥1 were observed in all patients with DFUs. DFUs were predominantly complicated by infection (88%), followed by foot deformity (87%). Patients with AID scores of 3 demonstrated the worst wound healing despite comprehensive management. The Cox proportional hazards model demonstrated a significantly (P=0.002) lower healing rate, and there was a 32% decrease in the hazard for wound healing with every 1-point increase in the AID score (HR, 0.678; 95% CI: 0.528-0.870).
Conclusions: Foot deformity is a dominant factor affecting clinical outcomes in patients with DFUs; therefore, pressure off-loading is essential. AID scoring shows a significant difference in wound healing during the management of DFUs.

P23.03

Prognosis of Diabetic Foot Ulcer at One Year Follow-Up : Differences between Genders

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Aim: The aim of this study was to explore prognostic factors related to ulcer healing and to identify differences between genders in outcomes of diabetic foot ulcer at one year follow-up.
Methods: We have retrospectively evaluated 172 patients with diabetic foot ulcer between January and December 2016.For the study period 155 patients with diabetic foot ulcer were included, while 17 patients were excluded because lost to follow-up.We divided population in two groups based on gender. After one year of follow-up the following outcomes were evaluated: healing, minor amputation (below the ankle), major amputation (above the ankle),revascularisation,death.
Results: The majority of patients were male (n.106, 68%).The mean age was longer in women (77.6± 9.75 vs 71,6± 10.3 years p<0.001).Women and men had similar diabetes duration (17.9±8.0 vs. 19.0±11.2 years) while women had worse metabolic control (HbA1c 7.92%±1.94 vs 7.66%± 1.36) and higher prevalence of chronic kidney disease.Men were more common ex smokers (52.8% vs 14.2% p<0001),they had higher prevalence of ischaemic heart disease (34.9% vs 18.3% p<0.03).Both groups presented a similar rate of neuropathy and peripheral arterial disease. The total rate of healing was 81,9% but the outcomes for women and men were respectively: healing(91.8% vs 77.3% p<0.02) minor amputations(16,1% vs 10,2%) major amputations (2% vs 1,88 %) revascularisation (22.4% vs 15%) death (2.0% vs 9.4%). At the multivariate regression model of all predictors found at univariate analysis only sex male resulted an independent predictor of non-healing even after correction for age and HbA1c levels. Presence

of Ischaemia and of Infection at baseline were associated (p < 0,019 and < 0,0001 respectevly) with worse outcome (healing) in Males but no in Females.
Conclusions: Data from this study show that women with diabetic foot ulcer were older but have better rate of healing, while men had higher rate of ex smokers and higher prevalence of ischemic heart disease.Sex Male were independently associated with poor outcome (Healing) at one year. The first explanation it's probably linked to a more frequent smoking habit.With the limitation of little study sample the negative effect of ischaemia and infection to outcome appear to be more pronounced in Man.

P23.04

Multiple Ulcers in Patients with Diabetes – Clinical Characteristics and Outcome

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Introduction: Patients with diabetes and a foot ulcer have a high risk for complications. In the presence of multiple ulcers, this risk would seem to be even greater. However, patients with diabetes and multiple foot ulcers are usually not studied separately. The purpose of this study was to gain knowledge of this patient group with emphasis on characteristics and outcome.
Patients and Methods: During the observation period (January 1st 1983 to December 31st 2013) 543 patients fulfilling the inclusion criteria presented with multiple foot ulcers. Fifty patients were lost to follow-up. A total of 493 patients (319 men, 174 women) with a median age of 73 (range 32-95) years remained for analysis.
Results: Twenty six per cent (126/493) of the patients healed without the need for foot surgery, 11% (55/493) healed after foot surgery, nine per cent (42/493) healed after minor amputation, 20% (99/493) healed after major amputation, and 35% (171/493) died unhealed. Multiple regression analysis of factors related to outcome was performed.
Median duration of diabetes was 15 (0-70) years, and severe peripheral vascular disease was present in 49% of patients.
Conclusion: Despite these patients being elderly and often present with extensive comorbidity, more than one third still heals without amputation. Patients with diabetes and multiple foot ulcers have a high mortality rate. Preventing diabetic foot ulcers, and specifically multiple foot ulcers, is an important part of treatment for this patient group.

P23.06

Comparison of Disease and Foot-Related Mechanical Factors in High Risk Patients with and without Ulcer History

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Aim: The Scottish Diabetes Group foot risk stratification system has a new ulcer remission sub-category for patients at high risk. This pilot study aimed to compare demographic, disease and foot-related mechanical factors in high risk patients with ulcer history (remission) compared to no ulcer history.
Methods: We studied 52 participants (37 male / 15 female) with a mean (SD) age 65.4 (8.8) years classified as high risk on the Scottish Diabetes Group foot risk stratification system. Demographic, clinical and foot related information was extracted from the Scottish Diabetes Care Information system (SCI- Diabetes). Patients underwent barefoot plantar pressure analysis using an EMED-X platform (Novel GmbH, Munch, Germany) to identify peak plantar pressures at the forefoot regions of interest. Variables were compared using the mean difference and associated confidence intervals from the t distribution and Chi-Square analysis.
Results: In comparison with high risk participants with no ulcer history (n=19), those with an ulcer history (n=33) had higher HbA1c (mean difference 14.4mmol/mol, 95% CI 2.9, 26.0) and higher levels of social deprivation (52% with ulcer history and 16% no ulcer history). There were no differences between groups for disease duration, BMI, estimated glomerulus filtrate rate, and comorbidities; and equivalent levels of peripheral arterial disease and peripheral neuropathy. Foot deformities occurred more frequently in the patients with ulcer compared to no ulcer history on the right (75% Vs 68%) and left (85% Vs 58%) feet. On presentation plantar callus requiring debridement was found more frequently in participants with ulcer history for the right (52% Vs 26%) and left feet (51% Vs 26%). Forefoot peak pressures were comparable for both groups (1019kPa in those with ulcer history Vs 920kPa without history, mean difference 99kPa, 95%CI: [-83kPa; 281kPa]), hallux (508kPa Vs 528kPa, mean difference -20kPa, 95%CI: [-220kPa; 180kPa]), and lesser toes (211 Vs 194kPa, mean difference 16kPa, 95%CI: [-88kPa; 120kPa]).
Conclusions: High risk patients in ulcer remission have comparable peak plantar forefoot pressures but more frequent deformity and callus in comparison with those with no ulcer history. In addition, these patients have poorer glycaemic control and are exposed to more social deprivation. Sub-categorisation appears merited.

P24.01

Insoles To Ease Pressure (INSTEP): an Offloading Algorithm for the Manufacture of Chairside Insoles for Diabetic Foot Ulcer Protection.

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Aim: To develop an instant offloading intervention for people with diabetes featuring a novel clinical decision-making algorithm. This utilises temporal loading patterns combined with pressure patterns from in-shoe pressure measurement technology.
Methods: Development work employing a range of methodologies

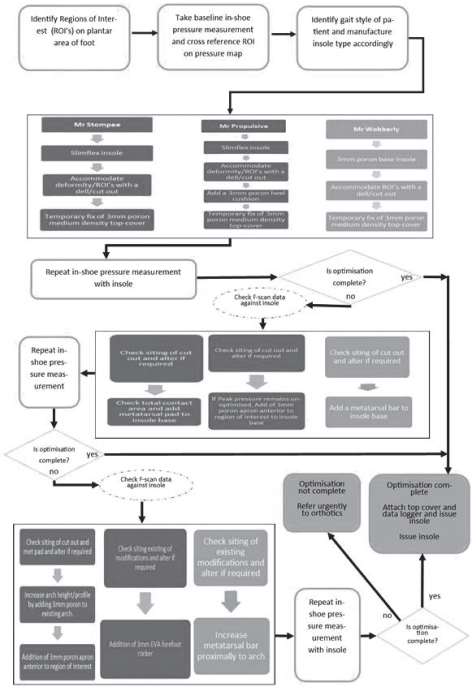
informed this instant offloading insole solution. Definitive RCT data underpinned the theoretical concept and directed the utilisation of in-shoe pressure technology (Paton et al, 2012). A systematic review identified the best type of insole and modifications for offloading. A proof of concept study showed potential for implementation. Patient focus groups assessed intervention acceptability. Expert NHS podiatrists input with context experience was received.

Results: Customised chairside insoles, utilising in-shoe pressure technology, are as effective as casted TCI's. Meta-analysis identifies the metatarsal dome and aperture as the best offloading modifications. The insole protocol can be completed within 1.5 hours utilising readily available materials and this was acceptable to patients and clinicians. Patients perceived they were receiving a better insole if they saw technology being used to direct the manufacture. The data culminated in the insole algorithm (figure 1).

Next steps: A mixed methods feasibility RCT study is underway to evaluate the operational experience of the insole algorithm to inform the design of a definitive trial.

Funding: Supported by National Institute for Health Research Clinical Academic Training (NIHR CAT) Clinical Doctoral Fellowship.

References: Paton et al. Journal of Foot and Ankle Research 2012, 5:31



P24.02

Changing Concepts–Changing Minds: Ulysses Contracts in the Treatment of Diabetic Foot Ulcers With Non-Removable Offloading Devices

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Aim: To change concepts is important to change how clinicians and patients conceptualize and act on diabetic foot disease. Different concepts have been introduced for different purposes, e.g., "diabetic foot attack" to emphasize urgency (1), "in remission" to emphasize the high risk of reulceration (2), and "latent diabetic foot disease" to emphasize diabetic foot disease as a single process, encompassing both active and latent phases (3). The aim was to review and discuss conceptualizations of treatment with non-removable offloading devices.

Methods: Review and analysis of literature.

Results: The "forced compliance" concept has been used to denote the use of non-removable offloading devices as a means to secure a high level of compliance/adherence (4). However, this concept may be inappropriate for two reasons. First, the concept has a paternalistic connotation of patients obeying doctors, which is not compatible with viewing patients as partners in decision making. Second, the concept conveys the meaning of doctors as being active ("forcing" compliance) and patients as being passive (being "forced"). Although these connotations are unintended they still may counteract the active and long-term personal responsibility for self-care that we wish to stimulate in our patients.

"Ulysses contracts" (originating from Homer's Odyssey) denote freely made decisions that bind the person in the future. Conceptualizing non-removable offloading devices as Ulysses contracts rather than means to force compliance has two advantages. First, Ulysses contracts emphasize that patients make choices by free will. Second, the "forcing" (i.e., eliminating the alternative to be non-compliant/adherent in the future) does not happen between the doctor and patient, but between the patient's current and future self. Hence, the patient remains an active and responsible agent during the treatment period which hopefully will spill over into the in remission periods, when removable devices are used and personal responsibility for adherence is crucial.

Conclusions: Ulysses contracts could be a viable way to conceptualize treatment with non-removable offloading devices.

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2. Armstrong, DG. J Am Podiatr Med Assoc. 2013;103:161-2.
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P24.03

Insoles for Balance Enhancement and Ulcer Prevention (BEUP insole): a Proof of Concept Crossover Randomised Control Trial

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Aim: To compare the clinical functionality and patient acceptability of two dual-purpose insoles designed for balance enhancement and ulcer prevention.

Methods: A crossover randomised control trial recruited 15 neuropathic participants with diabetes, that were sequentially randomly allocated to two customised insoles, featuring augmented cutaneous stimuli, for a two week period separated by one week washout.

Participants trialed i) a total contact insole with metatarsal cushioning and novel textured top cover heel section, ii) a cushioned insole with metatarsal bar and novel proximal ankle bracing. The prototype insole designs were informed by data gathered from talking to people with diabetes who wear insoles, a literature review, and an exploratory study comparing different insoles to see which was best at improving the postural stability of people with diabetes. Computer generated permuted block randomisation balanced intervention allocation across groups. The F-scan pressure measurement system captured in-shoe plantar peak pressure and bilateral standing balance (eyes closed) at issue and two weeks. Participants completed insole adherence and acceptability daily diaries. At study end, participants revealed which insole they would prefer to keep and reasons why.

Results: Whilst both insoles reduced plantar peak pressure by a significant amount there was no difference in effectiveness (20% vs 22%). There was no difference ($p>0.05$) in centre of pressure excursion or area in anterior-posterior or medio-lateral direction for any comparisons made. The total contact insole with textured heel section was preferred by our volunteers, because it was easier to take on and off and was less visually intrusive.

Conclusion: Validation of the concept that an insole, utilising cutaneous stimuli design specifications to enhance residual sensory information, can improve postural stability in people with diabetes and sensory loss, cannot be made at this time. User convenience and maintaining an outward visual perception of 'normal' are key acceptability factors among users of insoles with diabetic neuropathy.

Acknowledgement: This is a summary of independent research funded by the National Institute for Health Research (NIHR)'s CAT Clinical Lectureship Programme. The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

P24.04

Methodological Considerations of Investigating Adherence to Using Offloading Devices Among People With Diabetic Foot Complications

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Aim: Adherence to using offloading devices is often low (1) and studies on adherence are difficult to compare due to methodological heterogeneity. The aim was to explore aspects of investigating adherence and provide recommendations for future studies.

Methods: A literature review was conducted of quantitative studies focusing on study designs, definitions of adherence, measurement methods, and conceptual frameworks.

Results: Most studies are cross-sectional and observational, limiting the potential to rule out confounding and establish causality (Table 1). Studies defining adherence as wearing time often use self-report to measure adherence, which can be unreliable. Studies that measure adherence with activity monitors often define adherence as the number of steps taken with the device, which excludes weight-bearing activities where no steps are taken. Conceptual frameworks are not made explicit in current research.

Conclusions: Future studies should be longitudinal; observational studies to identify non-adherent patient groups and factors that influence adherence, and experimental studies to evaluate interventions to improve adherence, focusing on these patient groups and factors. Adherence should be defined in terms of relative adherence to using offloading devices during all weight-bearing activities (walking, standing, etc.), and objective measurement of adherence should be used whenever possible. Conceptual frameworks should be defined to guide the choice of factors to include in the study and the analysis. Implementation of these recommendations could lead to a stronger evidence base in the future, supporting interventions to increase adherence and thereby improve outcomes for people with diabetic foot complications.

References: 1. Waaijman R. Diabetes Care 2013;36:1613-18.

Aspect	Dominating approaches in current research (number of studies)	Recommendations for future studies
Study designs	Cross-sectional, observational	Use longitudinal study designs; observational studies to identify non-adherent patient groups and factors affecting adherence and experimental studies to evaluate interventions to improve adherence.
Definitions of adherence	Wearing time (n=11) or number of steps taken with the device (n=6)	Define adherence as device use during all weight-bearing activities.
Methods to measure adherence	Interviews (n=6), questionnaires (n=7) temperature monitors, (n=6) pedometers (n=6), accelerometers (n=1)	Use objective methods (accelerometers and temperature monitors) whenever possible. Validated questionnaires can be used for surveys.
Conceptual frameworks	Frameworks not defined, focus on a narrow range of factors (e.g., patient-, therapy-, and condition-related factors).	Use clearly defined frameworks (e.g., the health belief model or the common-sense model of illness behavior) and include a wide range of factors (e.g., social and economic circumstances and health system-related factors).

Table 1. Approaches in current research and recommendations for future studies

P24.06

Can New Embedded Pressure Insoles Identify the Clinical Grade of Risk in Diabetic Foot?

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Aim: High foot plantar pressures have been identified as increasing the risk of diabetic foot ulcers (DFU). The development of reliable devices to measure plantar pressure in routine care is important to improve the prevention of DFU. The aim of the study was to evaluate the new pressure connected insoles during gait.
Methods: Diabetic patients with grade 1, 2 or 3 according to IWGDF risk classification were included in two diabetic foot centers in France. New embedded pressure insoles were used for measurements in standardized shoes (1). These connected soles have a matrix of 70 capacitive sensors connected wirelessly to a smartphone. The metrics analyzed were: pressure peak, mean pressure and pressure-time integral. Two statistical methods were applied either on all steps (AS) or on the step with the highest value (OS) for each parameter.
Results: A total of 120 patients (72% men) were included: 9 grade 1; 52 grade 2; 59 grade 3; average ± SD age was 66 ± 11 years; BMI was 30 ± 6 kg/m2. They were mostly type 2 diabetes (91%) and the duration of diabetes was 20 ± 11 years. The step analysis with the highest value per metric (OS) showed a significant difference between grade 2 and 3 (p=0.002) only for the pressure-time integral. The analysis taking into account all steps (AS) showed a significant difference on all metrics (mean pressure: p=0.016, peak pressure: p=0.0002, pressure-time integral: p=0.0001).
Conclusions: We confirmed that grade 3 patients have a higher pressure-time integral than grade 2 patients by applying both statistical methods (OS and AS). AS analysis showed significant differences for each of the three measured parameters and seems to guarantee discrimination between grades 2 and 3. We cannot conclude for grade 1 patients due to the small number of inclusion. This study opens the prospect of further studies to assess the impact of this easy-to-use wireless system in everyday activities to prevent DFU.

P25.01

A Finite Element Analysis Investigation Into the Measurement of Shore Hardness of the Plantar Soft Tissues of the Foot

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Aim: The aim of this study was to investigate the physical meaning of Shore hardness in assessing plantar soft tissue stiffness.
Methods: A Finite Element Analysis (FEA) model was created to simulate Shore hardness testing (Figure 1). Both skin and soft tissue were modelled as Ogden hyperelastic (1st order). Parametric analysis was conducted to investigate the effect of changes in the mechanical properties of both skin and subcutaneous soft tissue on the measurement of Shore hardness.
Results: A one unit increase in the measurement of Shore hardness could be a result of either 0.09% vs 0.25% or 0.26% vs 0.26% stiffening of skin vs stiffening of subcutaneous soft tissue respectively. A one unit decrease in the measured value of Shore hardness could be a result of either 0.12% vs 0.31% or 0.31% vs 0.32% decrease in stiffness of skin vs decrease in stiffness of subcutaneous soft tissue.
Discussion: The results of this study have shown that the measurement of Shore hardness is not just influenced by the skin hardness but is instead affected by a combination of both the mechanical properties of the skin and those of the subcutaneous soft tissue. The smallest possible change in mechanical properties detectable was either a 0.09% increase in the stiffness of the skin or a 0.25% increase in the stiffness of the subcutaneous soft tissue. This makes the measurements of Shore hardness unable to differentiate between the stiffness of subcutaneous soft tissue and that of the skin.

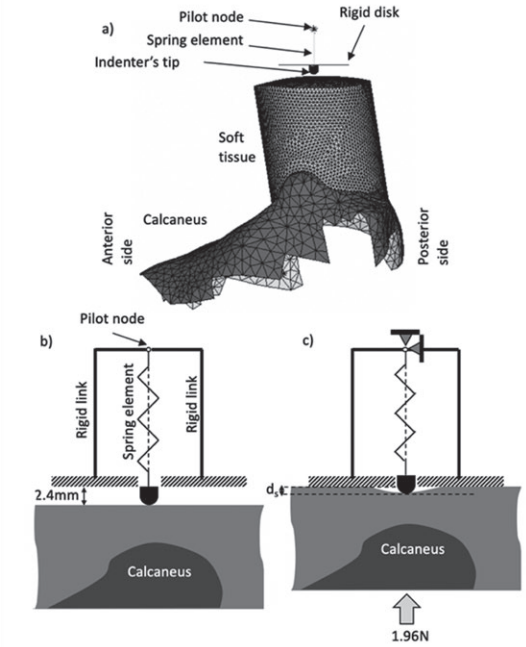

Figure 1: a) Pictorial representation of the meshed model of the heel model and the simulation of the Shore hardness durometer. b) A simplified view of the FEA model showing the durometer in contact with the surface of the heel before indentation. c) Boundary conditions and applied loading during indentation.

P25.02

WoundVue Camera: a Novel Ddevice to Assess Diabetic Foot Ulcers

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Aim: The initial wound measurement and regular monitoring of diabetic foot ulcers is critical to assess treatment response. There is no standardised, universally accepted, quick, reliable and quantitative assessment method to characterise diabetic foot ulcers. To address this need, a novel topographic imaging system has been developed. Our project aims to assess the feasibility and practicality of the WoundVue camera technology.
Methods: The WoundVue camera is a prototype device using the Ensenso N10-408-18 camera system. The camera system consists of two infrared cameras which image the wound from a vantage point and an infrared projector which projects a textured pattern of light to correlate the images generated. The process of triangulation combines the range of all points in the image, thus obtaining a three-dimensional reconstruction of the wound. Fifty-seven diabetic foot wounds from patients seen in multidisciplinary foot clinics in Australia were photographed from two slightly different angles and distances using the WoundVue camera. Wound area, volume and maximum depth were measured for assessment of reliability. Thirty-one of these wounds also had area calculated using the Visitrack™ system (Smith and Nephew) and correlation between area obtained using both systems was assessed.
Results: WoundVue images test-retest analysis showed excellent agreement for area [ICC 0.995 (95% CI 0.991 – 0.997)], volume [ICC 0.988 (95%CI 0.979 – 0.993)] and maximum depth [ICC 0.984 (95% CI 0.975 – 0.990)] measurements. Good agreement was found for area measurement using the WoundVue camera and Visitrack™ system [ICC 0.874 (95% CI 0.754 – 0.937)].
Conclusion: The WoundVue system is capable of recreating a 3D model of diabetic foot wounds and produces accurate and reproducible data. Digital images are ideal for monitoring wounds over time and the WoundVue camera has the potential to be a valuable adjunct in diabetic foot wound care.

P25.03

Exergame: a Novel Foot and Ankle Exercise During Hemodialysis to Improve Postural Balance

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Postural balance is significantly deteriorated in patient with end-stage renal disease undergoing hemodialysis, even when compared to people with diabetic peripheral neuropathy [1]. While exercise is beneficial to improve motor function, it is very limited among people with diabetes undergoing hemodialysis, due to issues such as lack of time availability, post-dialysis fatigue, and limitation of transportation to exercise facility. In this study, we examined the feasibility and effectiveness of a new game-based non-weight bearing exercise (Exergame) during hemodialysis to improve postural balance. 70 subject with diabetes undergoing hemodialysis were recruited and randomly assigned to either intervention (IG: n=37, age=61.8±7.0years, BMI=30.9±6.4kg/m2) or control (CG: n=33, age=66.8±10.3years, BMI=33.1±8.4kg/m2) groups. Both groups underwent a 4-week foot and ankle exercise program, twice per week for duration of 30-min during hemodialysis. The IG received exercise via the Exergame program, which integrates data from wearable sensors attached to subject's feet into an interactive interface designed for game-based cognitive-motor adaptation training. The CG received traditional exercise without technology. Postural balance were performed at baseline and conclusion of the program using validated wearable technologies. The IG had improved balance control for most of the balance parameters after 4-week of exercise, while the CG had increased body sways. When comparing the balance changes of the IG to the CG, significant improvements were observed for CoM sway during double-stance eyes-open and eyes-closed tests (p=0.010 and 0.040), CoM, ankle, and hip sways during semi-tandem eyes-open test (p=0.003, 0.008, and 0.038, respectively), and ankle sway during semi-tandem eyes-closed test (p=0.002). Results also showed that individuals with poorer balance enjoyed more benefits from the intervention. This study demonstrated feasibility and effectiveness of a novel Exergame program to improve postural balance in hemodialysis patients. The key innovation includes its practicality to be applied during hemodialysis process, which could address the low adherence of conventional exercise intervention in this vulnerable population. Further study will examine long-term benefit of the proposed intervention including prevention of foot problems.
Reference: 1. Zhou, H., et al., Hemodialysis Impact on Motor Function beyond Aging and Diabetes—Objectively Assessing Gait and Balance by Wearable Technology. Sensors, 2018. 18(11): p. 3939.

P25.04

Telemedicine and Home-Monitoring Applications for the Diabetic Foot: a Systematic Review

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Aim: to assess the medical-scientific literature on telemedicine and home-monitoring applications in the diabetic foot with respect to prevention, assessment/monitoring, and treatment.

Method: This is a systematic review. The MEDLINE database was searched on August 31, 2018 for original research articles on telemedicine and home-monitoring approaches used for the prevention, assessment/monitoring, or treatment of patients with diabetes and signs of foot complications like (a history of) ulceration, infection or Charcot arthropathy. All study designs were included and the search was limited to English language papers. The included interventions/modalities were dermal thermography, hyperspectral imaging, digital photographic imaging, and video/audio/online communication tools. Primary outcome measures were: validity, accuracy, feasibility, usability and (cost-) effectiveness.
Results: The search yielded 1311 articles of which 66 were found eligible for analysis. Most studies (24) were on the use of dermal infrared thermography as home-monitoring tool; four randomised controlled trials (RCTs) showed this method to effectively diagnose foot temperature changes and contribute to a significantly reduced incidence of foot ulcers compared to usual care. The cost-effectiveness of this approach is unknown. Hyperspectral imaging show conflicting results regarding the prediction of ulcer healing in clinical studies and is therefore not yet a reliable nor a feasible telemedicine solution. Photographic imaging can accurately and reliably assess foot ulcers and ulcer areas, and is feasible as modality in the patient's home, however photographic imaging cannot be used as a stand-alone diagnostic instrument. Two RCTs showed no differences in healing rate and amputation rate of ulcers treated at home by specialised nurses using an interactive Web-based ulcer record compared to regular outpatient care. Key-factors for this telemedical setup are: adequate wound care training for visiting nurses, user friendly technology and training, and effective communication channels at organisational level.
Conclusion: This systematic review shows that telemedicine and home monitoring for the diabetic foot is still in its infancy, but several promising technologies are available that may be of additional value in the prevention, assessment/monitoring, or treatment of foot disease. For some of these approaches, effectiveness, and in some cases even feasibility is not known yet and these aspects require further investigations.

P25.05

Rehabilitation Technology for Self-Care: Customized Foot and Ankle Exercise Software for People with Diabetes

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Aims: The use of technology by health providers has not only improved patient monitoring and adherence but has also reduced demands on healthcare facilities. A number of studies with diabetes mellitus (DM) patients have been conducted using e-health technologies that allowed people to engage in activities in their preferred environment, thereby taking up less of the health professional's time and decreasing demands on health centers. We develop and validate a web-based software (desktop and mobile applications) in Portuguese and English for self-management and customized foot-ankle exercises for people with DM and diabetic neuropathy (DPN).
Methods: The development of SOPED-Educational Diabetic Foot Software was based on gamification principles and addressed three main areas: foot-care recommendations; self-assessment of feet according to the main complications of diabetic neuropathy; and customized foot-ankle exercises to strengthen muscles, increase range of motion, and improve functionality, which was previously developed by a clinical trial and proven the efficacy of the exercises[1].Content was validated using Delb phi methodology and a quantitative approach in two rounds with diabetes specialists(n=9) and users with diabetes (n=20).A 70% approval rate was considered sufficient in the second round for final validation purposes. Data analysis was conducted by descriptive statistics, absolute and relative frequencies, and content-validity index(CVI).
Results: Among specialists, CVI was 0.812 after the first round, and final approval was 100% after the second round. Among users, CVI was 0.902 in the first round, and final approval was 97%.
Conclusion: The free access web-software (www.usp.br/labimph/fuzzy) achieved a high agreement between specialists and users and has the potential to prevent DPN complications. It allows self-monitoring and promotes personalized exercises, following a preventive model, to be applied in primary and secondary-care services as a complementary treatment for chronic complications.
Acknowledgements: CAPES(financial code 001),CNPq (305606/2014-0) and FAPESP (2015/14810-0).
References: [1] Sartor CD et al.BMC Musculoskelet Disord. 2012;13:36.

P25.06

The Effectiveness of Calf Muscle Electrostimulation in Patients Living with Type 2 Diabetes Mellitus and Peripheral Artery Disease

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Aim: To investigate whether calf muscle electro-stimulation improves arterial inflow and walking capacity in claudicants with peripheral artery disease and diabetes mellitus.
Methods: A prospective, one-group, pretest posttest study design was employed on forty participants (n=40) with bilateral limb ischemia (ABPI <0.90), diabetes mellitus and calf muscle claudication. Participants received a fixed program of calf muscle electrical stimulation with varying frequency (1- 250Hz) on both ischemic limbs (N=80) for 1-hour per day for 12- weeks. Spectral Doppler waveforms of pedal arteries; ankle brachial pressure index (ABPI); absolute claudication distance (ACD) and infrared thermal temperature patterns on the soles were recorded at baseline and following intervention to evaluate for therapeutic outcomes.
Results: Following sixty minutes of calf muscle electro-stimulation for twelve consecutive weeks on ischemic limbs (N=80) in diabetes patients; the ACD improved significantly by a mean of 137 meters' (p=0.000); the ABPI improved significantly by a mean of 0.04 (p=0.001); resting foot temperatures across all regions of interest on the soles of the foot increased significantly (p= 0.000). Mean-

while, the post-exercise temperature drops across the regions of interest were approximately halved across all locations at follow-up with two out of the four regions of interest reaching statistical significance (hallux, p=0.005; lateral forefoot, p=0.038). Spectral Doppler waveforms did not change (p=0.304) between both serial assessments.
Conclusion: Electrical stimulation of varying frequency (1-250Hz) for 1-hour per day for 12- consecutive weeks registered statistical significant improvements in outcome measures that assess arterial inflow and walking capacity in claudicants with diabetes mellitus. These results warrant further research in field of ES and its therapeutic potential in this vulnerable population. Future studies should ideally constitute randomized control trials with blinding to provide definite conclusions and strong basis for inference.

P26.01

An Autologous Leukocyte and Platelet-Rich Fibrin Patch Provides Immune Cells, Cytokines and Growth Factors Relevant for Treating Diabetic Foot Ulcers

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Aim: To investigate in vitro immune responsiveness and growth factor release of an autologous leukocyte-and-platelet-rich fibrin patch (APFP) for treating chronic wounds.

Methods: APFP were prepared from healthy donors as described in Lundquist, et al 2013[1]. In short, 18 ml blood was filled into a vacuumed device[2] and processed for 20 min in an automated 2-step program. The resulting 3-layered patch consist of fibrin, platelets and leukocytes. APFP were analyzed for immune cells by histopathology and flowcytometry. Cytokine and growth factor production was analyzed in culture supernatants after in vitro stimulation with: lipopolysaccharide (LPS), IL-4/IL-13 and Chronic Wound Fluid (CWF) and cytokine and growth factor production were assessed by ELISA. APFP culture supernatants were added (10%) to keratinocyte monolayer cell line (HaCaT) cultures for 18 hours and proliferation was assessed by MTT assay, and migration by scratch assay. A skin explant model (approval number: H-17041884) was used to evaluated APFP effect on epithelization.
Results: We show that APFP contain intact monocytes, T cells and B cells. APFP respond with production of IL-1β, IL-6, IL-10 and IL-1Ra to LPS and CWF in vitro stimulation (48 hours), respectively. In contrast, IL-4/13 stimulation result in exclusive IL-1Ra production. Furthermore, supernatants from APFP cultures (48 hours) induce proliferation by MTT and migration in HaCaT keratinocyte cell line and a skin explant. Topical application of APFP biopsies on skin explant wounds showed migration of the advancing epithelial tongue that is not enriched for Ki67.
Conclusions: We find that APFP can respond and adapt appropriately in the treatment of chronic wounds by delivering immune cells, cytokines and growth factors.
References:
1 Lundquist R, Holmstrøm K, Clausen C, et al. Characteristics of an autologous leukocyte and platelet-rich fibrin patch intended for the treatment of recalcitrant wounds. Wound Repair Regen 2013; 21:66–76.
2 3C Patch Device, Reapplix, Denmark

P26.02

Topical Application of Platelet Gel in Diabetic Foot Ulcers

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Topical application of platelet gel has been used to improve tissue repair.
Aim: assessment of diabetic foot ulcers treated with allogenic platelet gel between 01/01/2014 and 15/11/2018.
Platelet gel was produced from homologous platelet concentrate activated with calcium gluconate. Patients had hard to heal ulcers (over 4 weeks of evolution with gold standard treatment) and were followed prospectively with weekly follow-up registering demographics, comorbidities, glycemic control (HbA1c), ulcer size, number and time interval between applications, compliance, adverse reactions, and efficacy evaluation, namely: complete healing, partial improvement (50% reduction in the ulcer area) or no evolution.
Results: Sixty patients (47 males, 13 females), with a median age of 68 years (range 44-86) were proposed for platelet gel. On the 1st application they had a hard to heal not infected ulcer, with a median evolution of 8 months (range 1-168). The following associated comorbidities were observed: peripheral vascular disease (n=38), polyneuropathy (n=32), retinopathy (n=20), cardiac ischemic disease (n=19), nephropathy (n=18). On the 1st application median HbA1c was 7.7 % (range 5.2-11) and median ulcer area 1.85 cm2. The most frequent ulcer locations were plantar fore and mid foot (n = 16) and hind foot (n=11). The median number of applications was 16 (range 2-67), during 8 weeks (range 1-38). Twenty two patients (36.7%) achieved complete healing, 6 patients (10%) had a partial response and 30 (50%) had no improvement. Two patients were lost in follow up. Nine patients had at least 1 episode of ulcer infection during gel treatment (7 out of 9 with no response and 2 out of 9 with partial response). We did not observe a statistically significant relationship between HbA1c and response (chi-square p>0.05) nor beetween presence of some comorbidities (diabetic nephropathy, peripheral arterial disease) and response (chi-square p>0.05). Although not measurable, we observed a better response in patients with good compliance.
Eight out of 60 patients died of diabetes complications (n=2 during the 1st year since 1st application, n=3 during the 2nd and n=3 during the 3rd year).
Conclusion: Allogenic platelet gel may be an effective therapeutic alternative in diabetic foot ulcers, provided compliance is assured.

P26.03

Clinical Effects of Intralesional Injections of Recombinant Human EGF on Wound Healing in Diabetic Patients with Neuropathic or Neuroischemic Ulcers

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Aim: to evaluate clinical effects of intalesional injections of rhEGF (Heberprot-P, Cuba) on wound healing in diabetic foot ulcers (DFU)
Methods: Open prospective randomized clinical trial included 20 patients, resistant to standard management ≥ 4 weeks prior to study, who received at least 1 maximum 10 injections of rhEGF. The duration of treatment was 6 weeks. The follow-up period lasted 20 weeks. Routine clinical examination, transcutaneous oxygen measurement (TcpO2), evaluation of wound area and depth before and after treatment were performed. All patients received the offloading with the AirCast (diabetic Walker).
Results: We observed 20 patients (13men; 7women) with neuropathic and neuroischemic diabetic foot ulcers. Before treatment the surgical debridement of ulcer was performed. The wound bed should have been filled with granulation tissue less then 20%. TcpO2 less than 35 mmHg was the exclusion criteria.
The group was represented mainly by patients with type 2 DM, median age was 56 [52; 62] years, mean duration of diabetes was 15 ± 9 years, meadian HbA1c - 8,4 % [7.2;10.3], 12 neuropathic, 8 neuroischemic - 8 (at least 4 weeks after revascularization), meadian wound size before treatment was 6.5 [4.2; 11.6]cm2, wound depth 1.7 [0.9;2.2] cm, TcpO2 - 43,7 ± 17mmHg.
After 2 weeks period of treatment (6 injections were performed) the significant reduction of wound size was found: the median area was 3.4 [1.2; 5.3] cm ($p< 0.01$); wound depth decreased to 0.5 [0.0; 3.8], $p<0.01$.
Within the 5±1 weeks 100% of wound bed was filled with granulation tissue. The full epithelization was achieved in 72% of cases during 12 weeks. At the 20th week we observed the lack of wound healing in 1 case (due to non-compliance of patient for offloading). No serious adverse events were registered.
Conclusion: The adjuvant treatment by rhEGF significantly reduces wound size and depth and lowers the duration of wound healing. However, this method requires further studies on a larger patient population and the placebo-control arm.

P26.04

The Effect of Autologous Blood-Patch Treatment Among Patients with Hard-To-Heal Wounds; a Clinical Perspective.

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Aim: To describe the effect of treatment with an autologous blood patch(I) among patients with hard-to-heal wounds, including both diabetics and non-diabetics.
Methods: The treatment is implemented in a multi-disciplinary outpatient clinic specialized in advanced wound treatment, as a supplement to standard care (off-loading, compression, debridement, infection control etc.). Only patients with hard-to-heal wounds (wound duration>6 weeks) are included. The indication for blood patch treatment is set after clinical assessment by a consultant wound specialist. We administer the autologous blood patch(I) weekly, and measure the wound size at the beginning and at the end of treatment. Furthermore, we register time to healing and potential adverse events.
Results: From June 2016 to October 2018, 26 patients were included. Wound-categories were: diabetic foot ulcer(n=4), pressure ulcer(n=7), related to surgical incision(n=9) venous(n=3) and other(n=3). The mean age was 65 years (SD 13.6), 58%(n=15) were males. Median pre-treatment time before inclusion was 21.5 weeks (IQR 28). The median number of blood patch treatments were three ranging from 1-19 treatments per patient. The median time to healing was 73 days (IQR 156). 54 %(14/26) healed <20 weeks, 27%(7/26) healed >20 weeks, and 19%(5/32) did not heal. A reduction in mean wound size was seen, from 2.75 cm2(SD 3.55) at the start of treatment versus 1.62 cm2(SD 2.48) after completion of treatment, (95%CI 1.29;4.22) versus (95%CI 0.59;2.64) $p=0.0058$. In all cases with pain prior to treatment, the patients reported less pain after treatment start. All patients had weekly controls and treatment was stopped ahead of time for 3/26 patients: one because of difficulties obtaining the blood sample, one had an infection and one was amputated.
Conclusion: Autologous blood patch(I), as supplement to standard wound treatment, among patients with hard-to-heal wounds treated in a highly specialized clinic, seemed to expedite wound healing and reduce pain, without any negative side effects.

(I): Leukopatch by Reapplix

Acknowledgment: Reapplix, blokken 45, 3460 Birkerød, Denmark provides the needed equipment for the treatment. Otherwise, the treatment is performed under the budget of the public Wound Center Viborg, Department of Vascular Surgery, Viborg Regional Hospital, Heibergs Alle 4, 8800 Viborg, Denmark.

P26.05

Does Autologous Peripheral Mononuclear Cells Implant Allow Foot Surgery in Diabetic Patients with Critical Limb Ischaemia not Eligible for Revascularization?

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Aim: To evaluate the outcomes after foot surgery in a series of diabetic patients with critical limb ischaemia (CLI) not eligible for revascularization treated with autologous peripheral blood mononuclear cells (A-PBMNC) implants.
Method: From June 2018 to October 2018 we collected 12 diabetic patients with CLI (14 limbs), all with ischemic not infected foot lesions, not amenable for foot surgery following failed revascularization. In all patients we implanted in the leg and in the perilesional area 12 mL of A-PBMNC, 0.2–0.3 mL for each bolus, collected by selective filtration from 120mL of peripheral blood. The A-PBMNC treatment was repeated for a maximum of three times. In patients with pain relief, reduction of ischemic signs and increased TcpO2 value foot surgery was performed at the same time of the last implant.
Results / Discussion: the 12 patients enrolled (8 male/4 female) had a mean age of 77,4±5,2 years, mean diabetes duration of 16±7,4 years; mean HbA1c of 7,4±0,4%. Peripheral neuropathy was present in 7 patients (58,3%). Three patients (25%) had a bypass occlusion and 9 patients (75%) had unsuccessful previous percutaneous transluminal angioplasty because of very distal arterial occlusion and/or severe calcifications. Mean transcutaneous oxygen tension (TcpO2) was 15,8±6,6 mmHg. Rest pain was present in all cases. Texas University Classification (TUC) grade was 3C in all patients; Wifi Classification System score was W3I3Fi0 in all patients. Lesion site was forefoot in all patients. After a mean follow-up of 174±114,35 days mean TcpO2 was 40±14,6 mmHg. Two patients healed without surgery. Foot surgery has been performed in 8 limbs (3 phalangectomies, 1 sequestrectomy, 1 ray amputation, 2 digital amputation, 1 transmetatarsal amputation), 2 patients underwent major amputation and than they died, one with both feet affected. One patient without pain rejected surgery. Complete wound healing was achieved in 10 patients (71,4%) with a mean healing time of 43±11,9 days. No side effects were recognized.
Conclusion: Implant of A-PBMNC shows to be efficacy in diabetic patients with CLI not eligible for revascularization to perform foot surgery and increase healing rate.

P27.01

Comparison of Pedal Soft Tissue Thickness in Diabetic Patients with and without Sensory Neuropathy

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Ulceration is a serious consequence of diabetes that can lead to patient disability. One of the risk factors for ulceration is high plantar pressure1. The thickness of the pedal soft tissue (PST) is important because it has a cushioning effect. Soft tissue atrophy causes elevation in the plantar pressure, which, in turn, causes ischemia and subsequent ulceration2. Therefore, we compared the PST thickness opposite the metatarsal heads (MTH) in diabetic subjects with and without sensory neuropathy (SN), cases with peripheral arterial disease were excluded. We examined the feet of 48 patients using high-frequency-ultrasound-imaging (10-13 MHZ). We divided the patients into 2 groups. The first group included 24 patients with SN (Age 56±6), and the second group included 24 diabetic patients without SN (Age 57±5). We measured and compared the vertical distances of soft tissue thickness under all MTHs in between the 2 groups using independent-sample-t-test. There was statistically significant difference in PST thickness under all left MTHs (first 5 vs 6.4; second 6.1 vs 7.8; third 6.2 vs 7.4; fourth 5.6 vs 6.9; fifth 4 vs 5.7; $p<0.05$), and the first, second, third and fifth right MTHs (first 5.1 vs 6.3; second 6.1 vs 7.5; third 5.8 vs 7.3; fifth 4.4 vs 5.9; $p<0.05$) between the first and second groups, respectively, fig 1. Aging, BMI, sex had no effect on PST atrophy in either group. In conclusion, our study confirmed that diabetic patients with SN experience more PST atrophy than diabetic patients without SN.
Acknowledgements: No Fund
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2. Mickle KJ. Soft tissue thickness under the metatarsal heads is reduced in older people with toe deformities. J Orthop Res 29:1042-1046,2011.

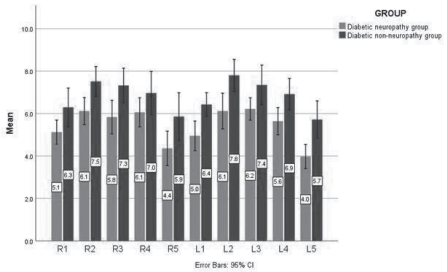

Figure 1 The difference in thickness of pedal soft tissue in diabetic patients with and without sensory neuropathy

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P27.02

The Influence of Diabetes Duration on the Dynamics of Protective Sensory Loss

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Aim: Loss of protective sensation (LOPS) is a significant risk factor for diabetic foot ulceration. Examination of light touch sensation with standardized 10-g Semmes-Weinstein monofilament (SWME) is a method of screening for LOPS [1]. Clinical data from consecutive SWME were analysed in order to obtain an insight into the dynamics of LOPS over time.
Methods: Results of routine SWME were obtained from the local database at a single tertiary diabetic foot clinic. 3054 subjects (1418 women, 1636 men; 482 with type 1, 2340 with type 2, 232 with other types of diabetes) were included in the study. 8910 SWME were performed between the years 1998 to 2018. The results were grouped according to years of diabetes duration (1 to 35 years). LOPS was defined as more than two insensitive points on SWME on either foot. A relative proportion of patients with LOPS was calculated for each year.
Results: Correlation between the proportion of patients with LOPS and years of diabetes duration was strong, positive and signifi-

cant (r=0.87, P < 0.001). A significant linear regression model was obtained when predicting LOPS rate from the years of diabetes duration (regression coefficient 0.46%/year; CI: 0.37 to 0.56, P < 0.001). Progression of LOPS was faster in men (0.64 %/year; CI 0.50 to 0.79) than in women (0.39 %/year; CI: 0.28 to 0.50) and in patients with type 2 diabetes (0,57 %/year; CI 0.45 to 0.68) than in type 1 (0.43 %/year; CI 0.27 to 0.59). Progression of LOPS was not influenced by positive history of smoking (smokers 0.49 %/year; non-smokers 0.47 %/year).
Conclusions: A faster rate of LOPS progression was observed in patients with type 2 diabetes and in men. A prediction model for LOPS was created that could be used in diabetic foot care resource planning.
Reference: 1. Feng Y, Schlösser FJ, Sumpio BE. The Semmes Weinstein monofilament examination is a significant predictor of the risk of foot ulceration and amputation in patients with diabetes mellitus. J Vasc Surg. 2011; 53(1): 220-226.

P27.03

Degree of Sensory Loss Predicts Risk for Ulceration in Diabetic Patients

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Aim: The loss of sensation diabetic patients are confronted with due to neuropathy can be graded precisely. The screening instruments from the 39-item Rotterdam Diabetic Foot (RDF) Study Test Battery can validly categorize the sensation in patient's feet in the following categories: no loss of sensation, loss of two-point discrimination, loss of vibration sense, loss of protective sensation or severe loss of sensation. We investigated the relationship between degree of sensory loss and risk for diabetic foot ulceration in a cohort of patients with diabetes.
Methods: Patients without and with symptoms of neuropathy participating in the prospective RDF Study were followed for three years. Subjects underwent sensory testing of the feet annually using the RDF Study Test Battery. Patients at baseline were categorized in one of five categories of incremental sensory loss. Data on incident diabetic foot ulceration were collected annually. Ulceration rates at three-year follow-up were estimated with Kaplan-Meier survival analysis. Events were diagnosed as the occurrence of an ulcer and time to event was time to diagnosis of ulcer.
Results: Of the 416 patients studied, 1.4% had no loss of sensation (Group 0), 59.9% lost two-point discrimination (Group 1), 15.6% lost vibration sense (Group 2), 12.7% lost protective sensation (Group 3) and 10.3% had severe sensory loss (e.g. aberrant cold sensation) (Group 4) at baseline. The median follow-up was 871.5 days (IQR: 579.8 to 1095.5), including survivors and patients who died during the study period. Forty-three ulcers developed during follow-up; Group 0: n=0 (0%), Group 1: n=9 (3.6%), Group 2: n=6 (9.2%), Group 3: n=10 (18.9%) and Group 4: n=18 (41.9%). Three-year ulceration rates were significantly higher for the groups with more severe sensory loss (p < .0001).
Conclusions: The degree of sensory loss at baseline was associated with progression to diabetic foot ulceration during follow-up. Grading the loss of sensation using the RDF Study Test Battery may improve the current screening of the feet at risk and support the stratification of patients at risk, aiding clinical decision making.

P27.04

Associations between Small Fibre Impairment and Plantar Pressure During Walking in People with Diabetes

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Aim: The aim of this study was to investigate the association between small fibre impairment and plantar pressure in patients with diabetes.
Methods: 2127(M/F:1199/928) diabetic patients (Age:51.4±12.1; BMI:29.8±6.3; Duration of diabetes:5.2±6.1) with no history of ulceration, amputation or Charcot foot recruited to this study. 591 (vs 1536) patients presented large fibre sensory impairment measured by insensitivity to 10-g monofilament in more than 2 out of 10 sites. Small fibre sensory impairment was measured by assessing the Temperature Sensation Threshold (TST) and Temperature Tolerance Thresholds (TTT) to cold and hot stimuli at Hallux, 3rd Toe, 5th Toe, and at the heel. Average Plantar Pressure (APP) at the above-mentioned sites was measured during walking. Spearman's rho test of association was performed to find relationships between the plantar pressure and TST/TTT to cold/hot stimuli at each corresponding site at each foot.
Results: Significant ($p<0.05$) positive correlations were found between the plantar pressure and TST to cold probe at: Hallux (rho=0.088), 3rd Toe(rho=0.051), 5th Toe(rho=0.071), and heel(rho=0.117) in the right foot; and at Hallux(rho=0.071), and 5th Toe(rho=0.046) in the left foot; also between the APP and TTT to cold probe at: Hallux(rho=0.103), 3rd Toe(rho=0.050), 5th Toe(rho=0.074), and heel(rho=0.093) in the right foot and at Hallux(rho=0.060), and 5th Toe(rho=0.045) in the left foot.
Significant ($p<0.05$) negative correlations was found between the APP and TST to hot probe at: Hallux (rho=-0.105), 3rd Toe(rho=-0.084), 5th Toe(rho=-0.110), and heel(rho=-0.091) in the right foot; at Hallux(rho=-0.077), and 5th Toe(rho=-0.047) in the left foot; also between the APP and TTT to hot probe at: Hallux(rho=-0.101), 3rd Toe (rho=-0.082), 5th Toe(rho=-0.083), and heel(rho=-0.098) in the right foot; at Hallux(rho=-0.073), 3rd Toe(rho=-0.050) and the heel(rho=-0.43) in the left foot.
Conclusion: Plantar regions with further small fibre impairment; observed as lower sensitivity to temperature stimuli; showed to be exposed to significantly lower average peak plantar pressure during walking. Although the observed associations were weak, it was contrary to the commonly expected positive association between plantar pressure and indicator of large fibre impairment. Further investigations into the role of small fibre impairment in assessing the risk of mechanical trauma to the foot are warranted.

P27.05

Validity of the Tinel Sign and Prevalence of Tibial Nerve Entrapment at the Tarsal Tunnel in Diabetic and Nondiabetic Subjects

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Aim: Nerve entrapments like carpal tunnel syndrome are more prevalent in patients with diabetes, especially in those with diabetic polyneuropathy. Our study aims were to investigate the validity of the Tinel sign in diagnosing tibial neuropathy and determine the prevalence of tibial nerve entrapment in both a diabetic and non-diabetic population.
Methods: 240 non-neuropathic subjects with diabetes and 176 diabetic subjects with neuropathy participating in the prospective Rotterdam Diabetic Foot Study and 196 reference subjects without diabetes and without neuropathy complaints were evaluated. All subjects underwent sensory testing of the feet and complaints were assessed using the Michigan Neuropathy Screening Instrument. The Tinel sign was defined as discriminative valid to diagnose tibial nerve entrapment when the nerve related MNSI sub-score of neuropathic symptoms differed at least 5% between the Tinel-positive and Tinel-negative subjects. When valid, prevalence estimates of tibial nerve entrapment at the tarsal tunnel were calculated.
Results: Significantly more neuropathic symptoms ($p < .002$) and higher sensory thresholds ($p < .0005$) were observed in (compressed) tibial nerve innervated areas, indicating that a positive Tinel sign at the tarsal tunnel is a valid measure of tibial nerve pathology. The prevalence of tibial nerve entrapment in diabetic patients was 44.9% (CI: 40.1-49.7%) vs. 26.5% (CI: 20.3-32.7%) in healthy controls ($p < .0001$).
Conclusions: Tibial nerve entrapment is more prevalent in diabetic subjects than in controls. The significantly more frequently reported neuropathic complaints and concomitant sensory disturbances provide evidence for the role of super-imposed entrapment neuropathy in diabetes related neuropathy.

P28.01

Research on the Interaction of Autophagy and Pseudomonas Aeruginosa in Diabetic Wound Infections

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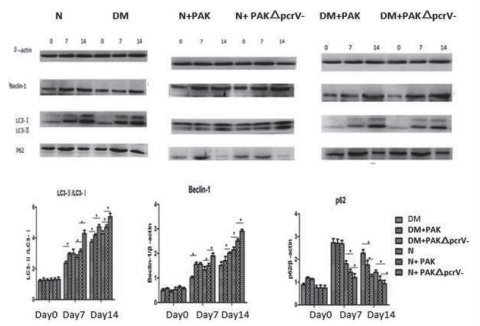
Aim: To study the effect of T3SS (Type III secretion system) of PA (Pseudomonas Aeruginosa) on the expression of autophagy-related proteins LC3、Beclin-1、p62 in diabetic ulcer wounds, and to further investigate its effect on diabetic ulcer wound healing.
Methods: 36 SD rats were randomly divided into six groups: diabetic with PAK(a standard strain of PA) infection group (DM+PAK$^{\Delta}$, diabetic with PAK$^{\Delta}$pcrV-(without T3SS) infection group (DM+PAK$^{\Delta}$pcrV-), diabetic without infection group(DM),non-diabetic with PAK infection group(N+PAK),non-diabetic with PAK$^{\Delta}$pcrV- infection group(N+PAK$^{\Delta}$pcrV-), non-diabetic without infection group(NDM).
A full-thickness skin ulcer were performed on all rats. Wound healing was observed at different time points in all groups. Autophagy-related proteins LC3、Beclin-1、p62 were detected by western blot(WB) at different time points.
Results: Compared with DM and DM + PAK $^{\Delta}$ pcrV- , there were more black callus, necrosis and swelling around on the 3rd day, more purulent secretions on the 7th day, and more secretions and larger wound area on the 21th day in DM + PAK. Compared with NDM and N + PAK $^{\Delta}$ pcrV- , there were more purulent secretions on the 3th day and wound area was reduced on the 14th day in N + PAK. The expression of LC3 and Beclin-1 increased on day 0, 7 and 14. And the expression of p62 protein decreased gradually on day 7 and 14 in all groups ($P < 0.05$). The difference of all groups see figure.
Conclusion: Autophagy ability is gradually enhanced both in non-diabetic and diabetic wounds. But autophagy in the diabetic group is significantly lower in the non-diabetic group, and the wound healing is delayed and impared in diabetic group compared with non-diabetic group. In the state of diabetes with impared autophagy, T3SS of PA can inhibit the expression of autophagy-related protein.



The LC3II/LC3I,beclin 1,p62 difference of all groups

P28.02

Moderately and Severely Infected Diabetic Foots' Microbiological Profile, Management and Clinical Outcomes: National Registry of Infected Diabetic Foot Ulcer (RENAPEDI)

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Aim: To 1) describe the bacteriological profile of pathogens isolated from individuals with diabetes and moderate or severe lower limb infection (M/S-LLI), 2) assess the therapies used to treat M/S-LLI, and 3) evaluate the clinical outcomes.
Methods: A multicentre study (RENAPEDI - Portuguese Society of Diabetes) was conducted, consecutively including individuals with diabetes and M/S-LLI (PEDIS grade 3 and 4), attending to 9 hospital diabetic foot clinics, from 10/2012 to 12/2015. At baseline, several patient, foot and ulcer-related characteristics were collected. During follow-up (1 month), clinical management, microbiological profile, microbial sensitivity test results, antibiotics used and clinical outcome were recorded.
Results: In total, 451 individuals were included (mean age 65 years, mean HbA1c 8.3%). The majority were male (74%), with type 2 Diabetes (90%), previous ulcers (63%), complete autonomy (77%), limited visual acuity (54%) and neuro-ischemic foot (56%). Our sample presented 554 M/S-LLI, being the majority PEDIS 3 (70%, ranging from 40 to 100% between institutions) with osteomyelitis (63%, 0-80%). During follow-up, 199 (36%, 0-70%) of the cases required a minor LEA and 56 (10%, 0-19%) a major LEA. The most commonly used wound dressings were iodine based, Dakin solution or had silver in their composition. Offloading was conducted mainly using a felt pad, customized shoes and contact cast. The most common microbiological culture collection methods were deep biopsy (28%, 0-33%) and aspiration (16%, 0-32%). In 21% (0-37%) no collection was made.
Altogether, 861 microbiological samples were assessed. The most common isolated pathogens were MRSA (21%, 8-40%), enterobacteriaceas (18%, 0-36%) and pseudomonas aeruginosa (10%, 0-14%). Several microorganisms were found in 14% (0-36%) of the cultures. Identified pathogens were mainly susceptible to gentamicin (33%, 24-73%), trimethoprim/ sulfamethoxazole (28%, 0-75%) and ciprofloxacin (19%, 15-55%).
Overall, 1298 antibacterial drugs were administered, mainly intravenously (58%, 0-100%). The most prescribed drugs were clindamycin (8%, 0-50%), ciprofloxacin (7%, 0-41%) and penicillin (5%, 0-12%).
Conclusions: Moderate and severe diabetic foot infection is a very complex therapeutic challenge, that may be associated with a poor prognosis. Although it represents a selected spectrum of this complication, clinical features vary greatly which lead to the necessity of multiple approaches.

P28.03

Evaluation of the Bacteriological Profile in Diabetic Feet Infections (DFI): are we Treating Properly?

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Aim: The aim of this study is to identify the prevalence of pathogens in moderate to severe DFI in patients hospitalized in a private hospital and to characterize the antimicrobial sensitivity profiles of these microorganisms.
Methods: We retrospectively analyzed the cultures and antimicrobial sensitivity tests of microrganisms identified in materials collected during amputation or debridement surgery of 31 patients with community-acquired moderate and severe diabetic foot infection, between 2013 and 2015.
Results: Of the 107 cultures obtained, Gram positive cocci (GPC) were the most prevalent microorganisms - Enterococcus sp. and Staphylococcus sp., corresponded to 54.2% of the samples. Gram negative bacilli (GNB) were isolated in 40.1% of the samples, and Pseudomonas sp. was isolated in only 10% of the samples. The sensitivity of Staphylococci to first line drugs (oxacillin, ciprofloxacin and clindamycin) was very low, as was the sensitivity of GNB to penicillin + β-lactamase inhibitor (such as amoxicillin + clavulanate). The most sensitive drugs for GNB were quinolones, aminoglycosides and carbapanem. All of the Enterococci strains isolated were sensitive to ampicillin and vancomycin.
Conclusions: In our study, most DFI were monomicrobial, with equivalent distribution between GPC and GNB. The bacteriological profile was different from other equivalent samples described in the literature, mainly due to the high prevalence of Enterococcus sp. In addition, the GPC and GNB strains had high antimicrobial resistance rates to first line drugs. Thus, the empirical treatment indicated in the literature was ineffective or insufficient for the profile of bacterial sensitivity found, making the use of penicillin + inhibitor of β-lactamase or quinolone + clindamycin questionable .
Our protocol suggests as empirical treatment for moderate and severe DFI the association of clindamycin + ceftazidime or clindamycin + cefepime. However, after this evaluation, revision of the protocol is expected and we would suggest the use of an glycopeptide + piperacillin/tazobactam. It is important to emphasize that empirical antimicrobial treatment should be initiated only after culturing deep tissues, and it is necessary for each medical center to know their local prevalence of microorganisms and antimicrobial sensitivity profile in DFI, thus allowing the elaboration of their own protocol treatment.

P28.04

Multi-drug Resistant (MDR) Bacteria: an Increasing Complication of Diabetic Foot Ulceration (DFU)

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Aim: To assess prevalence of MDR phenotypes of different bacterial strains in DFU followed in our clinic from 2001 until 2014.
Methods: We retrospectively analysed 7.826 cultures from wound specimens from consecutive DFU. We selected more prevalent bacteria and analysed antimicrobial sensitivity pattern. We evaluated the prevalence of Staphylococcus aureus (SA), Pseudomonas aeruginosa (PA) and Enterobacteriae (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). To test if the MDR pattern changed, we divided results in two groups: Group A, from 2001 until 2007 and Group B from 2008 until 2014.
Results: SA was detected in 2.483 specimens in Group A and 2.131 in B (NS), presence of MRSA was 58.7% in Group A and 51.2% in B (NS). PA was observed in 1.428 specimens in Group A and 1.783 in B (p<0.03): in particular, CiproRPA was detected in 45.1% of cultures in Group A and 64.1% in B (p< 0.04) while CRPA in 32.7% in Group A and 34.2% in B (ns). Presence of EB was detected in 1.516 specimens in Group A and 2.032 in B (p<0.001); CiproRE prevalence was 28.0% in Group A and 47.7% in B (p< 0.02) while ESBL prevalence was 23.0% in Group A and 39.7% in B (p< 0.05).
Conclusion: Our data confirm the high prevalence of MDR bacteria infections in DFU and their increase overtime, stressing the importance of a close monitoring of antimicrobial drugs susceptibility.

P28.05

Association Between MicroRNAs in Diabetic Foot Ulcer Swabs and Clinical Characteristics of Diabetic Foot Ulcers

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Aim: Diabetic foot ulcers (DFU) is a serious complication of diabetes and strategies for risk assessment of newly diagnosed wound are needed. MicroRNAs (miRNA) are known to be important in the wound healing process. The purpose was to investigate if specific miRNAs in DFUs can be used as a biomarker to predict the clinical outcome of newly diagnosed DFUs.
Methods: We recruited 28 patients with new foot ulcers, following written consent. Samples were collected using Copan brush and RNA was isolated using Tri-reagent (Sigma-Aldrich). Mean RNA yield was 1100ng/swab (+/-500ng). Complementary DNA and quantitative PCR was used to determine the microRNA level of 8 miRNAs involved in wound healing (miR-29a, -34b, -146a, -155, -210, -223, -411 and -720). After a 6 mo follow-up patient characteristics were extracted from patient records. Patients were divided into non-healing or healing ulcer groups based on the median DFU healing time (heal-time). Significance levels (p<0.05) were calculated using Students t-test or Fishers' exact test and correlations were assessed using Pearson. The study followed the Declaration of Helsinki II and was approved by the regional scientific ethics committee.
Results: Patients were equally divided into groups of healing (n=14, heal-time: 30±14days (mean±SD)) versus slow-healing ulcers (n=14, heal-time: 129±48 days, p<0.001). There were no significant difference between groups in area and volume of wound at diagnosis, age at inclusion, BMI, p-Creatine, systolic blood pressure, diabetes duration, RNA yield/swap, ulcer diagnostic code, diabetes type (1/2) or insulin/oral hypoglycemic treatment.
Levels of miR-146a, miR-29a, miR-411 and miR-223 were increased in slow-healing ulcers when compared to healing ulcers (all p<0.05). Further, larger ulcer size positively correlated with levels of miR-223 (r^2=0.44, p<0.05) and miR-146a (r^2=0.48, p<0.01). MiR-223 levels in wounds at diagnosis give a fair prediction of whether an ulcer heals slowly (ROC-AUC=0.85, p<0.001).
Conclusion: In this small pilot study, levels of miR-146a, miR-29a, miR-411 and miR-223 were significantly increased in slow-healing ulcers compared to well healing ulcers. MiR-223 levels were correlated with large ulcer volumes and may predict whether a DFU heals well. It is notable that further and larger studies are necessary to confirm this result.

P28.06

Acinetobacter Baumannii Infection - a Risk Factor for Amputation in Diabetic Foot Ulcer Patients

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Back ground: Foot complications are found to be a significant frequent, complication of Diabetes mellitus. Diabetic foot infections are the leading cause of hospitalization for diabetic patients worldwide and in developing countries like India, it accounts for 20% of hospital admissions. Carbapenem-resistant Acinetobacter baumannii is gradually becoming dominant among Diabetes patients in urban population. The aim of this study was to evaluate the clinical outcomes of Acinetobacter baumannii infection and their resistance mechanisms in patients with diabetic foot infections.
Methods: An observational study of 620 patients with infected ulcers in diabetic feet was conducted in Hycare for Wounds a tertiary care centre exclusively dedicated for Wound care and Management in South India for a period of one year.Processing and identification was done as per standard guidelines. The bacteriological assessment was performed in deep tissue cultures and amputation was considered to be major when performed above the foot's middle tarsus.
Results: Out of 620 patients studied 360 were positive for bacterial growth. Commonest isolate was Pseudomonas aeruginosa followed by Staphylococcus aureus (MSSA) species, Klebsiella and E. coli. We observed that 22 patients were infected with Acinetobacter baumannii and more than 50 % were carbapenamase producers.
Clinical Outcomes: Out of 22 patients infected (19 male and 3 female) with Acinetobacter baumannii 13 were major amputees and 5 were minor amputees and the rest 4 patients are under medical management.
Conclusion: The present study evidenced Carbapenem-resistant Acinetobacter baumannii infection is a serious threat to Diabetic patients and can be considered as a risk factor for amputation.
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P29.01

Results of Minor Lower-Extremity Amputation with and without Revascularization and Post-Operative Outcomes in Patients with and without Diabetes Mellitus

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Aim: To investigate outcomes after minor amputation with and without revascularization in patients with peripheral artery disease (PAD) among patients with and without diabetes mellitus (DM).
Methods: Patients with PAD were identified in the American College of Surgeons-National Surgical Quality Improvement Program (NSQIP) database. Patients who underwent minor amputation with and without revascularization were matched according to age, sex, DM and amputation level. Post-operative outcomes were reported up to 30 days after minor amputation.
Results: A total of 156 patients were included in the study. By amputation level, 12 (3.8%) were midtarsal (Chopart), 98 (31.2%) transmetatarsal (TMA), 96 (30.6%) ray resection, 70 (22.3%) metatarsal phalangeal joint (MTP) and 38 (12.1%) interphalangeal joint (IPJ). In the univariate analysis, no effect of revascularization was seen in 30-day perioperative surgical site complications (7.6% vs. 10.8%, p=0.33), reoperation (7.6% vs. 14.0%, p=0.07), reamputation (3.2% vs. 7.6%, p=0.08) or readmission (19.1% vs. 20.4%, p=0.78). However, revascularization among DM patients correlated significantly with reduced 30-day reoperation rate (5.6% vs. 13.6%, p=0.03) but no differences were noted with readmission (20.0% vs. 18.4%, p=0.75) or wound complication (8.0% vs. 11.2%, p=0.39). However, no effect of revascularization was seen among non-DM patients in any of these parameters. In the multivariate analysis, male patients with DM had higher risk of reoperation (adjusted odds ratio [aOR] 3.22, 95% CI 1.04-14.1), but revascularization was associated with 67% reduced odds of reoperation in patients with DM (aOR 0.33, 95% CI 0.12-0.81).
Conclusions: In the current study, revascularization was associated with reduced reoperation after minor lower-extremity amputation in the univariate and multivariate analysis. Interestingly, improved outcome, specifically with reoperation after minor amputation, were noted in patients with DM than in those without DM. Furthermore, although we found no differences among surgical site complication and reamputation with revascularization, nonsignificant reductions in both parameters in patients with DM were observed. Further studies are required to better characterize the potential benefits of revascularization in patients with PAD undergoing minor foot amputation.

P29.02

Pro-Active Screening (PAS) of Critical Limb Ischemia (CLI) and Fast-Track Endovascular Revascularization (FTR) for Diabetic Foot (DF) Patients

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Aim: we recently implemented in our DF section a multidisciplinary PAS/FTR for DF patients with CLI. Aim of this study was to assess its efficacy and efficiency compared to standard-track endovascular revascularization (STR).
Methods: we prospectively collected data (May - October 2018) from 55 consecutive DF patients with CLI who underwent in our Department to PAS/FTR [male/female 39/16; age 72.8±9.7 yrs; duration of diabetes 25.8±13.53 yrs (2-50), HbA1c 7.1±0.68%, Charlson Index (CI) 4.5±1.76 - Group A] compared with 32 (male/female 24/8; type 1/ type 2 diabetes 2/30; age 65.8±6.7yrs; duration of diabetes 11.0±7.8yrs, HbA1c 7.8±1.9%, CI 5.3±2.2 - Group B) DF in STR. The Groups were compared for efficacy [angiosome target (AT), healing rate (HR), major amputation rate (AR) and angioplasties patency rate (PR)] and efficiency [length of hospitalization (LH) and the delay to revascularization (DR)] of management strategies.
Results / Discussion: at baseline, the two groups showed no significant differences. No differences were found between the groups for any of the efficacy parameters (AT 67% vs 78%; HR 76% vs 65%; AR 1.8% vs 6%) except for PR (91% in Group A vs 70% in Group B - p<0.05). Efficiency was significantly (p<0.05) higher (LH 3.0±0.5 vs 10.5±9.2 days, DR 10.5±9.2 vs 45.1±10.2 days, respectively) in Group A.
Conclusions: PAS/FTR is as effective but significantly more efficient than STR for managing DF patients with CLI with indication to endovascular revascularization.

P29.03

Neuroischemic Diabetic Foot – the EndoRevolution

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Introduction: The prevalence of Diabetes Mellitus(DM)in Portugal is 13,3%.Patients with DM have a 15-25% lifetime risk of developing a foot ulcer.This number increases to 25-30% if the patient has arterial disease.Additionally,diabetic angiopathy is a unique vascular disease that has predilection for below-the-knee arteries.Meanwhile,endovascular techniques have been revolutionizing the revascularization of neuroischemic diabetic foot(NIDF) patients,showing consistently higher limb salvage rates.
Methods: Retrospective institutional review of patients requiring endodistal revascularization(Jan 2010 - Dec 2017).The aim of this study is to report our experience concerning NIDF patients who underwent tibial arteries revascularization.We evaluated demographics and co-morbidities data and performed statistic analysis to determine factors and outcomes as limb salvage,major and minor amputation rates.
Results: The technical success was achieved in 85% of the procedures.The iliac sector was only treated in 0,7% of the procedures and femoro-popliteal sector in 63,2%.Antegrade femoral approach, was obtained in 91, 3% of the procedures.A complementary retrograde distal approach was performed in 7,6% of procedures.Direct angiossomic revascularization was obtained in 60,9% of the cases.In the femoral and popliteal arteries, PTA was performed in 56,3% of the procedures and recanalization, PTA and stenting in 42,4%.During FU, 14,1% of patients was submitted to major amputation and 36,4% to minor amputation.The major amputation free-survival rate was 80,1% at 12 mo and the rate of healing at 12 mo was 63,2%.The 12 mo global survival was 79,8%. Direct angiossomic revascularization (p=0,014) and the number of tibial arteries recanalized (p=0,01)were both associated with a higher limb salvage rate and a faster healing of the ulcer.In the opposite side, there was an association between the increasing of renal dysfunction and poor healing (p=0,04).The endovascular reintervention rate was 20,4%.The results of the author's study on endodistal revascularization,highlights the need to prioritize investigation and revascularization in NIDF patients to improve the outcome of foot ulcer, giving the possibility of salvaging a greater number of limbs.
Conclusion: With the introduction of guidewires and balloon catheters designed for treatment of below-the-knee vascular disease,recanalization of the these arteries has become technically feasible.The results of our work on endodistal revascularization highlights the need to prioritize investigation and treatment of NIDF patients to improve the outcomes.

P29.04

Clinical and Imaging Characteristics of Patients with Diabetic Foot Under Endovascular Treatment of PAD. March 2015 – June 2017. SACA.

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Aim: The diabetes mellitus and his complications are the leading causes of death for non transmisible disease. The 50% of this patient have vascular injury that need bypass surgical treatment, but endovascular treatment has demonstrate to decrease the morbidity and mortality in this patients. The diabetes in our country represent the 7.5% of the cause of death and in the social hospital the diabetic foot department has attended 2500 patients in 9 years since its creation. 1,3
The objective of this research is to describe the clinical and imaging characteristics of diabetic patients who underwent endovascular treatment for peripheral arterial disease.
Methods: A retrospective descriptive study was carried out. We reviewed the data in the clinical and radiological file of the patients, they were collected in a survey sheet previously authorized by the Bioethics Committee. The data obtained were tabulated in the "EpiInfo v7.2" program and graphed using the "Excel 2016" program.
Results: Fifty patients were included in the study, 52% of them were women, mainly between 61-70 years old. Arterial hypertension was the most frequent comorbidity in the study population with 78% of the total patients. Arterial disease below the knee was more frequent, with involvement of the anterior tibial artery in 84% of the patients evaluated. Balloon angioplasty was performed in 100% of the cases, while stent placement was necessary in 10% of the procedures performed. The result of the procedure was not successful only in 4/50 patients performed. 84% of the patients presented primary patency at 6 months of evaluation.
Conclusion: Peripheral arterial disease mainly affects the vessels of the leg below the knee. Endovascular treatment of peripheral arterial injuries is a safe method with a high success rate in the initial procedure, as well as a low recurrence of intervention at least 6 months after the procedure.
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P29.06

A Mexican Regional Experience on Infragenicular Distal Bypass for Limb Salvage of the Ischemic Diabetic Foot

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Aim: Our aim is to show our work during the last 10 years with regard to distal infragenicular bypass of the lower extremity for limb salvage.
Methods: We reviewed and present our cases of distal infragenicular bypass done for limb salvage during the last 10 years.
Results: We present 74 patients that were operated on for limb salvage by infragenicular distal bypass surgery. 51 male and 23 female, youngest patient was 58, oldest patient was 85 years old. 72 patients were type II diabetics. 21 patients had end stage chronic renal insufficiency. We performed 44 femoral to anterior tibial bypasses, 23 femoral to posterior tibial bypasses, 5 femoral to pe-

roneal artery bypasses and 3 femoral to plantar artery bypasses. Bypass conduit was long saphenous vein 71 patients, 69 In situ technique. 3 composite bypasses and 1 PTFE graft. Limb salvage was accomplished in 91% of the cases. Minor amputations in 88% of the cases. Major supracondilear amputations in 6 patients (8.1%). Procedure related 30-day mortality 5.4% (4 patients), 1 infection related and 3 myocardial infarctions. Morbidity was 12.1% (9 patients), 6 wound infection, 2 patients required hemodyalisis 48 hours after surgery and 1 patient had postoperative major bleeding that required surgery. Our primary one-year patency rate was 84%.
Comments: In an era of endovascular first revascularization for the treatment of critical limb ischemia, we, as a vascular surgery group based in a mid-size town in Mexico where we treat low income patients and in a country that has a very high prevalence of diabetes mellitus among adults (9.8% of all adult population). Our population has also a low level of health education, so when we see the patients, they have advanced states of gangrene and or infection with big areas of tissue lost. Our policy in the group is to use as a first line treatment bypass surgery for the treatment of suitable patients with critical limb ischemia. Open revascularization procedures done on a careful patient selection basis are a valuable and real option for patients with critical limb ischemia and high risk of limb loss.

P30.01

Diabetic Foot Disease: Positive Impact on Referral and Treatment Delays Following the Introduction of a Novel Vascular Limb Salvage Clinic

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Aim: Dedicated limb salvage clinics may reduce delays in the management of diabetic foot disease (DFD)[1]. We report the outcomes of a novel vascular limb salvage (VaLS) clinic for patients with DFD.
Methods: Analysis of consecutive patients referred to the VaLS clinic over a 9 month period from inception (February–November 2018). Data was prospectively collected on: a) times from referral to assessment and revascularisation and b) major amputation rates. Times were compared to local institution outcomes before the establishment of the VaLS clinic (2011-3).
Results: Overall 193 cases (191 patients) were reviewed (median age=74 years, median follow-up=152 days) with 123 cases (64%) being in patients with diabetes. Times from referral to management are shown in Table 1.
Referral to assessment times were longer in patients with diabetes compared to patients without (median 2 days vs 1 day, P=0.01): 118 diabetes cases (96%) underwent same-day arterial duplex ultrasound. Fifty-two diabetes cases underwent 58 revascularisation procedures (endovascular=48, surgery=10). Eleven major amputations were performed in patients with diabetes following the establishment of the VaLS clinic, compared with 46 in 2017.
Conclusion: The introduction of the VaLS clinic has reduced referral delays and improved management of DFD. Early outcomes are promising, however longer follow-up data is required. Further evaluation is required to reduce delays in assessing patients with diabetes.
Acknowledgements: VaLS and AN are funded by the George Davies Charitable Trust. RS is part-funded from this source.
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Table 1

Times from referral to:	Patients with Diabetes(d)	2011-3 Data(d)
Assessment	2.1	7.0
Angioplasty	8.1	16.0
Surgery	8.4	11.0

Comparison of times from referral to management in patients with DFD

P30.02

Sole Searching: Administrative Delays for Prescriptive Shoes as a Cause of Re-ulceration in Early Diabetic Foot Remission

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Aim: The goal of this presentation is to illustrate how administrative delay in dispensing diabetic shoes may be an additional cause of diabetic foot re-ulceration amongst patients in early remission.
Methods: A series of patients who were in diabetic foot remission clinic but re-ulcerated while waiting for prescribed diabetic shoes were identified and presented. A detailed process analysis of diabetic shoe dispensary at a university teaching institution was conducted to identify the process defect and root cause.
Results: Based on the process analysis and presented cases, multiple process modifications were implemented. The most immediate modification was changing the vendors that could provide high quality diabetic shoes efficiently. The team also established a new and close relationship with the Department of Family Medicine to expedite primary physicians sign-off as part of the diabetic shoe qualification. Patients who had no primary care physician and/or had lost follow up with primary care physician could have an immediate referral. Patient data that was necessary for diabetic shoe approval was also collected during the initial consult.
Conclusions: The presented case series includes an example of systematic approach to identify and address the process defects and root cause analysis. While the long term outcome of current modifications was not readily available but it would be worthwhile. The authors advocated to recognize defects in the healthcare system as potential risk factors for diabetic foot re-ulceration among patients in remission.

P30.03

The Fast-Track Pathway: a Specific Tool for Improving Early Referral of Patients with Diabetic Foot Ulcers

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Aim: Late referral to specialized diabetic foot centers is worldwide a common theme. A multidisciplinary team of experts on diabetic foot management developed a specific Fast-Track Pathway (FTP) for achieving early referral of patients with diabetic foot ulcers (DFUs) managed in primary care. We aim to evaluate its usefulness and applicability in clinical practice.
Methods: The FTP identifies three categories of severity in patients with DFUs in relation to patient's co-morbidities, vascular status, infection and ulcers findings. According to each category, the management of DFUs and the time of referral to specialized diabetic foot clinics have been defined. The usefulness and applicability of FTP have been evaluated by international Professionals involved in diabetic foot care through an anonymous questionnaire.
Results: Seventy Professionals including Diabetologists, GPs, Podiatrists, Surgeons, Nurses and Educators coming from 51 different countries across Europe, America, Africa, Asia and Oceania contributed to this survey. 50% of interviewed reported they don't have a validated pathway for DFUs patients (89% in Africa, 75% in Asia and 57% in Central-South America); 82.8% of Professionals who have a pathway in their country reported this FTP is better and more effective than what they already use; 95.3% consider this FTP can be useful and applicable in their country (82.8% consider FTP could be used as it is now, 12.5% adapting it to their area).
Conclusions: There is a lack of a specific pathway for DFUs worldwide, mainly in developing countries. The FTP could be a useful and practical tool for improving early referral.

P30.04

Do Patients Receive the Input of the Multidisciplinary Diabetic Foot Team Prior to Amputation Secondary to Diabetic Foot Disease?

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Aim: This study considered those who underwent amputation in a tertiary referral centre in 2016. How many of these patients received input from the multidisciplinary diabetic foot team (MDfT) prior to amputation? Care of diabetic foot ulceration should be delivered in a multidisciplinary manner in order to optimise limb salvage and prevent amputation. When care is delivered in this way outcomes are improved (Edmonds et al 1986)
The study also identified the number of people who received preventative podiatry in primary care as most amputations are preceded by a foot ulcer in those with diabetes. Preventative care including education may reduce the incidence of foot ulceration in at risk individuals (Singh et al 2005).
Method: A retrospective chart review of patients who underwent amputation in 2016 was completed to ascertain whether MDfT input or preventative podiatry occurred prior to amputation. MDT input was defined as documented assessment by Enodcrinology, Podiatry, Infectious Disease, Vascular and Orthopaedics prior to surgery in any record systems
Results / Discussion: In 2016 44 amputations were performed secondary to diabetic foot disease. 95% of these had vascular input, 90% endocrinology input, 88% Podiatric input, 61% orthopaedic inputs and 48% Infectious disease input prior to amputation. 68% received preventative podiatry in primary care.
Given the retrospective nature of this analysis some MDfT consultations may have not been recorded or have occurred in an informal manner. Prospective data would overcome this challenge. This highlights the need for more robust documentation of MDfT discussions.
Conclusion: Access to the MDfT and to preventative podiatric care is important in the prevention of lower limb amputation. Steps need to be taken to ensure that all patients receive full access to the members of the MDfT and preventative podiatric care in order to ameliorate this debilitating condition.
Reference: Edmonds et al (1986); Singh et al (2005)

P30.05

Identification of Barriers for Adherence to Therapeutic Shoe and Wound Care Advices in Patients with Diabetic Foot Ulceration

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Aim: Increasing adherence to therapeutic shoes and wound management is crucial in improving treatment outcomes and to lower the risk of re-ulceration in patients with diabetic foot ulceration (DFU).(1,2) The World Health Organisation (WHO) describes five interacting dimensions that may affect adherence, i.e. related to the patient, therapy, condition, social-economic status, and health system.(3) Our aim is to identify and prioritize barriers for adherence to treatment advices in patients with DFU, within the five dimensions of the WHO model.
Methods: A comprehensive literature review was performed to identify barriers for adherence. Subsequently, an expert meeting was held to identify additional barriers. In a second expert meeting the barriers as identified by the experts were prioritized. Experts were health care professionals from an experienced multidisciplinary diabetic foot team.
Results: From the literature, barriers for adherence were identified in all dimensions of the WHO model, except for the health system related dimension. Several, non-studied, barriers were added and prioritized based on the opinion of the experts. Identified barriers in the patient related dimension include cognitive dysfunction, illness beliefs, limited perception on risk for complications, depression and anxiety, poor disease management and low self-confidence. Discomfort and appearance of therapeutic footwear, as well as pain and discomfort during wound management were found to be barriers in the therapy related dimension. Neuropathy, cognitive dysfunction, limited joint mobility and vision were identified as important barriers in the condition related dimension. Absence of financial contribution to treatment and absence of a social network were barriers for adherence in the social-economic related dimension. Delay in patient referral to health professionals and limited communication due to different electronic patients reports systems were identified as barriers within the health system related dimension.
Conclusion: Barriers for adherence to treatment advices in patients with DFU are identified, both from the literature and from expert meetings. A framework to identify, integrate and target barriers for adherence for easy use in clinical practice, is our aim for future research.
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P31.01

Which Ulcer and Patient Characteristics can Guide Clinicians in Determining the Risk of Non-Healing of a Diabetic Foot Ulcer?

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Background/Aim: Diabetic foot ulcer (DFU) outcomes are determined by a series of characteristics. Characteristics observed at first presentation play a key role in the choice of an efficient treatment strategy. We determined which patient and ulcer characteristics at baseline adversely contribute to DFU healing.
Methods: A nation-wide initiative for quality improvement was conducted in 2013 in Belgian diabetic foot clinics (N=34). Overall, 1664 patients with DFU of Wagner grade 2 or more were followed for six months. A very detailed description of patient and foot characteristics was recorded at baseline. Missing values were handled by multiple imputation. To identify the characteristics associated with DFU healing, we performed bivariate Cox proportional hazard regression.
Results: Median referral delay was 4 weeks. Sixty-eight percent of patients reported prior DFU. Toes was the most prevalent ulcer location (48.91%). Peripheral arterial disease (PAD) was diagnosed in 55.89%. At 6 months, healing probability was 55.5%. Patient characteristics significantly associated with an adverse healing probability were: age >78 years (hazard ratio (HR) 0.75 [95% CI 0.631-0.912]), referral delay > 4 weeks (HR 0.65 [95% CI 0.536-0.794]), contralateral DFU (HR 0.64 [95% CI 0.533-0.776]), additional ipsilateral DFUs (HR 0.75 [95% CI 0.647-0.875]). Related to medical history, we found adversely associated: renal disease (HR 0.84 [95% CI 0.733-0.971]), lower-limb revascularization (HR 0.70 [95% CI 0.603-0.812]), DFU (HR 0.79 [95% CI 0.691-0.908]) and minor amputation (HR 0.74 [95% CI 0.639-0.869]). Ulcer/limb characteristics adversely associated were: Wagner grade 4-5 (HR 0.64 [95% CI 0.511-0.802]), surface area ≥ 1 cm2 (HR 0.70 [95% CI 0.608-0.811]),ischemia (HR 0.64 [95% CI 0.567-0.736]), and ulcer site: compared to toe ulcers a worse outcome was observed in plantar midfoot (HR 0.65 [95% CI 0.548-0.780]), dorsum (HR 0.61 [95% CI 0.440-0.860]) or heel (HR 0.42 [95% CI 0.337-0.529]).
Conclusions: DFU healing probability is significantly affected by some well-known ulcer characteristics in addition to newly identified patient characteristics. It is important that clinicians know which baseline parameters affect prognosis permitting better risk stratification and more appropriate choice of treatment and follow-up. Using a multivariable model suggests which parameters are most useful to collect.

P31.02

Influencing Factors of Clinical Recurrences of Diabetic Foot Ulcers

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Aim: to investigate the influencing factors of clinical recurrence of diabetic foot ulcers (DFUs), and explore the guiding principles of self-management of DFUs patients.
Methods: A total of 349 patients with DFUs from March 2015 to August 2017 were collected. According to whether they had recur-

rence, The subjects were divided into the initial group (242 cases) and recurrence group (107 cases), and the related factors that may affect recurrence were analyzed. All statistical analysis were performed using SPSS 22.0 software. P value less than 0.05 was considered significant. If normality was established, Student's t test was used to assess differences. Otherwise, the nonparametric Mann–Whitney U test was used. Chi-square test was used for categorical variables between these 2 groups.
Results: The percentage of recurrent DFUs was 26.8%. Compared with the patients with primary DFUs, those with recurrent DFUs were with longer diabetic duration [196.35m±77.68 vs 161.94m±90.27,p<0.05] ,lower HbA1c level [8.49%±2.02 vs 9.34%±2.68, p<0.05], higher amputation rate [37.2% vs 2.9%, p<0.05], and higher percentage of vascular intervention [25.5% vs 3.6%, p<0.05] . There were no statistically significant differences between the two groups in gender, age, smoking, diet control, oral medication, diabetic micro-complications and footwear wearing. Multiple factors logistic regression analysis showed that the absence of socks in summer (OR=2.066, P=0.042), the frequent absence of socks (OR=3.434, P=0.023), and the history of vascular intervention (OR=5.083, P=0.000) and amputation (OR=16.011, P=0) were independent risk factors for the recurrence of DFUs.
Conclusions: The recurrence of DFUs had longer diabetic duration, lower hemoglobin a1c. Outdoor activities without socks, history of vascular intervention and amputation were independent risk factors for recurrent DFUs. In order to avoid recurrent of DFUs, Nurses should strengthen diabetic foot care education to patients with DFUs, especially who had the history of lower limb vascular intervention and amputation history.

P31.03

Outcome and Prognostic Factors of Deep Heel Lesions

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Aim: deep heel lesions are frequent in people with multiple comorbidity and frail situation, their treatment represents a challenge for high risk of failure and of major amputation. Aim of the study: to evaluate outcome of deep heel lesions and prognostic factors in diabetic patients.
Method: interrogation of surgical database between January 2008 and December 2017, founded 71 patients with surgical treatment of calcaneus osteomyelitis in diabetic patients. 99% of patients have type 2 diabetes, mean age was 72±11 years(mean±SD), 82% were male, long history of diabetes 20±12years and quite good metabolic control(HbA1c 7.5%±1.5) were founded. 13(18%) patients presented chronic renal damage and 12(17%) end stage renal failure, 29(41%) ischaemic heart disease.
Results: the 71 patients presented lesions at heel level, 52% on rear of calcaneous and 48% on plantar surface, all Texas grade3: 12 B (with infection), 7 C (with ischaemia), 52 D (with infection and ischaemia). 59(83%) patients underwent revascularization, 41(58%) targeted to peroneal or tibial posterior artery.
Outcome: 44(61%) patients healed, 9(13%) underwent below the knee or syme amputation, 14(20%) patients died with lesions, 4(6%) are still ulcerated. Mean healing time was 257±134 days. Surgical treatment consisted: surgical removal of the lesion in 9(13%) patients, surgical removal of lesion + partial calcanectomy in 62(87%). In 29(41%) patients we used negative pressure and dermal substitute or skin graft to obtain healing. Mean follow up was 3.3±1.6 years. Relapse rate was 11%. Prognostic factors: failure of treatment and early death were associated with walking disability at presentation and presence of lesion in the rear of calcaneous(p<0.01), renal impairment or cardiovascular disease(p<0.05), not targeted or successful revascularization(p= 0.01). Age, diabetes duration, metabolic control, lesions of contralateral leg, were not significantly associated with outcome.
Conclusion: deep heel lesions are a critical event for diabetic patients with low healing rate, high incidence of major amputation and early death and walking disability in particular when they occur in frail patients with typical bedsores lesions. In absence of renal failure, cardiovascular disease and walking disability healing of the lesion is possible with a long time to heal, low incidence of relapse and long survival.

P31.04

Diabetic Foot Ulcer Recurrence Rate In Our Setting: A Seven-Year Follow up

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Aim: The prevalence of diabetes among Saudi is almost 24%, and mainly type 2 due to lifestyle and genetic background. The high recurrence rate of diabetic foot ulceration requires a new management approach. John D. Miller et al report the annual recurrence rates of diabetic ulcerations is as high as 34%, 61%, and 70% at 1, 3, and 5 years, respectively, with studies reporting 20% to 58% recurrence rate within 1 year. Therefore, we should not only focus on fast ulcer healing but also maximizing diabetic foot in remission and preventing ulcer formation.
Methods: Medical podiatric records of 1010 healed diabetic foot ulcers between 2010 and 2017 were collected. Podiatric exam includes sensory testing using vibration perception threshold (VPT), vascular status evaluation was based on pedal pulses palpation and/or ankle brachial pressure index (ABPI). Wound care was done up on the standard of the International Working Group on the Diabetic Foot [IWGDF] (debridement, infection control, vascular control, and offloading). Wound assessment was done up on PEDIS classification and Healed wound was defined as complete closure without discharge. Patient was considered with recurrence ulcer if he developed a new ulcer in the same site of the previous healed one.
Results: Most of our patients were quite young with a mean age of 58.5±0.6, 94.2% were neuropathic (VPT >25) and 35.13% were found to have abnormal ABI. Mean diabetes duration was 17.9 ±0.4 and poorly managed with a mean HbA1c of 9.4 ±0.1. 60% of patients had some degree of foot deformity while Charcot was present among 7.8%. Wound baseline was 47.35 weeks and wound types were mainly neuropathic and located at the plantar

aspect of the foot with a mean size of 5.2 cm². Among healed patients, 45% had more history of ulceration and 22% amputation 22%. The Mean Recurrence Rate per year was 13.82% compared to 40% reported by Armstrong et al. 2017.
Conclusion: Appropriate therapy during active foot ulceration coupled with a special insight on improving care with compliance to the IWGDF while keeping patients in remission can lead to more ulcer-free days, and better quality of life.

N=1010	2010	2011	2012	2013	2014	2015	2016	2017
Healed Ulcers	162	194	164	125	90	73	97	105
Recurrence Rate	23 14,20%	31 15,98%	26 15,85%	19 15,20%	12 13,33%	9 12,33%	11 13,34%	13 12,38%

Recurrence Rate Data Results between 2010-2017

P31.05

Ulcer Recurrence in Diabetic Foot

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Background: Recurrence of lesions in diabetic foot patients is a critical problem. Literature analysis underline a high rate of recurrent ulceration. Aim of the study: to evaluate risk and prognostic factors for recurrence in diabetic patients with previous ulcer.
Methods: We analized patients presenting at diabetic foot visit from September 2018 to November 2018. We identify 50 patients with recurrence after previous ulcers and 33 patients with previous lesions but without any recurrence. Population study presented 94% of patients with type 2 diabetes, mean age 68±12 years(mean±SD), 82% male, long history of diabetes 19±12years, overweight with mean BMI 30±5 and not optimal metabolic control (HbA1c 7.8%±1.9) were founded. Mean renal function was 74ml/min, 4 patients with end stage renal disease. Group with recurrence compared to group without recurrence, presented similar age, diabetes duration, metabolic control, BMI and renal function. Prevalence of neuropathy, vascular disease and ischaemia were not statistically different into the two groups.
Results: Data from this study evidenced the 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 only 17(34%) patients use orthopaedic shoes more than 6 hours/day. Absence of compliance increased the risk of recurrrence despite adequate shoes. Direct causes of recurrence were traumatic event in 20 patients (40%) and conflict with shoes in 27(54%). Analysing risk factor, multivariate analysis founded that compliance is a protective factor independent to age, diabetes duration, deformity level and sex.
Conclusion: 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. Compliance is the key element in prevention resulting protective independent to other factors.

P31.06

Case-Mix Adjusted Variation in Diabetic Foot Ulcer Outcomes in England and Wales

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Aim: To examine variation in the outcome of diabetic foot ulcer (DFU) management, it may be necessary to use case-mix adjusted models. We have, therefore, developed such models to study variation at service level in the UK for four different outcomes: (a) being alive and ulcer-free (12 weeks from presentation) and (b) DFU-related hospital admission, (c) major amputation, (d) death (each within 6 months of presentation). Factors related to the structures and processes of local care (such as time to first expert assessment) were excluded from the models.
Methods: Geographical areas and providers in England and Wales were compared in funnel plots using model-derived standardised ratios for each outcome. Analyses were performed for individual providers when numbers allowed.
Results: a. Being alive and ulcer-free at 12 weeks (14 variables, 26,779 ulcers, 126 providers included).
Six providers had lower than expected (>3 SD) and four providers higher than expected (>3 SD) numbers of patients that were 'alive and ulcer-free' at 12 weeks. However, the strength of the underlying model was weak (c-statistic 0.69).
b. Having a DFU-related admission within 6 months (11 variables, 27,111 ulcers, 121 providers included). Five providers had lower than expected (>3 SD) and five providers higher than expected (>3 SD) numbers of patients that had a foot-disease related admission. The strength of the model was reasonable (c-statistic 0.74).
c. Undergoing major amputation within 6 months (7 variables, 26,543 ulcers, 32 areas included).
Two areas had lower than expected (>3 SD) numbers of patients having major amputations. The strength of the model was reasonable (c-statistic 0.79).
d. Death within 6 months (9 variables, 9,699 ulcers, 42 areas included).
All areas were within expected levels for mortality within 6 months. The model was in the strong range (c-statistic 0.80).
Conclusions: Using case-mix adjusted data, we have found considerable variation (both geographically and by provider) in the numbers healed by 12 weeks and the numbers admitted for foot disease. There was also geographical variation in major amputation. In contrast, there were no significant differences in the high mortality rates, which may be independent of the structure of foot care.

P32.01

Characterising Physical Activity Levels and Physical Function in Diabetic Foot Ulcer Patients

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Aims: Our aim is to provide insight into the levels of physical activity and physical function in Diabetic Foot Ulcer (DFU) patients, and to see how this contrasts to those with diabetes without a foot ulcer (Non-DFU). DFU patients are often under offloading instruction to facilitate ulcer healing, as such it is anticipated that this cohort will engage in less physical activity. It can be further hypothesised that lower levels of physical activity and higher levels of co-morbidities in DFU patients lead to impaired physical function and increased physical frailty.
Methods: We analysed data from an ongoing cohort study (CODEC-NCT02973412). Participants with established T2D (>6months), aged 18-75years inclusive were recruited from secondary care within the East-Midlands, UK. Measures of physical function were determined using the short physical performance battery (SPPB); a score of <10 was used to define impaired physical function. An accelerometer worn on the non-dominant wrist for 7 consecutive days determined habitual activity levels.
Results: 43 DFU patients (age = 61 [55,66] years, female = 18.6%, BMI = 32 [28,35] kg/m2) and 560 Non-DFU patients (age = 66 [60,71] years, female = 37%, BMI = 31 [28,35] kg/m2) were included. DFU patients spent significantly less time in moderate to vigorous intensity physical activity (4.5mins [0.8,18.8] vs 14.4mins [6.7,31.7]), light intensity physical activity (100mins [74,128] vs 127mins [103,158]), and had a lower average acceleration during their most active 30mins compared to Non-DFU (70.2mg [53.4,98.2] vs 89.8mg [72.1,115.6]). DFU patients had a lower SPPB score (8 [5,9] vs 10 [9,12]), with 75% of DFU patients classified with impaired physical function compared to 28% in Non-DFU. Significant correlations were observed between SPBB score with a) time spent in moderate to vigorous physical activity (DFU ρ=0.557, Non-DFU ρ=.350), b) average acceleration of the most active 30mins (DFU ρ=0.570 and Non-DFU ρ=0.367).
Conclusion: DFU patients engage in significantly less physical activity and have higher levels of impaired physical function. Stronger correlations between physical activity with physical function in DFU, compared to Non-DFU, may demonstrate the necessity of finding ways to increase physical activity while under offloading instruction in order to preserve physical function.

P32.02

Is it Necessary to Restrict Weight-Bearing Physical Activity During Treatment of Diabetic Foot Ulcers?

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Aim: Patients are often instructed to reduce their weight-bearing physical activity to promote healing of plantar foot ulcers, even when appropriate offloading devices are used. This limits working ability and daily activities but it is not clear whether this contributes to ulcer healing. The aim was to investigate whether reduced weight-bearing physical activity contributes to ulcer healing when offloading devices are used.
Methods: A literature review was conducted.
Results: Three studies, published in four articles, were identified (Table 1). Saltzman et al. (1) found that taking more steps prolonged the time to ulcer healing, but the effect seemed rather small. Najafi et al. (2) found a negative correlation between step count and ulcer healing rate, but no correlation between standing time and healing rate. Crews/Vileikyte et al. (3,4) found no effect of number of steps taken on ulcer size after 6 weeks of treatment.
Conclusions: There is limited evidence for recommending patients who use offloading devices to reduce weight-bearing physical activity to promote healing of plantar foot ulcers. Two out of three studies found a negative association between step count and ulcer healing but the clinical significance of this is uncertain. Future studies should investigate the effects of reducing weight-bearing physical activity from a broader perspective, including effects on ulcer healing, daily activities, health, and well-being.
References:
1. Saltzman CL. J Bone Joint Surg Am. 2004;86-a(12):2714-9.
2. Najafi B. J Diabetes Sci Technol. 2017;11(4):657-67.
3. Crews RT. Diabetes Care. 2016;39(8):1371-7.
4. Vileikyte L. Diabetes. 2017;66(suppl 1):A168.

Study	Device	Analytic methods	Findings
Saltzman (2004)	TCC	Statistical model of impact of step count on time to healing	Doubling the median number of steps (2083/day) would prolong the time to healing with 16%
Najafi (2017)	iTCC*	Correlation between physical activity and weekly reduction of ulcer area	Negative correlation (r = -0.33) between step count and ulcer healing. No correlation between standing time and ulcer healing.
Crews (2016) & Vileikyte (2017)	Mainly RCWs	Multiple regression analysis	No effect of step count on ulcer size after 6 weeks, when controlling for adherence

TCC: total contact cast; RCW: removable cast walker; iTCC: "instant" TCC, i.e., a RCW rendered non-removable. *RCWs were also used but only the results from participants using iTCC are presented here.

Table 1. Studies investigating the association between weight-bearing physical activity and ulcer healing

P32.03

Predictors of Adherence to Using Therapeutic Shoes Among People with Diabetic Foot Complications

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Aim: Therapeutic shoes can prevent diabetic foot ulcers but adherence to using them often is low. Studies are needed to identify

nonadherent patient groups and factors affecting adherence, laying the groundwork for interventions to improve adherence (1,2). The aim was to investigate predictors of adherence to using therapeutic shoes.

Methods: A questionnaire, mainly based on the Health belief model, was posted to 1245 people who used therapeutic shoes because of diabetic foot complications. Variables that significantly correlated with adherence (Spearman's correlation coefficient $p<0.10$) were entered into a stepwise linear multiple regression analysis where p-values <0.05 were considered statistically significant.*

Results: 443 (35.6%) questionnaires were analyzed (66.4% men, mean age 69.2 years). On average, people used their therapeutic shoes 50.3% of daytime (SD 32.8%). Adherence was higher among people who did paid work, made consistent choices about what shoe type to wear, kept their therapeutic shoes visible in their home, and had put their conventional shoes away (Table 1).

Conclusions: People not doing paid work may need extra support to improve adherence. The results provide insights in the mechanisms of adherence, where the establishment of new shoe wearing habits, daily cues to use therapeutic shoes, and daily temptations to wear conventional shoes seem important for adherence. Future studies should explore this further and develop interventions to improve adherence, focusing on these factors.

References:

1. Jarl G. Patient Prefer Adherence. 2016;10:1521-8.
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*IBM SPSS Statistics 22.

Variables that predicted adherence	B	Beta	P-value
How do you choose between wearing therapeutic and conventional shoes? [Decides from time to time = 1, Always chooses in the same way = 2]	0.176	0.277	<0.001
Where do you keep your conventional shoes? [Visible at home = 1, Have put them away, e.g., in a wardrobe = 2]	0.174	0.269	<0.001
Where do you keep your therapeutic shoes? [Visible at home = 1, Have put them away, e.g., in a wardrobe = 2]	-0.285	-0.232	<0.001
Does paid work [No = 1, Yes = 2]	0.147	0.182	<0.001
Model $R^2 = 0.282$, $R^2_{adj} = 0.272$			

Table 1. Variables that significantly predicted adherence in multiple regression analysis

P32.04

Assessment of Patients' Needs and Prototype Development Regarding Custom-Made Diabetic Footwear for Indoor Use

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Aim: Footwear adherence is a problem in people with diabetes at high-risk of ulceration. Adherence is lowest indoors, while patients are most active inside their house. The aim of this study was to assess patients' needs, expectations and preferences regarding custom-made indoor footwear and to develop a prototype with similar plantar pressure reduction compared to patients' current custom-made footwear while easier to use, to increase footwear adherence.

Methods: Needs, expectations and preferences regarding custom-made indoor footwear were evaluated with a self-designed questionnaire in 51 high-risk diabetic patients who already wore custom-made shoes. A multidisciplinary team of specialists developed a prototype custom-made shoe for indoor use based on a predefined set of 12 requirements regarding required offloading, ease of use, weight, durability, aesthetics and costs; the primary requirement was similar peak plantar pressure relief compared to the patient's current custom-made shoes. Nine high-risk diabetic patients received the prototype and in-shoe plantar pressures were measured with Pedar-X (Novel); other requirements were evaluated by the users and the project team.

Results: 82% (n=42) of patients expressed a need for special indoor footwear. 68% (n=35) expected this to increase their adherence. 83% (n=43) of patients indicated to walk barefoot or on socks/slippers indoors, especially at night when leaving their bed. Peak plantar pressures were similar or lower (± 10%) compared to their current custom-made footwear in 7/9 patients, and were below the 200kPa target pressure in 8/9 patients. All other requirements were scored as adequate, with the prototype easier to use and lower in costs.

Conclusion: High-risk patients express a clear need for special custom-made footwear for indoor use, and expect such footwear to increase their adherence. We developed a custom-made indoor shoe, showing adequate pressure relief, superior usability, adequate durability and at lower costs than the current custom-made shoe. The effect on footwear adherence will be evaluated in a follow-up study.

P32.05

Impact of Prefabricated Footwear and Custom-Made Ortheses in Prevention of First Ulcer in High-Risk Diabetic Foot Patients

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Aim: Diabetic foot ulcer is the most cause of lower amputation, therefore the prevention of first ulcer is of paramount importance. The aim of this study was to assess the impact of prefabricated footwear and custom-made ortheses in prevention of first ulcer in high-risk diabetic foot patients.

Methods: Between January 2016 and December 2017, we have retrospectively evaluated 44 patients with peripheral neuropathy associated with foot deformities or peripheral vascular disease and no previous foot ulcer or amputation (Category 2 IWGDF Risk Classification System 2015).

We divided population in two groups :group A (n.27), in which the patients were beneficiaries of prescribed prefabricated diabetic footwear and custom made ortheses according to algoritms of Dahmen et al., and group B (n.17) , in which the patients were not reimbursed and therefore were advised to wear comfortable shoes with nontraumatizing characteristics. Incidence of diabetic foot ul-

ceration was evaluated during 1 year of follow-up.
Results: The mean age of the patients was 70±11 years , 59% were males, the diabetes duration was 20±10 years, 93% had T2D, HbA1c was 7.62±1.17 %, all patients had neuropathy and 29% of patients had also peripheral vascular disease. Deformities were largely accounted for by hammer toe (65.9%), hollow claw foot (59%), hallux valgus (36%), whereas flat foot (4.9%) . During 1 year of follow-up, 36% of patients (16/44) developed a diabetic foot ulceration, in particular 11.1% of patients in group A developed a diabetic foot ulceration compared with 76.4% in group B ($p < 0,0001$). One patient of group B had minor amputation.
Conclusions: With the limitations of retrospective study and little sample, our study seems support to the efficacy of custom-made ortheses and prefabricated footwear in prevention of first ulcer in high-risk diabetic foot patients.

P32.06

Efficacy, Safety and Acceptance of a New, Interim Orthosis in Patients with Diabetes after Chopart Surgery.

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Aim: Chopart amputation is the consequence of severe diabetes-related foot complications. Current clinical management after surgery consists of promoting healing until the patient is able to wear a custom-made prosthesis.
A new interim orthosis (1) allowing the patient a greater degree of mobility after Chopart surgery than currently used systems is now available.
Aim of our study was to evaluate the efficacy of the new orthosis compared with traditional treatment. Safety and level of patient acceptance of the device was also investigated.
Methods: We performed a retrospective observational study involving people with diabetes who underwent Chopart amputation between January 2016 and January 2018. After surgery, the patients were followed up until prosthesis application. The sample of subjects was compared with an historical cohort of consecutive patients we treated with traditional management.
The only patients selected where those without complications requiring re-amputation in the immediate post-operative period. The main study outcomes included major amputation occurrence, ulcer recurrence, healing time and patient acceptance of the orthosis. Patient satisfaction was evaluated by using the Italian validated version of the Orthotic Prosthetic User's Survey (OPUS) questionnaire.
Results: Overall, 27 subjects using the new device were enrolled (mean age 68.7±8.4 years, 70.4% males, mean diabetes duration 22.7±15 years). Clinical baseline characteristics were comparable between the cases and the historical cohort. There was no difference between the groups in the healed wound rate (81,5% vs. 80,0% for cases and the control group, respectively p= 0,53). Ulcer recurrence rate was higher in control group compared with subjects using the new orthosis (62,5% vs. 14,8%, p 0,01). No between groups difference was detected for major amputation rate. The wound healing time was faster for cases compared with controls (160,4 ± 114,1 vs. 256,5 ± 112,9 days p 0,05).
No adverse events related to the use of the new orthosis were recorded. Patient acceptance of the orthosis was high.
Conclusions: As we have shown in this study this interim orthosis can be recommended as an efficient, safe and well accepted device for patients with diabetes who have undergone Chopart surgery.
References:
1. Body Armor® Pro Term (Molliter®, Civitanova Marche-Italy)

P33.01

Systematic Review of Techniques to Monitor Resolution of Acute Charcot-Neuroarthropathy in People with Ddiabetes.

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Aim: The management of acute Charcot-neuroarthropathy (CN) relies on offloading which is costly and time consuming. Definition of resolution is however poorly understood and variable. Offloading studies have relied on imaging and thermographical monitoring, with unknown effectiveness. We aimed to review different techniques for monitoring response to offloading in acute CN.
Method: Inclusion criteria: studies on off-loading which evaluated or described monitoring techniques in acute CN. We excluded surgical and pharmacological studies. EMBASE, CINAHL and Cochrane databases were searched (January 1993–July 2018). We screened 781 titles, 140 abstracts and 45 full-texts, and included 26 studies. Paper screening and data extraction were validated.
Primary outcomes extracted were cost, clinical applicability, sensitivity and specificity, safety and patient acceptability. Secondary outcome was time to resolution.
Results: Studies evaluating monitoring techniques: We found 4 prospective observational studies without controls at high risk of bias. 2 evaluated thermography monitoring, showing skin temperature reduced as CN resolved. They concluded that thermography could be used to guide withdrawal of immobilisation. Another study found a 90% agreement between MRI, thermography and mid-foot/ankle circumference in identifying resolution of CN. The final study compared Doppler spectrum analysis with clinical indicators of inflammation and X-rays, concluding that Doppler spectrum analysis could be used as a guide to begin weight–bearing.
Studies evaluating offloading which describe monitoring techniques: We found 22 observational studies without controls at high risk of bias. Frequent monitoring used were serial X-rays, objective temperature measurement, and MRI. Protocols were not standardised. 3 studies used alternative radiological methods for monitoring; F-FDG PET/CT scanning, bone scintigram, and iso-

tope bone scans. Other monitoring techniques included objective and subjective measures of inflammation.
None of the 26 studies reported all the primary outcomes. Time to resolution ranged from eight weeks to over one year.
Conclusion: Multiple techniques have been used to evaluate resolution in acute CN but there remains uncertainty around their effectiveness. High-quality RCTs are needed.
Funding: NIHR Integrated Clinical Academic Program (ICA), ICA-CDRF-2015-01-050.

P33.02

Treatment of Acute Charcot Foot from Diagnosis to Definitive Remission: Observational Study on a Cohort of Diabetic Patients

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Aim: classically Treatment of Acute Charcot Foot (ACF) has been Total Contact Cast (TCC) together with off-bearing for 3 to 6 months. During the last 10 years, other approaches have been proposed such as Removal casts or boots. These “new” treatments lacked to demonstrate a real efficacy, despite a prolonged treatment time, guided by remission of acute signs at MRI. Aim of the study was to confirm efficacy of TCC as gold standard for the ACF treatment.
Methods: we studied 18 consecutive diabetic patients, 10 Men, 8 women, mean age 57 yrs, no history of trauma.
All enrolled pts were at Shibata stage 0 without ulcers, infection signs or PVD. ACF involved midfoot (12) or ankle (6).
Patients underwent foot MRI and RX to confirm ACF and absence of fractures and were evaluated at onset and 1 or 3 MONTHS after conservative treatment (TCC changed every two weeks). MRI was carried out every 45 days until clinical remission.
Patients attended clinical controls at our institution for 6 years.
Results: all patients reached clinical remission (no edema and normal skin temperature) with a median time of 108 days without any complication.
Final MRI shown nearly complete remission on bone edema. 6 years follow- up demonstrated no recurrence of the disease.
Conclusions: our study confirm that TCC, even “ancient”, remains the gold standard treatment for patients with ACF. Remission criteria must be clinical and not only radiological.

P33.03

Treating Acute Charcot Osteo-Arthropathy: the Maastricht Experience

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Management of acute Charcot (AC) in diabetes is a challenge: treatment with a total contact cast (TCC) is effective but cumbersome, with reactivation if stopped too early and increased risk of complications if continued too long. Due to recurrent ulceration there is a high risk of amputation.
Aim: We analyzed the results of long-term treatment by a multidisciplinary team of patients with an AC episode using a highly standardized protocol.
Methods: A retrospective chart analysis was performed of all AC patients treated between 2011-2018 at the Maastricht University Hospital. Data were obtained on duration of TCC, interventions (surgical procedures, shoe types and orthotic devices) and recurrence of AC.
Results: In 42 patients, mean age of 57.6 (range 37-84) years, 43 AC episodes were observed (one was bilateral), median duration of follow-up was 33,7 (4-56) weeks; all follow up files were complete. Median duration of TCC treatment until complete resolution of disease was 17,3 (4-54) weeks, in total 352 TCC’s were applied. After TCC treatment there was no reactivation or recurrence of AC, one patient developed AC in the contralateral foot. Directly after the TCC period, 40 patients were fitted with bespoke high shaft shoes. During follow-up each of these patients received at least one pair of orthopedic shoes/year. Approximately half (52%) of the patients had a foot ulcer on the affected foot during follow-up. Treating these ulcers with repeated TCC took on average 6,0 weeks (1-14) weeks. One patient had a Chopart amputation due to osteomyelitis, no major amputations were observed. Eight patients (19%) underwent corrective foot surgery because of recurrent ulceration. During follow-up in 4 % of patients the shoe prescription was changed from high shaft to normal height shoes.
Conclusions: we observed good results with TCC and orthotic treatment of acute Charcot, with no new episodes of ipsilateral AC or major amputation. However, foot ulceration was a frequent long-term complication, resulting in 1 Chopart amputation, the other ulcers were healed with off-loading. Treatment with TCC, surgery and adequate shoe fitting is an intensive team effort with expertise of different team members.

P33.05

Mid- and Hindfoot Reconstruction of Charcot Foot with Super Construct Device

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Aim: Charcot foot reconstruction surgery has been disapointing, due to a high complication rate. During recent years Super Construct implants have been available, including strong intramedullary screws and reconstruction plates.
The surgical concept is complete fusion of medial and/or lateral column, to increase stability.
The aim of this study is to present our results of the first eight Charcot Foot patients treated with this concept at our Institution.
Methods: 8 patients with severe deformity due to Charcot foot deformity were operated from July 2017 to May 2018. All patients had a threatening pre ulcer situation or instability. Mean age was

59.5 years, 5 males and 3 females with a mean weight og 127 kg, mean BMI 38.9. Peripheral vascular supply was good in all cases. Patients were immobilized in a plaster cast mean 19.3 weeks, until acute inflammation had decreased and surgery was safe. Standard surgical technique with preparation of all joints was performed. In case of talocalcaneal instability, this joint was also fused. Fusion of medial column was mandatory, lateral column if required. A tourniquet was used in the first 4 cases, but was abandoned in the last cases.

Results: Mean surgical time was 223 min. Medial fusion was performed in all cases, 2 cases as an isolated procedure. 4 cases had both medial and lateral column fusion. 2 cases had talocalcaneal and medial column fusion. Mean follow up time is 40.4 weeks, 2 patients in the tourniquet Group had skin necrosis, one requiring plate removal. 1 patient without tourniquet had skin necrosis. All 8 patients had healing of incision and bone fusion, despite scattered screw breakage in the reconstruction plate. All patients are ambulated in orthopedic footwear. We had no Deep infections or amputations.

Conclusions: The preliminary results in this small series of Charcot foot reconstruction with super construct device seems promissing. There is a learning curve and tourniquet should be abandoned. We are encouraged to continue reconstruction with this technique.

P33.06

Midfoot Charcot Reconstruction with and without Subtalar Arthrodesis: a Case Series

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Aim: To describe failure of midfoot beams after midfoot reconstruction of Charcot neuroarthropathy (CN) with and without subtalar arthrodesis.

Methods: Medical records of patients with diabetes mellitus (DM) and CN of the foot were retrospectively reviewed.

Results: Thirteen patients who underwent midfoot reconstruction for CN were included. The average age was 53.6 years (±7.7 years), 6 (46.2%) were male, and the average body-mass index (BMI) was 34.9 kg/m2 (±10.5). The average follow-up time in this series was 8 months (±3.9 months). Nine out of 13 (69.2%) patients underwent subtalar fusion along with midfoot fusion. Screw breakage occurred in two patients, one at the 1st tarsometarsal joint and 2nd-4th tarsometarsal screws in another patient at 9 and 6 months respectively (Table 1). Both patients with screw breakage had subtalar fusion. A third patient who had subtalar fusion subsequently developed collapse of their talus leading to subtalar screw removal 3 months after initial surgery. Patients without subtalar fusion did not experience screw breakage.

Conclusion: An extended medial column fixation with subtalar arthrodesis has been previously proposed to provide better fixation after midfoot CN reconstruction with beaming screws as it restricts motion of the hindfoot. However, little to no evidence has been reported in favor of this technique. Our findings suggest that subtalar arthrodesis may result in fixation that is too rigid, which may place the beaming screws at higher risk of breakage. However, further studies comparing these techniques are needed to fully evaluate the effect of subtalar arthrodesis on midfoot beaming.

Table. Diabetes and comorbitidies characteristics

Case	Age	Sex	BMI	DM type	DM duration*	HbA_{1C}	Subtalar Fusion	Result	Follow-up
1	49	M	30.8	II	4		No	Fused	8 months
2	56	F	21.2	II	8	8.7	Yes	Hardware intact	3 months
3	38	F	32	II	17	5.8	Yes	**1st TMT screw failure**	9 months
4	42	F	55.26	II	15	6	Yes	Collapse of talus with removal of subtalar screw	3 months
5	57	F	26.8	II	4	7.0	Yes	**2nd, 3rd and 4th TMT screw failure**	6 months
6	55	F	55	II	5	7.9	Yes	Fused	5 months
7	51	M	30.6	II	1	11.8	No	Fused, wound dehiscence	6 months
8	55	M	29.4	II	Dx at visit	7.3	Yes	Fused	12 months
9	54	F	27.5	II	18	13.4	No	Below-knee amputation	3 months
10	66	F	27.46	II	11	5.9	Yes	Fused	12 months
11	65	M	39.8	II	10	8.5	Yes	Fused	4 months
12	54	M	36.16	II	10	9.4	Yes	Hardware intact, expired (septic shock with MOF)	6 months
13	55	M	42.1	II	27	7.4	No	Hardware removal due to suspected osteomyelitis	15 months
Mean	53.6		34.9		10.0	8.3			8 months
SD	7.7		10.5		7.7	2.3			3.9 months

BMI = Body-Mass Index, DM = Diabetes Mellitus, HbA_{1C} = Glycated Hemoglobin, TMT = Tarsometatarsal, MOF = Multiorgan Failure, Dx = Diagnosis, SD = Standard Deviation
*DM duration is reported in years

Description of case series

P34.01

Is Surgical Debridement Necessary in the Diabetic Foot Treated with Photodynamic Therapy?

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Diabetic patients are susceptible to developing foot ulcers with serious complications such as osteomyelitis and amputations. Treatment approaches are still empirical and the benefit of usual procedures such as surgical debridement has not been properly evaluated. Photodynamic Therapy (PDT) is a non-invasive and highly efficient method for the treatment of the diabetic foot, being able to eradicate the infection and to stimulate healing, decreasing considerably the amputation risk. In the day-to-day practice of our service, we have been faced with the question whether debridement is necessary before PDT. In here, we designed a study to answer that question.

Methods: Patients were divided in two groups: In one of the groups (n = 17), debridement was performed before PDT and in the other (n = 40) only PDT treatment was performed. PDT sessions were performed once a week in all patients until healing was achieved, as indicated by visual inspection as well as by radiographic and laboratory exams. At the start of the study, the two groups had no statistical differences concerning their clinical features: average age, gender, insulin use, diabetes mellitus onset time and previous amputations.

Results: PDT was effective in the treatment of 100% of the patients showing no relapses after one year of follow up. The group submitted to PDT without previous debridement had a statistically significant (p = 0.036, Mann-Whitney) shorter cure time (29 days, ~27%). Conclusion: Our data indicates that debridement is not necessary in the treatment of diabetic foot in patients that have enough peripheral arterial perfusion. In addition, we reproduced previous studies confirming that PDT is an efficient, safe, simple and affordable treatment method for the diabetic foot.

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P34.02

Treatment Status of 20 Patients of Diabetic Ulcer Based on Traditional Iranian Medicine: a Comparative Study of Low-Power Laser Treatments

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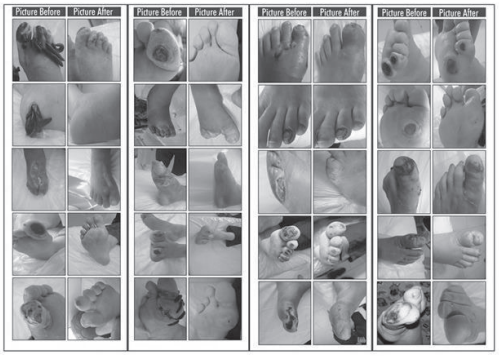
Introduction: Diabetic foot ulcer is one of the most common problems occurred in diabetic patients. The treatment of diabetic foot ulcer is very complicated and needs to be considered carefully, so that inappropriate responses to various therapeutic and surgical treatments have made this as a disadvantage. The purpose of this study is to present the clinical experience of modern Iranian traditional medicine, which has the greatest therapeutic effect in the shortest amount of time.
Methodology: In this study, 20 patients with second and third grade of diabetic foot ulcers were selected based on the treatment protocol were treated by traditional Iranian medicine in Bojnoord. All patients were between 45 and 75 years old who were hospitalized in Bojnoord, Mashhad and Gonbad hospitals during the years of 2015-16 and were undergone the initial treatments including control diabetes and infection control drugs. The patient's foot ulcers did not respond to common treatments, and according to counseling by orthopedic physician, an amputation was ordered for patient by doctor. In other words, the patients have had infections with severe inflammation. After entering the traditional medicine clinic, the patients were undergone the healthy nutrition and the drug was treated due to the health condition and disease status including medicinal herbs, combined drugs and modern drugs for controlling blood glucose. Ediat application was performed at the end of each treatment until the healing was finished; massage therapy and radiotherapy were performed on and around the ulcer, ones with 10 to 12 small, medium and large lesions in every 3 to 7 days for 10 sessions for the patients. Findings: In all patients, the diabetic foot ulcer was recovered after 40 to 60 days of treatment, the physical and mental status of the patients has improved and the patient's blood glucose has been controlled.
Conclusion: Effective medicine as an integrated school obtained from two fields of knowledge in two schools including modern medicine and traditional medicine of Iran can provide effective clinical findings in the treatment of certain diseases, such as diabetic foot ulcer disease.



Pictures before and after treatment of diabetic foot ulcers

P34.03

An Investigation on the Effectiveness of Combined Modulated Ultrasound and Electric Current Stimulation (CUSECS) in Treating Diabetic Foot Ulcers (DFU)

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Aim: Ultrasound and electrostimulation both individually contribute to different mechanisms to promote wound healing and combined, they complement and supplement each other. The effect of CUSECS on DFUs is still only a new focus. Therefore, the aim of this study is to investigate if CUSECS is an effective adjunctive treatment in treating chronic DFUs.
Method: A clinical case series design was employed. 13 participants with 14 chronic stagnant DFUs from two centres attended diabetic foot clinic. Participants received CUSECS and standard wound care treatment twice a week for four weeks. The CUSECS device utilized delivers ultrasound at modulating frequency (1.0-3.0 MHz) and intensity (0.0- 2.0 W/cm2) via a probe and electrostimulation at varying intensity (4000Hz–4250Hz) via electrodes which were placed at the wound boundaries. Wound size percentage was documented via photograph and measured for size.
Results: The average age of participants was 65 years old (SD 15; 43-83). The mean wound healing at the end of the four week trial was 66% (SD 15%; 27%-100%) with 2 ulcers completing full healing. Average ulcer duration prior the trial was 6 months (SD 4; 2-17). There were no statistically significant findings due to small sample size. There were no direct adverse reactions to this therapy. One participant dropped out from the study due to a cellulitis infection which was unrelated to the treatment.
Conclusion: All of the wounds treated exhibited wound size reduction within the treatment period. The results of this case series evaluation must be considered in the light of the small sample size. Results suggest that CUSECS is a useful adjunctive therapy for the treatment of chronic DFUs and it offers promise as there was a wound size reduction in all participant's DFUs. Further large-scale studies involving control groups are needed to gather further evidence and to ascertain the effectiveness of CUSECS.

P34.04

Investigating the Use of Low Frequency Ultrasonic Debridement in the Treatment of Diabetic Foot Ulcers

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Aims: This multifaceted study aimed to determine the proportion

of DFUs healed using non-surgical sharps debridement versus low frequency ultrasonic debridement (LFUD). Secondary aims included; quality of life, assessment of ulcer pain before, during and after each treatment and cost effectiveness.
Method: Individuals with DFUs attending the Podiatry Department 2013-2015, at a major metropolitan health network in Melbourne, Australia, were screened against study eligibility criteria. Eligible participants were randomly allocated to either the non-surgical sharps debridement (control) group or the LFUD (intervention) group and received weekly treatment for 6 months. Participants also completed a quality of life at regular time points, and completed a visual analogue pain scale before, during and after each treatment. A break-even analysis was undertaken to determine how many DFUs would need heal when treated with LFUD for it to be as cost effective as non-surgical sharps debridement.
Results: Ten participants with 14 ulcers received weekly debridement for 6 months. Results were analysed using a survival analysis approach. Ulcers treated with non-surgical sharps debridement healed more quickly (61.6 days ± 24.4) compared with those treated with LFUD (117.6 days ± 40.3). In both groups, quality of life was observed to improve as ulcers healed. In both groups, pain levels were observed to increase during treatment and then reduced again following treatment. The economic analysis found that for LFUD to break-even, one in every 22 DFUs that didn't heal with non-surgical sharps debridement would need to be healed.
Conclusion: This study resulted in an interesting observation that non-surgical sharps debridement may lead to faster healing of DFUs when compared to LFUD, and that LFUD may be more expensive but the difference is dwarfed by the even more costly outcome of unhealed DFUs. However, the small sample size makes it challenging to draw conclusions that will impact clinical practice. The greatest limitation of this study was the difficulty recruiting participants. Further research is required to investigate the clinical and economic efficacy of these two debridement modalities in the management of DFUs.

P34.05

Hyperbaric Oxygen Treatment for Complicated Diabetic Foot Ulcers – a Retrospective Cohort Study

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Aim: Diabetic foot ulcer (DFU) is a common complication of diabetes, which may lead to amputation of the affected limb if not properly treated. A more severe wound classification is an important risk factor for amputation(1, 2). The Dutch Healthcare Inspectorate reported that most ulcers with Texas grade 3 lead to amputation(3). Hyperbaric oxygen treatment (HBOT) has been suggested as adjunctive treatment to improve wound healing for these ulcers, thereby prevent amputations(4, 5).

Methods: Retrospective cohort study of complicated DFUs (i.e. Texas grade 3) that have been treated with HBOT in a single hyperbaric center. Patients breathed 100% oxygen once daily for 5 days/week, for 80 minutes per day at 2.4 atmosphere absolute (ATA). Standard wound care was performed once a week. Primary outcome measures are substantial improvement in wound healing (i.e. ≥80% ulcer area reduction) and amputation rate (minor; i.e. below ankle joint, or major). Secondary outcome measures are number of sessions and patient adherence to therapy.
Results: From 2013 to 2018, 139 patients with a Texas grade 3 DFU were treated with HBOT and standard wound care. 47 patients (33.8%) achieved complete wound healing, while 58 patients (41.7%) achieved substantial wound healing. Minor amputation was performed in 9 patients (6.5%) and major amputation in 10 patients (7.2%). Mean number of sessions was 41.5 (1-112), with 99 patients (71.2%) completing at least 30 sessions. Patients with complete healing received an average of 44.0 sessions and 49.8 sessions with substantial healing. On average, patients received 25.1 sessions before minor amputation and 16.1 sessions before major amputation.
Conclusions: Using HBOT as adjunctive therapy to standard wound care leads to improved wound healing of DFU with Texas grade 3. Despite the severe wound grade, few patients needed minor or major amputation. Patients who did need amputation often did not complete a full regimen of HBOT. Concluding, HBOT is able to improve wound healing and prevent amputations in complicated DFUs.

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P34.06

Hyperbaric Oxygen Therapy for the Ischemic Diabetic Foot: a Systematic Review and Meta-Analysis

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Background: Diabetic foot ulcers (DFU) are frequently associated with peripheral arterial occlusive disease (PAOD) and may ultimately lead to amputations of the lower extremity. Adjuvant hyperbaric oxygen treatment (HBOT) might foster better wound healing and lower amputation rates in patients with DFU and PAOD. We systematically reviewed current literature to assess the effects of HBOT in addition to standard treatment for patients with DFUs with PAOD.

Methods: Systematic review using the MEDLINE, EMBASE and Cochrane CENTRAL databases (from inception to October 2018). All original studies on the effect of HBOT on DFUs with PAOD were eligible.
Results: Seven RCTs and four cohort studies were included for analysis, of which four were suitable for quantitative synthesis. Meta-analysis showed significantly fewer major amputations in the HBOT group (10.7% vs. 26.0%; RD=-15%, 95%CI -25 to -6, NNT=7, 95%CI 4-20). No significant differences were observed in complete wound healing, healing time, amputation free survival, mortality, need for vascular interventions, quality of life and costs.
Conclusion: Current evidence shows adjuvant HBOT decreases major amputation rate in patients with DFUs and PAOD. Patient selection may help define which patients with DFUs and PAOD benefit most from HBOT as standard adjunctive treatment. Shared decision making should be used to weigh up the decreased amputation rate against the burden of HBOT.

P35.01

Health-Related Quality of Life and Physical Activity Levels in People with and without Diabetes and Foot Ulcers from Regional Australia

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Aim: This study aimed to evaluate the health-related quality of life, anxiety and depression and physical activity levels in a cohort of people with foot ulcers compared to type 2 diabetes and non-diabetes controls living in regional Australia.
Methods: This study was conducted in a single site in regional Queensland (Australia) involving 21 people with diabetes-related foot ulcers (DFU group), 69 diabetes controls without foot ulcers (DMC group) and 56 healthy controls (HC group). The Australian version of the Short Form 36 (v2.0) was utilised to assess Health Related Quality of Life (HRQoL) mental-health component summary (MCS) and physical component summary (PCS) scores. Anxiety and Depression was measured using the Hospital Anxiety and Depression Scale (HADS). The International Physical Activity Questionnaire Short Form (IPAQ-SF) and an Omron-2 pedometer worn over four consecutive days were used to measure physical activity and daily step counts respectively. Kruskal-Wallis tests, Pearson's chi-squared test or Fisher's exact test were used to assess between group differences.
Results: The median MCS was 53 [interquartile range 13.0] in people with DFUs, 51 [21] in the DMC group and 58 [7.5] in the HC group (p=0.001). The PCS was 36 [16] in the DFU group, 40 [15] in the DMC group and 52 [7] in the HC group (p<0.001). Significantly more people in the DMC group experienced symptoms of depression compared to other groups (p=0.043). There was no statistical difference in the median minutes per day spent in vigorous activity (p=0.062), moderate activity (p=0.315) or walking (p=0.080) between groups. The median daily step counts were 3740 [4906] in the DFU group, 5305 [5427] in the DMC group and 7517 [4719] in the HC group (p<0.001).
Conclusions: Findings indicate marked differences in Health-Related Quality of Life and daily step-counts but not physical activity levels between the three groups. The factors responsible for these differences and similarities between groups requires further evaluation, particularly with a focus on the predictors of health-related quality of life and the determinants of physical activity in people with diabetes and foot ulcers in line with Australian recommendations.

P35.02

Comparing Orthogonal and Oblique SF-12 and PROMIS Patient-Reported Quality of Life in Diabetic Patients with and without Foot Disease

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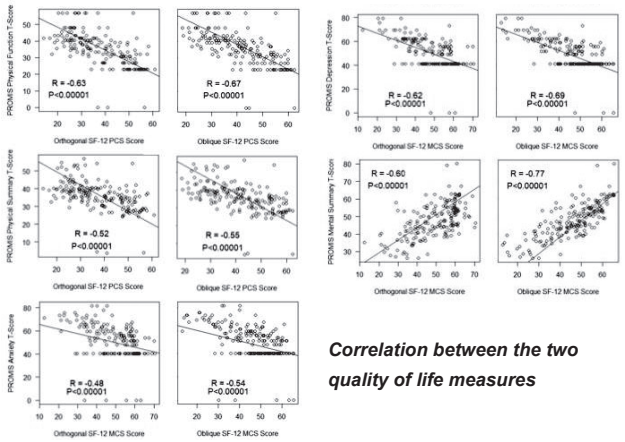
Aim: To determine correlation between orthogonally/obliquely scored Short Form 12-item survey (SF-12) Physical Component Summary (PCS) and Mental Summary Scores (MCS) and Patient-Reported Outcomes Measurement Information System (PROMIS) physical and mental health in patients with diabetes mellitus (DM) with or without foot disease and to compare the effectiveness of each survey tool.
Methods: Each patient completed the SF-12 and PROMIS surveys. Higher SF-12 scores indicate more favorable responses. Higher PROMIS scores indicate greater degree. Higher physical function scores indicate better physical function, while higher depression scores indicate greater depression burden. However, higher PROMIS Mental Summary score indicates better mental health.
Results: One hundred eighty-two patients completed the surveys. No ceiling or floor effects were noted in either SF-12 or PROMIS summary scores. Comparing SF-12 orthogonal and oblique PCS and MCS scores with PROMIS scores, oblique scores correlated better with PROMIS Physical Function, Depression, Anxiety, Physical Summary and Mental Summary scores (Figure 1).
Conclusion: The use of PROMIS in DM patients with and without foot problems has not been previously investigated. In contrast, the SF-12 survey has been previously described in this patient popula-

tion, but recent studies have suggested that SF-12 orthogonal MCS scores overestimate mental health in patients with DM compared to oblique MCS scores. Our findings suggest that PROMIS is better correlated with oblique MCS scores and is able to adequately capture mental health in DM patients with and without foot disease.



Correlation between the two quality of life measures

P35.03

Measuring the Effect of Diabetes-Related Foot Disease on Patient-Reported Quality of Life Using the SF-12 and PROMIS

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Aim: To compare patient-reported health-related quality of life (HRQoL) among patients with diabetes mellitus (DM) with or without foot disease using the 12-item Short Form (SF-12) and Patient-Reported Outcomes Measurement Information System (PROMIS) survey tools.
Methods: All patients completed SF-12 and PROMIS surveys. Patients were grouped by presence of foot disease. The survey tools were assessed by determining how each tool was able to capture HRQoL changes with foot disease.
Results: One hundred eighty patients were included. Of these, 87 (48.3%) had DM-related foot disease. Between groups, patients with foot disease were younger (p=.018), more often male (p=.005), had poorer DM parameters such as glycated hemoglobin (HbA¬1C) and duration of DM (p<0.05), worse renal function (p<0.05). In addition, they more often had neuropathy (p<.00001) and peripheral artery disease (PAD) (p<.00001). On SF-12, patients with foot disease scored worse among Physical Function (p=.007), Role Function (p=.007), General Health (p=.004), Social Function (p=.002) and Role Emotional (p=.011). On the PROMIS subscales, patients with foot disease reported worse Physical Function (p=.00003), Anxiety (p=.0006), Depression (p=.0003) and Social Role (p=.00008). Interestingly, despite the difference in Anxiety and Depression on PROMIS, no difference in the SF-12 subscale Mental Health (p=.490) was noted. All summary scores detected worse HRQoL with DM foot. (p<0.05) (Table).
Conclusion: Presence of DM-related foot disease significantly reduces patient HRQoL. Although worse physical function is reported across the survey tools, the SF-12 appears to do a poorer job of finding differences in mental health than the PROMIS.

Patient-reported outcomes with SF-12 and PROMIS

	Overall n = 180		DM Foot n = 87		No DM Foot n = 93		
Outcome Measure[a]	**Median**	**IQR**	**Median**	**IQR**	**Median**	**IQR**	**P-value**
SF-12 Subscale Scores							
Physical Function	50	(0-75)	50	(0-75)	25	(0-75)	**.007**
Role Function	0	(0-100)	0	(0-100)	0	(0-100)	**.007**
Bodily Pain	50	(6.3-75)	50	(0-75)	50	(25-75)	.112
General Health	60	(60-85)	60	(60-85)	85	(60-85)	**.004**
Vitality	40	(20-80)	40	(20-80)	60	(20-80)	.352
Social Function	75	(25-100)	75	(25-100)	50	(25-100)	**.002**
Role Emotional	100	(0-100)	100	(0-100)	100	(0-100)	**.011**
Mental Health	60	(50-60)	60	(50-60)	60	(50-60)	.490
SF-12 Summary Scores							
Physical component							
Orthogonal	36.6	(27.5-47.7)	32.8	(25.8-43.1)	40.4	(30.6-49.8)	**.006**
Oblique	41.4	(31.8-51.4)	37.1	(31.2-45.7)	46.2	(36.2-54.0)	**.001**
Mental component							
Orthogonal	52.5	(40.4-59.1)	48.7	(37.4-58.2)	55.0	(44.5-59.6)	**.024**
Oblique	48.0	(38.2-54.8)	44.0	(34.2-51.9)	50.1	(44.0-57.1)	**.002**
PROMIS Subscale Scores[B]							
Physical Function	35.6	(29.1-41.8)	39.1	(32.7-43.4)	32.1	(26.9-39.1)	**.00003**
Anxiety	51.2	(40.3-61.4)	55.8	(40.3-65.3)	48.0	(40.3-57.7)	**.0006**
Depression	49.0	(41-58.9)	55.7	(41.0-62.2)	41.0	(41.0-51.8)	**.0003**
Fatigue	48.6	(40.6-58.8)	51.0	(41.4-60.7)	48.6	(39.7-55.1)	.090
Sleep Disturbance	52.4	(50.5-54.3)	52.4	(50.5-54.3)	52.4	(50.5-54.3)	.287
Social Role	44.8	(38.8-51.6)	41.7	(32.4-47.3)	49.8	(41.7-55.6)	**.00008**
Pain Interference	58.5	(49.6-65.2)	61.2	(41.6-66.6)	55.6	(49.6-62.5)	.173
Pain Intensity	5	(2-7)	5.5	(2-8)	5	(1.8-7)	.338
PROMIS Summary Scores[A]							
Physical function	36.2	(32.4-40.1)	38.5	(34.7-43.5)	34.6	(29.7-38.4)	**.00005**
Mental health	47.0	(41.0-54.7)	43.9	(38.5-51.7)	51.2	(45.1-55.3)	**.0002**
FAAM							
FAAM (%)	59.5	(32.1-85.7)	42.9	(23.8-70.8)	72.6	(50.9-92.9)	**.00001**
FAAM Sports (%)	31.3	(6.3-57.8)	14.1	(0.0-37.5)	50.0	(23.4-75.0)	**<.00001**
Overall Function*	3	(2-3)	3	(2-3)	2	(2-3)	.070

* As reported by patient
[A]Factor coefficients from Hays et al 2018.
[B]Based on assumption of population average of 50 and SD of 10.

Comparison of responses between groups

P35.04

Care and Treatments Received Among Patients with Diabetes Who Have Undergone a Toe Amputation: A Qualitative Study

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Aim: The aim of this study was to use a qualitative approach to explore what patients think and understand about the treatment(s) they received for an infected toe ulcer, as it relates to the decision to amputate the toe.
Methods: We conducted semi-structured telephone interviews with a national sample of United States Veterans Health Administration (VHA) patients with diabetes who had undergone a toe amputation (n=42) in the year prior to interview. About half the sample (n=20) had one or more subsequent amputation(s) after the initial toe amputation. Interviews were recorded, transcribed, and analyzed using inductive content analysis.
Results: Almost all patients described both the decision to amputate and level of amputation as being determined solely by clinicians with the goal of “saving their foot.” Only a few patients de-

scribed the decision-making process as one in which they were presented with alternatives and were an active participant. Some patients who reported having undergone numerous surgeries/procedures described not understanding the reason for this clinical approach, and a few questioned their clinician's judgement. Many of those patients described difficult or complicated healing, including intensive wound care, long rehabilitation, pain, and restricted mobility. Some reported that had they known the possible impact and outcomes, they would have preferred a more definitive procedure earlier in the process. Patients described the importance of knowing what to expect during and after surgery, especially related to the treatment plan, healing time, and likely effects on mobility.

Conclusions: Most patients did not describe being active participants in amputation decision-making and some reported not understanding reasons for clinical treatment decisions, risks of complications, and the possible impacts of slow healing and repeated procedures. Identifying how best to involve patients in the decision-making process, including taking the time to ensure that patients understand advantages and disadvantages of treatment alternatives, may improve patient satisfaction and better align treatments with the patients' priorities.

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P35.05

Attitudes and Attributes of Women and Men Using Therapeutic Shoes Because of Diabetic Foot Complications

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Aim: Qualitative studies suggest that women have more negative attitudes toward therapeutic shoes than men do (1), but few quantitative studies have confirmed this (2). The aim was to compare attitudes and attributes of women and men using therapeutic shoes.

Methods: We constructed a questionnaire based on the Health belief model, but also included questions about adherence, foot complications, general health, locus of control, self-efficacy, etc. The questionnaire was posted to 1245 people with diabetes and experience of using therapeutic shoes. Answers of women and men were compared with two-sided t-tests, Mann–Whitney U tests and chi-square tests.

Results: 443 (35.6%) questionnaires were analyzed (66.4% men, mean age 69.2 years, SD 10.6). More men than women ($p<0.05$) did paid work (20.4 vs 9.4%) had someone who reminded them to wear their therapeutic shoes (27.6 vs 10.0%) and had a history of foot ulcers (62.9 vs 46.3%) or minor amputation (17.7 vs 6.7%). More women than men had disability pension (18.8 vs 10.2%). Women had worse general health, lower internal locus of control for ulcer prevention, and more negative attitudes to therapeutic shoes (appearance, price, and how it feels using them among other people). Other gender comparisons were non-significant ($p>0.05$): other shoe attributes, shoe adherence, education, diabetes type, present foot ulcers, major amputations, satisfaction with shoe services, understanding of neuropathy as risk factor, locus of control for ulcer healing, belief in shoes' efficacy, worries about ulcer healing and new ulcerations, self-efficacy, depression, fee paid for shoes, and social support.

Conclusions: Men had worse foot complications. Women had worse general health, more negative attitudes towards therapeutic shoes, lower internal locus of control, and less frequently were reminded to wear their therapeutic shoes. Health care needs to pay more attention to the concerns of women using therapeutic shoes. Research and development need to improve shoe appearance and investigate how to facilitate the process where patients change from only viewing shoes as items of clothing to also viewing them as medical interventions.

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Acknowledgement: Region Örebro County, Sweden, funded this study.

P35.06

A Systematic Review of Motivational Interviewing Training Outcomes for Health Practitioners Treating Persons with Diabetes.

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Aim: Motivational Interviewing (MI) is an evidence-based counseling technique directed at enhancing patient motivation for behavioral change. However, MI can only be effectively implemented with patients after training has been successfully implemented with health practitioners (HP). The aim of this systematic review was to investigate whether training diabetes-related HPs in MI improved their skills, and which type or structure of training gave the best outcomes.

Method: PubMed, EMBASE and PsycINFO were searched using the following terms individually and in combination: motivational interviewing, motivation enhancement, diabetes. MESH, keywords, titles and abstracts were searched for publications on the effectiveness of MI training for diabetes HPs. Two authors independently screened title and abstract, and full texts. Risk of bias was assessed using Cochrane forms and customised data extraction forms used to extract relevant outcomes.

Results: In total, 742 abstracts were screened, 57 full texts were examined with 16 articles meeting all eligibility for inclusion. Of the 16 articles, 5 were RCTs that primarily investigated outcomes of MI training on diabetes-related HP, but none specifically addressed diabetic foot disease. All had a high risk of bias. Another 5 RCTs that primarily investigated clinical outcomes reported training out-

comes in the intervention group only. Finally, 6 were uncontrolled studies of poor quality.
The five studies primarily measuring MI training outcomes all used different outcome measures. They generally found significant improvements after training with role-played practice in most measures of use of MI (p-values <0.01) and some measures of skills of MI (p-values <0.01). Length of training did not predict skills or use. Ongoing support and feedback gave more sustained effects. A common challenge for routine implementation was time in the clinical session, especially for longer forms of MI. No studies employed blind assessment.
Conclusion: Training in MI may improve practice and use of MI in diabetes-related HP. This is important information for clinicians and researchers considering implementing MI to improve diabetic foot care. However, it is important to note that limited information is available from controlled and well-designed studies, and no study has investigated this for clinicians treating people with diabetic foot disease.

P36.01

Do Microvascular Co-Morbidities Influence Mortality in People Undergoing Minor Amputations? A 6 Year Retrospective Cohort Analysis

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Aim: To establish which factors predict the risk of mortality in patients attending the diabetic foot clinic who underwent a minor amputation at our large secondary care institution.
Methods: A retrospective case note analysis of patients who underwent a minor amputation (i.e. below the ankle) attending our diabetic foot clinic between 2011 and 2016. Patients were followed up for a minimum of 1 year. A primary model analysis grouped patients according to those who did & did not die. Chi-squared tests were used for intergroup statistical analysis
Results: 1 year outcome data was available on 321 patients. 2 year data were available on 273. Two year mortality for this cohort was 29.7% (81/273). There were statistically significant associations between mortality at 1 year with number of previous successful revascularisations (p=0.02) and eGFR (p<0.01). Age (p<0.05), length of hospital stay [LOS] (p=<0.003), urinary albumin creatinine ratio (p=0.04) were also statistically significant at 1 year when comparing the median values. One year survival rates were significantly worse for those with sight threatening eye disease (R3M1) (p=0.0387), OR 2.45 (95% CI 1.03, 5.84).
At 2 years, the factors that remained significant predictors for mortality were age (p<0.05), LOS (p=0.01), eGFR (p<0.001) and maculopathy (p<0.03). For those with maculopathy at the time of their amputation, 47.5% did not survive beyond 2 years compared to 29.2% for no maculopathy.
Conclusions: We have shown that the presence of diabetes related microvascular disease in people attending a multidisciplinary diabetic foot clinic undergoing minor amputations significantly increases the risk of mortality. One year mortality is associated with the presence of nephropathy and sight threatening retinopathy, with 2 year mortality being associated with renal disease, and maculopathy.
These data suggest that the multidisciplinary foot team should highlight the increased risk of adverse outcomes to the person with foot disease, and aggressively promote multiple risk factor intervention at every opportunity

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P36.02

An Investigation of Foot Morbidity and Mortality Rates Following Toe Amputations in Diabetes

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Aim: To determine the one-year rate of healing, re-ulceration, re-amputation and mortality following toe amputations in patients with diabetes.
Methods: A single-centre non-experimental research design was employed. Eighty-One participants with type 2 diabetes admitted for an elective toe amputation were recruited. Subjects were followed every 3 months post-amputation for a period of 1 year. During each visit, subjects were assessed for progress of amputation site. At the end of the 12-month period, data was analysed to determine the rate of healing, re-ulceration, re-amputation and mortality following minor foot amputation.
Results: During the 12 months of study, 59.3% of patients underwent further surgery to revise the original amputation site or to amputate a new site whilst 45.7% of the patients presented with an ulcer at a different site. Mortality was recorded amongst 7.4% of the cohort. In 12.4% of participants the amputation site remained incompletely healed with half being infected. Only 20.9% of participants had no complications following the amputation implying that most participants had to go through multiple surgeries and events such as ulcerations and infections prior to complete wound closure. At 12 months, 80.2% of the study cohort had a completely healed amputation site.
Conclusions: This study focused on all the possible outcomes following minor foot amputations amongst a population with a high prevalence rate of diabetes. Similar studies only focus on one of the eventualities, mainly mortality or re-amputation but this study is unique since it evaluated all possible outcomes following amputation over a one-year period. Despite the high rate of healing noted amongst the cohort after one year taking measures to prevent infections, re-ulceration and re-amputation and ultimately death is very important for patients with diabetic minor foot amputations. Efforts should be made to minimize these risks since it has been documented that such complications following surgery decreases patients' quality of life and increases mortality rates. More studies are warranted to evaluate these outcomes further.

P36.03

The Five-Year Mortality Rate in People with Diabetic Foot Ulcer in the Years 2010: an Optimistic Message

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Aim: Mortality rate is decreasing in people with diabetes but if this observation also concerns patients with diabetic foot ulcer (DFU) needs exploration. This study evaluated the mortality rate at 5 years in patients with a DFU occurring in the years 2010.
Methods: Patients who successively attended a DFU center for a new foot ulcer during the years 2009-2010 were included. At year 5, data on mortality were collected by consulting clinical files or town hall registers on by phone call to the patient and relatives. The study was approved by the local ethic committee. Time to death after inclusion was analyzed using Kaplan Meier method. Patients who were known to be alive at five-year or lost-to follow up were censored. Multiple logistic regression modelling was used to identify mortality risk factors.
Results: 347 patients were included: 68 % were males, mean age was 65±14 years, median diabetes duration was 16 [10; 27] years; 70% had peripheral artery occlusive disease (PAOD), 13 % were on dialysis and 6 % had an organ graft. Median wound duration at inclusion was 49 [19; 120] days. At 5 years, 49 patients (14%) were lost to follow up. The five-year mortality rate was 35% [30; 41]. Patients with no PAOD had a five-year mortality rate of 16% [10; 25]. Independent predictors of five-years mortality were higher age, higher diabetes duration, PAOD, and non-healing at one year.
Conclusions: Mortality rate of patients attending with a DFU in 2009-2010 was not as high as published before the 2000s despite a high number of co-morbidities, suggesting that these patients benefit of a better health care. This result emphasizes that DFU should not be considered as a terminal illness, and that all means of prevention and treatment must be implemented to improve chances of survival. In patients with neuropathic foot ulcer, the chance to be still alive after five years is particularly high. Importantly, patients with a persistent non-healed ulcer after one year are at high risk of mortality independently of PAOD and age. These patients could probably have benefit of a better global care.

P36.04

Cardiovascular Determinants of Mortality after Major Amputation in Diabetic Patients

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Aim: Our main objective is to define and evaluate the mortality rate and the cardiovascular (CV) determinants of mortality after a major amputation in the diabetic population of our Diabetic Foot Clinic.
Methods: The retrospective cohort included diabetic patients who underwent a major amputation between January of 2000 and July 2009. Patient data up to january 2015 or untill the date of death were retrieved using the clinical records of the institution. We identified total and CV mortality in a 5 year period after amputation and divided it in: 30 days mortality rate, one year, and 5 years after surgery.
Results: A total of 151 patients met the inclusion criteria and were analyzed.
In the first 30 days 13.3 % of the patients died, 31.3 % died between the first and 12 months and 25.5% between the first year and the fifth year. Cardiovascular factors as Left Ventricular Hypertrophy (LVH) or Hypertension (HTA) were more prevalent in the group that died. 62 out of 151 had LVH (41%) and 83.9% of these patients died compared to only the 60% of deaths in the group without LVH (p 0.002).
Conclusions: In our population the mortality rate at the end of follow up was 70%, 106 out of 151 patient died between 5 years. Most of the patients died in the first year . Myocardial infarction was the main cause of death, sepsis being the second. We found LVH and HTA as risk factors for increased mortality.
It is necessary to pay special attention to this risk group, tailoring objectives and treatments to their situation and life expectancy.
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P36.05

Learning from Death - Mortality Review in Diabetes Foot Clinic

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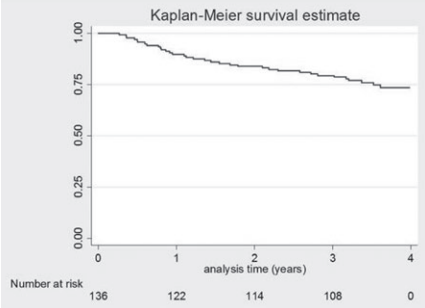
Aim: Diabetic foot ulcer (DFC) is associated with early and excessive mortality. This study is to investigate mortality rate in a hospital-based Multidisciplinary Diabetes Foot Clinic (MDFC) and use standardised hospital Mortality Review (MR) to determine the circumstances surrounding the death for quality improvement and shared learning.
Methods: 137 case records, MR including the diagnosis and the cause of death of patients who attended the MDFC with active foot ulceration from 2015-2018 were reviewed and variables including age, date of attendance to death, SINBAD, HbA1c, lipids, eGFR analysed using STATA.
Results: N=137 (97M:40F), 35/137 deaths occurred in the 3 years follow-up period. There was no difference in age, SINBAD. HbA1c, lipids, eGFR between the deceased and survival groups. 20 deaths occurred in hospital, among them 70% had MR which recorded no death directly due to diabetic foot disease but 93% of MR indicated

complications such as IHD, stroke and CKD, all known significant comorbidities related to diabetes.
Fig.1 Kaplan-Meier survival estimate in MDFC.
Conclusion: The mortality of patients with known foot ulceration remains high, 1 in 4 patients died in 3 years even amongst them some ulcers had healed. The majority of the deceased group had MR. While 100% MR target was not achieved, MR offered information on diabetes complications profile which was likely contributory to deaths. There are gaps of missing information on deaths particularly outside hospital and a joint mortality collaborative of MDFC and GPs with Community Foot Health Team is recommended.

Kaplan-Meier survival estimate in MDFC



P37.01

Identifying and Defining the Skills Needed by Multidisciplinary Teams in Order to Manage Diabetic Foot Ulceration - the POINT Project

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Aim: This piece of work aimed to identify and define the skills needed by multidisciplinary diabetic foot teams in order to provide best possible care to patients with diabetic foot disease. Such skills in many areas are provided by podiatrists where they exist.
Methods: An collaboration between D-Foot International and the International Federation of Podiatrists was formed and using the international guidance produced from the International Working Group on the Diabetic Foot (IWGDF), the TRIEPod UK document and with existing models of practice. An interdisciplinary panel discussed the relevant podiatric skills required to provided care in different health care systems and geographical locations. Following the initial discussions development of domains of care were developed. These domains were discussed among panel members via email and consensus reached. These domains were then cross referenced and discussed further to ensure consistency across all domains and levels
Results/Discussion: The POINT document presents a set of skills across 13 domains of practice at 4 separate levels. It is a document which will allow teams to benchmark their care delivery for content and consistency across the 4 levels of care. It will enable multidisciplinary foot teams to identify areas where they need to improve. In addition the tool highlights the skills of podiatrists and their importance in diabetic foot care teams which can be used by local decision makers in order to promote inclusion of such skills across the health service.
Conclusion: The POINT document is a consensus document base on the evidence included in the IWGDF guidelines. It defines the skills needed to provide podiatric skills to patients with diabetic foot disease irrelevant of the geographical location or healthcare system.
References: TRIEPod UK (2012); Wilson et al (2018); Acker, et al (2018)

P37.02

In-Hospital Pedicure Clinic for Diabetic Foot People at Siriraj Hospital Complex in Thailand

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Aims: It is well recognized that toenail problems can be the cause of foot ulcer and amputation in diabetic people. However they are under-recognized especially in low to middle income countries. In Thailand there are very limited numbers of standard pedicure clinic for diabetes both in public and private hospitals. The aim of this presentation is to share data of pedicure clinics at Siriraj hospital complex in both public and private sectors.
Methods: The study was conducted at 2 pedicure clinics at the Faculty of Medicine Siriraj Hospital (public sector) and the Siriraj Piyamaharajkarun Hospital (private sector). Data include patients and service profiles, common toenail problems, obstacles on patient side and healthcare provider side, and cost of services.
Results: At the public sector, the pedicure clinic serves only 2 days per week due to limited number of nurse specialist. There were approximately 40-45 patients per month. Most patients can get government healthcare coverage. At the private sector, the clinic serves every day with approximately 60-80 patients per month. At both clinics, the common problems were the same. About 75 percents were diabetes, average service time was 45 minutes, appointment interval varied from 6 to 12 weeks. The top 3 toenail problems were involution, Onychomycosis, and ingrown toenail due to improper care. Major patient obstacles of self-toenail care included elderly with poor vision, obesity with low back pain, and lacking of caregiver. Major healthcare provider obstacles included not enough number of nurse specialists, lacking of educated caregivers, high cost compared to salon shop services. The cost of service at the private sector was about 4 times compared to cost at the public sector. One of the reasons was the private one was only 4 years old with well-equipped technology but the public one was 12 years old with standard technology.
Conclusions: Toenail care is a problem among people with diabetes even in low or high economic status. The overall pedicure clinic data at both public and private sectors were the same. Involuted toenail was the most common problem. Major obstacles were limited physical function, lacking of caregivers and specialist nurses.

P37.03

Integration of Pedorthic Management into One-stop Interdisciplinary Diabetic Foot Clinic at Siriraj Hospital in Thailand

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Aim: The general foot clinic at Siriraj Hospital was established two decades ago as a result of an increasing number of diabetic foot patients. An increased demand for services necessitated the establishment of a stand-alone foot clinic in 2013. The current interdisciplinary diabetic foot clinic includes rehabilitation doctors, diabetic foot care nurses, physiotherapist, pedorthist, prosthetist orthotists, and shoe specialists. The International Working Group on Diabetic Foot (IWGDF) has been a formidable guide for the foot clinic. This study aimed at identifying the specific role of the pedorthist and core benefits provided to patient services while working within the multidisciplinary team at Siriraj Hospital, the largest public university hospital in Thailand.
Methods: A descriptive study was performed by exploring qualitative data collected from the year 2015 to 2018. Parameters of interest were the pedorthist clinical provisions to patients during this time period. Time of assessment and time to delivery were also evaluated.
Results: Approximately 240 patients per year received pedorthic intervention. The primary role of the pedorthist in the clinic was to evaluate the patient and design a suitable pedorthic prescription. The clinic practices a multidisciplinary approach to foot management. An active discussion amongst the team is undertaken in order to create best practices for pedorthic modalities. The final step in the current system is a “checking out and delivery” procedure with patients and doctors. A benefit of this system appears to be that all orthotic and footwear services are rendered by trained professionals who work in a closed loop communicative environment. Thus, quality one-stop services are provided to all patients regardless of condition. However, a major limitation is that the number of pedorthists is scarce , thus often times resulting in device delays of upwards of two weeks.
Conclusions: A comprehensive team approach to Pedorthic management plays a vital role in conservative management of the diabetic foot. Still, future studies are recommended to evaluate other factors such as long-term ulcer prevention outcomes and cost-effectiveness per pedorthic treatment.
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P37.04

National Collaborative Interdisciplinary Diabetes High Risk Foot Services Standards and Accreditation Program

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Aim: Effective diabetes-related foot care, including the appropriate referral to High Risk Foot Services (HRFS), is key to amputation reduction. This presentation will summarise national HRFS standards and outline the rationale for, and the process of, developing national standards and an associated nationwide accreditation program for HRFS.
Methods: Through the collaboration of a series of key stakeholder groups, principally national or leading healthcare organisations, Collaborative Interdisciplinary Diabetes HRFS Standards and an associated accreditation program have been realised.
In evaluating the standards and accreditation program, a pilot was conducted whereby seven HRFS were provided with a self-assessment accreditation workbook and Quality Improvement (QI) plan. Criteria that was assessed as ‘not or partially met’ required the HRFS to develop an action plan, with the aim of service improvement, through setting achievable and quantifiable goals. On submission of the workbook and QI plan, independent reviewers assessed the application resulting in the award of either Core or Centre of Excellence (COE) Level HRFS Accreditation or ‘Accreditation Standards not met’. Comprehensive feedback was obtained from contributing HRFS and assessors.
Results: A robust HRFS accreditation program has been implemented and HRFS standards are being universally adopted. The standards and associated accreditation program will help realise and maintain a high level of HRFS care nationally, aiding equity of access, and underpinning more consistent across-service outcomes in diabetes foot care.
Conclusion: Few countries have developed national standards and an accreditation program for diabetes HRFS. The national HRFS Standards can collectively be used as clinical indicators for sites aspiring to achieve HRFS standards at Core or COE level. They also help to inform health administrators of the resources required to establish HRFS and the dynamic interactive nature of interdisciplinary care needed to achieve quality care outcomes.
The accreditation model is aimed at the improvement of quality and safety, supporting benchmarking within HRFS, and focussing on a three-pronged approach combining governance, clinical and quality criteria. The accreditation program sets a benchmark level for HRFS nationally, however, can also guide any foot service aiming to benchmark and improve the quality and range of services provided to people with diabetes receiving footcare.

P37.05

The Role of "Diabetic Foot" Rooms in the Organization of Specialised Help to Patient with Diabetic Foot Syndrome in Uzbekistan

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Of all the late complications of diabetes, foot lesions are the most preventable. The multidisciplinary approach to providing specialized help for people with diabetes can prevent the amputations in 49-85% diabetic foots.
Aim: The organization of specialized help to patient with diabetic foot syndrome (DFS) by the establishing the network of "Diabetic foot" rooms and training of multidisciplinary team of specialists (endocrinologist, surgeon, GP, cardiologist and nurses-podiatrists) in order to decrease a number of lower limb amputations in peoples with diabetes in Uzbekistan
Methods: Within the framework of an international project WDF08-379 "Prevention of lower limb amputations in people with diabetes in Uzbekistan", implemented by "UMID" association jointly with Ministry of Health of Uzbekistan and Republican specialised scientific and practical medical Centre of endocrinology in 2010-2012, 288 "Diabetic foot" rooms were set up under 14 endocrinological dispensaries and in 274 rural district clinics. To work in these rooms, 288 special multidisciplinary teams (endocrinologist, surgeon, GP, cardiologist) and 615 podiatrists were trained to render a qualified medical help to peoples with diabetes and teach them rules of foot care.
Results: During the project, 22479 patients with diabetes have been screened and trained in the "Diabetic foot" rooms. As a part of Diabetes Self-Management Education courses, the nurses-podiatrists educate the peoples with diabetes on DFS prevention. Annually over 23,800 peoples with diabetes undertake feet examination and training in "Diabetic foot" rooms. The trained multidisciplinary teams (endocrinologist, surgeon, GP, cardiologist, podiatrist) from 14 regions provides specialized care to patients with DFS. The effective work of the trained team reduced a number of amputations in peoples with diabetes by 2 times in Uzbekistan.
Conclusions: Implementation of the project "Prevention of lower limb amputations in people with diabetes mellitus in Uzbekistan" improved a specialised help to people with DFS due to launching a network of "Diabetic foot" rooms and an effective work of podiatrists; training of multidisciplinary teams in 14 regions which resulted in the decreasing a number of amputations in peoples with diabetes by 2 times in Uzbekistan; increased awareness of rural people with diabetes on prevention of DFS.

P37.06

Cross-Regional Multidisciplinary Diabetic Foot Network: an Organizational Approach to Improve Quality in Screening and Treatment

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Background: Our institution is a highly specialized diabetes center with a long tradition and high expertise in screening and treatment of diabetes foot complications among individuals at risk. The screening is carried out by podiatrists in a specially designed foot clinic. As part of cross-regional collaboration, this model has been implemented at all diabetes out-patients clinics in the region treating app. 14,500 persons with diabetes (type 1 and 2). In addition, a regional multidisciplinary diabetic foot network has been established.
Aim: Improve and unify the quality of screening and treatment of the diabetic foot across hospitals by:
• Facilitating collaboration and knowledge exchange between health care professionals involved in the screening and treatment of the diabetic foot.
• Compliance of national and international guidelines to ensure standardized clinical practice across all hospitals.
• Uniform registration and documentation of the interventions to evaluate the effort.
Methods: In 2017, foot clinics were established/up-graded and podiatrists employed. In 2018, teams of relevant health care professionals (podiatrists, doctors and nurses) across hospitals were identified, and consecutive meetings have been held since August 2018. In addition to a commission for the network, well-defined evaluation parameters have been identified (process and outcome).
Results: Regular meetings in the cross-regional multidisciplinary diabetic foot network have been held, where the following themes have been discussed:

- Knowledge exchange and demonstration of correct registration in the electronic patient record (ICD-10 diagnosis for foot ulcers, registrations of activity and extended foot status).
- Vascular surgery of ischemia and visitation criteria.
- Cooperation with shoemakers and rehabilitation offers in the municipalities.
- Memory of messages among persons with diabetes after a consultation in the foot clinic.

Conclusion: The cross-regional multidisciplinary diabetic foot network is an innovative organizational approach aiming to improve and uniform quality of screening and treatment of the diabetic foot across hospitals. The initiative has not yet been evaluated, however, early experiences indicate that the network is valuable knowledge exchange forum, where challenges in clinical practice across hospitals, medical specialties and health professional groups are discussed.

P38.01

Hemodialysis Can Deteriorate Gait and Balance Beyond Diabetes and Aging

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Motor and cognitive functions are deteriorated along aging [1, 2]. Some chronic conditions may magnify this deterioration. This study examined whether hemodialysis would negatively impact gait and balance beyond diabetes among mid-age and older adults. 196 subjects (age=66.2±9.1years, body-mass-index = 30.1±6.4kg/m2) in 5 groups were recruited: mid-age adults with diabetes undergoing hemodialysis (n=38) and without hemodialysis (n=40); older adults with diabetes undergoing hemodialysis (n=36) and without hemodialysis (n=37); and non-diabetic older adults (n=45). Using validated wearable technologies, gait and balance performances were assessed [3, 4]. Compare to non-diabetic group, people with diabetes had overall poorer gait and balance ($p<0.050$). Among people with diabetes, hemodialysis groups had significantly worsened gait and balance when comparing to non-hemodialysis groups (Cohen's effect size $d=0.63–2.32$, $p<0.050$). In addition, between-group difference was more pronounced among older adults than mid-age adults. It can also be observed that deterioration in gait speed among hemodialysis people was negatively correlated with age ($r=-0.404$, $p<0.001$), while this correlation was diminished among non-hemodialysis people. This study confirmed that the presence of diabetes can deteriorate gait and balance, and this deterioration can be magnified by hemodialysis, while older adults are more vulnerable than mid-age adults. Among people with diabetes undergoing hemodialysis, age was a dominate factor describing poor gait. This study also demonstrated that motor function of hemodialysis patients can be assessed during their routine dialysis clinic visits by using wearable technologies. This may facilitate identifying early deterioration in motor function, which in turn may provide timely intervention and treatment.

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P38.02

Predicting Frailty in Chronic Limb Threatening Ischemia Using a Novel Wearable Device

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Introduction: Frailty is a known predictor of morbidity in people undergoing surgery. Several tools have been used to estimate frailty using clinical, laboratory data, as well as ability of patient to ambulate. Chronic limb threatening ischemia (CLTI) is a major cause of ambulatory deficiency and adoption of modern modalities to measure frailty is critical for patients with CLTI. The aim of the current study is to estimate the role of upper extremity frailty (UEF) index for CLTI patients.

Methods: UEF index was measured for all 40 consecutive people with CLTI admitted to two University Teaching Hospitals from September 2018 to December, 2018. All had frailty measured classical Fried criteria as well as a wearable upper extremity frailty meter (UEF). Medical records were reviewed for preoperative ambulatory deficiency due to CLTI. The difference of UEF index was measured between patients who were able to ambulate and those unable. Univariate and multivariate methods were used to analyze the data.

Results: All forty patients (27 male, 13 female, mean age 67.8 ± 11.8 years) , admitted for treatment of CLTI were able to undergo UEF index measurement. Twenty-one of them (52.5%) were frail (UEF Index < 0.28), with an average UEF index of 0.25 ± 0.13. Twelve patients (30%) had ambulatory deficiency and therefore were not able to complete the requirements by the classical Fried frailty index. Frailty rate by UEF index was similar between patients who were able and unable to ambulate, 57.1% and 41.7% respectively ($p=0.37$).

Conclusion: CLTI is a significant condition causing ambulatory deficiency, resulting in inability to assess frailty with existing tools. People with ambulatory deficiency are at least as frail as those without ambulatory deficiency, therefore the UEF index likely has a significant role for estimating frailty in patients with CLTI.

P38.03

Quantifying Stepping Thresholds as a Novel, Modifiable Measure of Fall-Risk in Older Adults with Diabetes

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Aim: Older adults with diabetes are at high risk for falls. Many fall-risk assessments evaluate balance during steady state, failing to consider responses to balance-loss following perturbations. This study evaluated whether responses by older adults with diabetes to externally applied perturbations could serve as a novel marker of fall-risk that is independent from simple balance tasks.

Methods: We recruited older (≥65 years) adults with (n=36) and without (n=36) diabetes, who did not use assistive devices and had no active lower extremity wounds. External perturbations were applied by pulling and then releasing a waist-mounted spring scale. Participants were instructed to resist stepping upon load-release. Stepping thresholds (ST) in the anterior and posterior directions were defined as the lowest loads (percent body-weight) that induced a step. Participants also completed the NIH Toolbox Standing Balance Test, which quantifies body sway during five standing postures. Finally, fall-risk was quantified as self-report of ≥1 falls over the past year. To examine the effects of diabetes and fall history on ST, we conducted ANOVAs for each direction. To determine if ST and balance independently predicted fall-risk, we first corre-

lated ST and balance. Next a stepwise logistic regression was conducted to assess ST, balance and diabetes status as independent predictors of fall history.
Results: ST was ~14% lower in both directions for diabetic participants (posterior p=0.033; anterior p=0.014). Anterior, but not posterior ST was significantly lower in fallers (p=0.005 and p=0.56, respectively). Only anterior ST was significantly associated with balance (r=0.516, p<0.001) and in the logistic regression fall-risk depended on anterior ST (p=0.03) but not balance (p=0.90) or diabetes (p=0.10).
Conclusion: Avoiding anterior steps following a perturbation involves activating ankle plantarflexors. Lower anterior ST in diabetic individuals and fallers may reflect lower plantarflexor strength in patients with diabetes and even lower strength in diabetic fallers. It is also possible that diabetic peripheral neuropathy leads to delayed production of corrective ankle torques. Although additional work is required to understand mechanisms of impaired anterior ST in persons with diabetes, if low ST predicts falls in these individuals then protective step training may help reduce fall risk.

P38.04

Use of Foot Worn Sensor to Monitor for the Progression of Frailty in Older Adults

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Aim: Frailty is highly prevalent in patients with diabetes [1]. Early screening can lead to more timely intervention to improve the prognosis of older adults, especially in patients with diabetic foot problem. Recently, wearable devices have shown the potential to track foot problem in patients with diabetes to alert and provide early signs of potential foot problems in real-time. The aim of this study was to determine whether foot-worn sensor could be used to track frailty syndrome in older adults and the prospect of developing a continuous monitoring system to assess foot problem during daily activities such as walking.
Methods: Gait performance of 161 older adults using a shin-worn gyroscope was used to investigate the feasibility of developing smart footwear to assess frailty. Sensor-derived gait parameters were extracted and modeled from a single gyroscope to identify different frailty stages, including robust, pre-frail, and frail. These gait parameters are: propulsion duration and acceleration, mid stance speed, speed norm, toe-off and mid swing speed. Kruskal-Wallis test was used to investigate the correlation among the three groups with alpha=0.050.
Results: Data from the shin-worn sensor demonstrated that frail group had longer propulsion duration when compared to the pre-frail (p=0.035) and robust group (p=0.003). The propulsion acceleration was also significantly lower in the frail group as compared to the pre-frail (+54%, p=0.002) and robust (+84%, p<0.001). The toe-off speed was significantly reduced in frail individuals when compared to pre-frail (p=0.030) and robust group (p=0.001). The mid swing speed was significantly lower in the frail group when compared to the robust (p<0.001) and pre-frail (p=0.007).
Conclusions: This study demonstrates that a shin-worn sensor-derived gait measures during the propulsive phase of walking could be used to assess frailty in older adults. This result could motivate the development and integration of single-sensor system into wearable footwear to assess frailty during daily living activities to monitor the development or progression of foot problem in patients with diabetes.
Funding: Partial funding for this project was provided by the National Institute of Health (NIH)
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P38.05

Peripheral Neuropathy Severity and Balance Impairments are Predictors for Falls in Community Dwelling Adults with Diabetes

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Aim: Identify predictive risk factors for falls within community dwelling adults with diabetes mellitus (DM), and diabetic peripheral neuropathy (DPN).
Methods: 762 participants were evaluated during two annual public campaign (2013-2014) and divided into two groups: control (n=664) and "fallers" (n=98, ≥2 falls in the last year). We included in a univariate logistic regression model (backward stepwise fashion) for risk of falls variables already known as predictors of falls and DM and DPN-related variables that could potentially contribute to falls: age; sex; visual deficiency; time of DM diagnosis; glycaemic level; quantity of medication taken; Functional Reach Test result; risk of falling (Functional Reach Test >15cm)[1]; global strength level (maximum handgrip test - dynamometer); use of gait aid; referred balance problems; referred leg weakness; referred fear of falling; vibratory (128Hz tuning fork) and tactile sensitivity (10g monofilament); DPN symptoms [2]; and DPN degree (score 0-10) determined by a fuzzy model (score 0-10) [3].
Results: The risk of falls was associated to balance problems, number of insensitive feet areas, functional reach test and degree of DPN (Table 1).
Conclusions: The strongest predictor for falls was the degree of DPN. This finding shows that a combination of aspects of DPN is a stronger predictor in comparison to a single parameter, since the fuzzy model combines DPN signs and symptoms.
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Acknowledgements: FAPESP (2017/15449-4)

Table 1 - Final model of the logistic regression analysis of risk of falls

Variable	OR (95% CI)	P
Age (years)	1.020 (0.995-1.045)	0.118
Visual deficiency	0.664 (0.416-1.062)	0.088
Balance problems	0.453 (0.284-0.722)	**0.001***
Number of insensitive feet areas	0.688 (0.534-0.885)	**0.004***
Vibratory sensitivity	0.376 (0.136-1.045)	0.061
Functional Reach Test (cm)	0.953 (0.924-0.984)	**0.003***
Neuropathy degree (score)	1.566 (1.217-2.016)	**<0.001***

(OR = Odds ratio; CI = Confidence interval)

P38.06

Too Frail or Not Too Frail: the Question of Preoperative Rehabilitation for Frail Patients with Critical Limb Threatening Ischemia

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Aim: Frailty is a condition of decreased reserve and response to stressors, making patients susceptible to adverse outcomes. Highly frail patients with critical limb threatening ischemia (CLTI) are more likely to have major adverse cardiovascular events (MACE). Moreover, frail patients undergoing interventions for CLTI have lower overall survival and amputation-free survival rates, irrespective of age and revascularization technique. We aim to demonstrate that frailty is a risk factor that can be modified utilizing a preoperative rehabilitation program (prehab) with improved postoperative outcomes and frailty.
Methods: The institution of prehab has been proven to decrease postoperative complications, wound complications, and increase postoperative activity and function in other surgical specialties. With an established interdisciplinary limb salvage team we are exposed to a large population of patients with varying stages of frailty and CLTI, due to common risk factors. Most frailty measures require patient ambulation; however, these measures are poor assessments in a CLTI patient who inherently has difficulty ambulating. Therefore, we use the Upper Extremity Frailty tool (UEF), a well validated frailty measurement device worn around the wrist, requiring only arm movement for assessment. Using this device, we have identified a cohort of frail CLTI patients who are significantly weaker, slower, and less flexible than not frail patients.
Results: With positive frailty assessment, dieticians evaluate nutritional status and tailor preoperative guidelines for each patient. This includes diet structuring, calorimetry, diabetes management, and supplements. Subsequently, our physical therapy team (PT) creates patient-specific programs targeting balance, locomotion, aerobic, endurance, and flexibility exercises. Preemptive training on wound care, assistive devices, and transfer means is also provided. The entire program necessitates 2 weeks prior to surgery and at least 3 PT sessions per week. Moreover, patients wear activity monitors which provide continuous feedback on daily physical activity, and receive other risk factor modification education.
Conclusions: When frail CLTI patients require operative intervention, it is imperative to optimize their frailty due to increased risk of limb loss, lower overall survival, and MACE. Implementing a prehab program can adequately modify factors contributing to their frailty, thus optimizing them for surgery and reducing postoperative complications.

P39.01

The Possible Impact of Baseline HbA1c at Presentation and Diabetic Foot Ulcer Healing Rate: a Paradox to the Norm

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Aim: The association between good glycaemic control and wound healing of diabetic foot ulcers (DFUs) is not completely understood. The aim of this study was to investigate the association between baseline HbA1c levels and 12-week wound healing in a single center multidisciplinary diabetic foot team (MDfT) cohort of patients presenting with an acute DFU.
Method: A retrospective analysis of consecutive patients attending a diabetic foot clinic with new foot ulceration with duration of less than 14 days was carried out. Data was extracted electronically, and patient records were reviewed for demographic characteristics and biochemical results. Patients were divided into two groups: Group 1 (healed at 12weeks) and Group 2 (non-healing at 12weeks) and data analyzed via SPSS software version 17.
Results: A total of 249 patients were included. At 12 weeks 112 DFUs (45%) healed and 137 DFUs (55%) were still active. Demographic characteristics of the study participants are presented in Table 1. Multivariate logistic regression analysis demonstrated that only CRP levels (OR=0.986, 95% CI=0.976-0.997, p=0.013) and ulcer area ≥1cm2 (OR=0.453, 95% CI=0.260-0.790, p=0.005) were significantly negatively and independently associated with wound healing at 12 weeks. Neither baseline HbAc1 levels of ≤7.5% nor ≤8.5% at presentation were associated with improved wound healing at 12 weeks of follow-up.
Conclusion: Baseline glycaemic control does not seem to be a significant predictive factor for wound healing at 12 weeks within an MDfT setting. However, presence of infection and SINBAD score seem to be important predictor of wound healing at 12 weeks.

Table 1. Demographic characteristics of the study participants.

	Group 1 Healed at 12weeks n=112	Group 2 Non-Healing at 12weeks n=137	p values
Age (years)	62.2 ± 15.5	65.6 ± 12.7	**0.061**
Gender – Male (%)	72 (64.3)	100 (73.0)	0.139
HbA1c (%)	8.65 (7.10, 10.48)	8.00 (6.90, 9.30)	**0.060**
CRP (mg/L)	6.9 (2.0, 16.5)	12.9 (5.8, 34.3)	**<0.001**
eGFR (mL/min)	73.5 (53.0, 90.0)	65.0 (46.0, 85.0)	**0.016**
WBC (x10^9/L)	7.42 (6.03, 8.72)	7.51 (6.22, 9.00)	0.362
Hb (g/L)	126.6 ± 21.0	123.3 ± 18.8	0.197
PAD (%)	30 (26.8)	59 (43.1)	**0.008**
SINBAD score =3	57 (50.9)	97 (70.8)	**0.001**

P39.02

Significance of HbA1c Determination for the Assesment of Frequency and Invasiveness of DF Treatment and Amputation in Patients with DM2

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Glycosylated hemoglobin (HbA1c) is important parameter for the assessment of long term metabolic control and risk for development of chronic complications in patients with diabetes mellitus (DM). This study investigates associations between achieved metabolic control in DM with the risk for the development of diabetic foot (DF) and its treatment modalities. The study included 111 patients (80 men and 31 women) with type 2 DM, aged 65.5 ± 9.8 years. DF lesions occurred 13.9 ± 8.8 years after diagnosis of DM. In 41 patients DF was treated by conservative approach, 41 patients underwent a minor limb amputation (foot amputation) and 29 patients underwent a major limb amputation (below-knee amputation). The levels of HbA1c and serum biochemical parameters were measured by standard laboratory methods. The most frequent risk factor for DF in the examined group (82% patients) was poor glycaemic control (HbA1c >8%). The level of HbA1c value was significantly higher in surgically treated patients than in conservative treated group (P<0.05). The number of patients who underwent surgical treatment were significantly higher in group with poor glycaemic control (62.8% patients with poor glycaemic control vs. 40% patients with optimal glycaemic control; P<0.05). We found that the patients with poor glycaemic control had 3.2 times higher risk for amputation (OR=3.21; 95%CI: 1.18-8.69; P<0.05). Also, our results have shown that an increase of HbA1c level by 1% was associated with 54% higher risk for amputation (OR=1.54; 95%CI: 1.02-2.31; P<0.05). In conclusion, our results demonstrated that optimal metabolic control in type 2 DM reduces the risk for DF development, as well as the invasiveness of DF treatment.

Significance of HbA1c determination for the assesment of frequency and invasiveness of DF treatment and amputation in patients with DM2

P39.03

Association of Inpatient Glucose Measurements with Amputaions in Patients Admitted with Acute Diabetic Foot

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Aim: Both hyperglycemia and hypoglycemia in hospitalized patients are known to be associated with worse clinical outcomes, increased morbidity, mortality and length of hospital stay (1,2). We studied the association of inpatient glucose measurements with any or major amputations in patients admitted with acute diabetic foot (DF).
Methods: In our hospital, patients presenting with acute DF are admitted to a dedicated DF unit and treated according to a detailed protocol, including a standard basal-bolus insulin protocol. In this retrospective study we reviewed the demographic, clinical, laboratory and point-of-care glucose data from the electronic medical records of patients hospitalized in the DF unit during 2015-2017. Hyperglycemia was defined as ≥3 episodes of glucose>250mg/dl during admission. Any hypoglycemia was defined as at least one episode of glucose<70 mg/dl. Severe hypoglycemia was defined as at least one episode of glucose<54mg/dl. Coefficient of variation (CV) was categorized as above or below the median.
Results: During the study period, 425 patients were hospitalized for a median of 17 days in the DF unit. Patients experiencing hyperglycemia, any or severe hypoglycemia or high CV were more likely to undergo any or major amputations during hospitalization (table). In multivariate analysis, any hypoglycemia was independently associated with major amputations.
Conclusions: Inpatient hyperglycemia, hypoglycemia and increased glycemic variability are associated with increased risk of any or major amputations in patients admitted with acute DF. Although these may be solely a marker of disease severity, the possibility of inpatient glycemia as a modifiable risk factor for amputation merits further investigation.

Association of glycemic measures and amputations

	Any amputation	No amputation	Major amputation	No Major Amputation	Total
Hyperglycemia	180 (58.6)**	127 (41.4)	88 (28.7)*	219 (31.3)	307
No hyperglycemia	51 (43.2)	67 (56.8)	21 (17.8)	97 (82.2)	118
Hypoglycemia	133 (65.8) †	69 (34.2)	71 (35.1) †	131 (64.9)	202
No hypoglycemia	98 (43.9)	125 (56.1)	38 (17.0)	185 (83.0)	223
Severe Hypoglycemia	66 (70.2) †	28 (29.8)	41 (43.6) †	53 (56.4)	94
No severe hypoglycemia	165 (49.8)	166 (50.2)	49 (14.8)	272 (85.2)	331
High CV	126 (59.2)*	87 (40.8)	65 (30.5)**	148 (69.5)	213
Low CV	105 (49.5)	107 (50.5)	44 (20.8)	168 (89.2)	212

Numbers are listed as n(%). CV - Coefficient of variation – calculated as standard deviation of all glucose measurements divided by the mean.
*p-value <0.05, **p-value <0.01, †p-value <0.001

P39.04

Prevalence of Vitamin and Mineral Deficiencies in Diabetic Patients with Foot Wounds

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Aim: Nutrition and wound healing are closely linked. Nutritional deficiencies, including deficiencies of vitamins and micronutrients, may impede normal progression through the specific stages of wound healing. The purpose of this study was to analyse serum vitamin and mineral levels in diabetic patients with foot wounds.
Methodology: Plasma levels of Vitamin A, C, D, E, copper, zinc and ferritin were measured at initial assessment of diabetic patients with foot wounds seen at multidisciplinary foot clinics or admitted to our hospital in Australia. The association between the nutrients most commonly cited as important for wound healing, vi-

tamin C, vitamin A and Zinc, and clinical factors including smoking status, duration of diabetes, HbA1c levels, BMI and burden of diabetic foot disease as assessed by WIfI score was analysed using using Kruskal-Wallis test (for Vitamin C) or Wilcoxon test (for Zinc and vitamin A).

Results: 131 patients were included in the study. Seventy-seven patients had a biochemical deficiency of at least one micronutrient. The most prevalent vitamin deficiency identified was vitamin D with 56% of patients presenting with levels below the normal range. Suboptimal levels of vitamin C affected 73% of patients, comprising marginal levels in 22.2% and deficient levels in 50.8%. Zinc deficiency, vitamin A deficiency and low ferritin levels were present in 26.9%, 10.9% and 5.9% of patients respectively. None of the patients had low levels of copper or vitamin E.

There was no correlation between BMI, duration of diabetes, HbA1c or smoking status and nutritional deficiency. Increased severity of diabetic foot disease was associated with lower vitamin C levels (p = 0.02).

Conclusion: Vitamins and micronutrients are required in small amounts, yet they are critical to cellular metabolism, especially during wound healing. These results show that in the diabetic population with foot ulcers/wounds, the prevalence of vitamin and micronutrient deficiency is high. The high prevalence of vitamin C and zinc deficiency is of considerable concern, given their key roles in wound healing. Although further research needs to be performed to determine the clinical implications of our findings, vitamin and mineral deficiency should be assessed in diabetic patients with foot wounds.

P39.05

Nutritional Status in Diabetic Patients with and without Diabetic Foot Ulcer: a Pilot Study.

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Aim: Hospitalization and diabetes mellitus (DM) are both directly related to nutritional status. Malnutrition is detected in up to 80% of patients and predisposes to infection, development of ulcers, worse wound healing, higher rates of hospitalization and mortality. Diabetic foot ulcer (DFU) usually develops in diabetic patients with higher comorbidities. We hypothesize that patients with DFU present worse nutritional status than diabetic hospitalized patients without DFU.

Methods: Fifteen diabetic patients hospitalized for DFU as main diagnosis were compared with 15 diabetic hospitalized patients for any other diagnosis. Nutritional screening tests (MNA, MUST) were performed within 72 hours of admission, as well as medical history, anthropometric measurements, use of hand dynamometer, laboratory data and mediterranean diet adherence questionnaire. For descriptive purposes we used median and quartile 1 and 3 for non-normally distributed continuous variables and percentage for discrete variables. By univariate analysis we compared discrete variables using the $\chi 2$ test; for continuous variables we used the non-parametric Mann–Whitney U test. Statistical analysis was performed with SPSS statistical package version 20 for MacOS (SPSS Inc., Chicago, IL, USA) and a P value < 0.05 was set as the threshold of statistical significance.

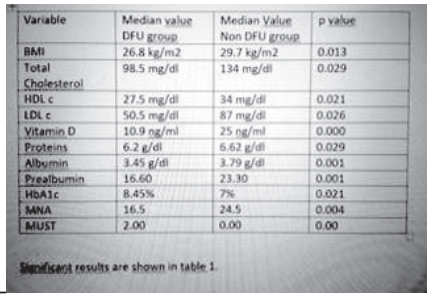
Results: Malnutrition according to MNA was found 46.7% in patients with DFU in comparison with 0% in those without DFU (p=0.009).

Using MUST screening tool, risk of malnutrition was found in 100% of patients with DFU in comparison with 26.7% of diabetic patients without DFU (p=0.000).

Adherence to Mediterranean diet was found 20% patients with DFU and 66.7% in non DFU patients (p=0.01). No differences were found in toxic abuse, antidiabetic treatment, leucocites, neutrofiles or haemoglobin or C reactive protein levels.

Conclusions: Malnutrition detected in MNA and MUST screening tests was more prevalent in diabetic patients with DFU in comparison with diabetic patients hospitalized for other reasons. Lower parameters at admission were found for BMI, albumin, prealbumin, total proteins, total and cholesterol fractions and vitamin D. A poor metabolic control was found in HbA1c levels in patients with DFU. Due to secondary effects associated to poor nutritional status, early detection and treatment should be provided for patients with DFU.

Significant results



Variable	Median value DFU group	Median Value Non DFU group	p value
BMI	26.8 kg/m2	29.7 kg/m2	0.013
Total Cholesterol	98.5 mg/dl	134 mg/dl	0.029
HDL c	27.5 mg/dl	34 mg/dl	0.021
LDL c	50.5 mg/dl	87 mg/dl	0.026
Vitamin D	10.9 ng/ml	25 ng/ml	0.000
Proteins	6.2 g/dl	6.62 g/dl	0.029
Albumin	3.45 g/dl	3.79 g/dl	0.001
Prealbumin	16.60	23.30	0.001
HbA1c	8.45%	7%	0.021
MNA	16.5	24.5	0.004
MUST	2.00	0.00	0.00

Significant results are shown in table 1.

P39.06

Nutritional Status, Ulcer Severity and Outcome in DFU Patients: Is There a Link? A Single Centre Prospective, Observational Cohort Study.

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Aim: Malnutrition is suggested to negatively influence the prognosis of a diabetic foot ulcer (DFU). The relation between malnutrition, other risk factors, DFU severity on admission and outcome at 6 months was evaluated.

Patients and methods: This prospective, observational cohort study included 94 patients admitted between July 1st, 2016 and June 30th, 2018. Informed consent was provided by all patients. Treatment was conducted by the same multidisciplinary team according to international guidelines.

Nutritional status was assessed within 48 hours of admission, using three methods. First, 2 screening (NRS-2002 and MNA-SF) and second, 2 assessment questionnaires (SGA and MNA) were performed. Finally, impedance measurements determined body

composition. Nutritional status was assessed by the standardized phase angle (SPA), with a SPA < -0,8 indicating malnutrition.
After scoring according to each of the above individual methods, nutritional status was arbitrarily assigned: 'normal', 'at risk', or 'malnourished', if respectively no, one or two or more of these methods revealed abnormalities. Risk factors were identified in medical records. Wagner classification was determined upon admission. Outcome was evaluated after 6 months.
Results: See Table 1.
Discussion: In general, risk factors were comparable between groups, except for BMI and cardiac history. A high burden of comorbidities is noted in all groups, slightly higher when compared to the national Belgian average (IQED data). Ulcer severity did not differ between groups. The authors speculate that the standard implementation of an intensive nutritional treatment protocol since many years, might explain the relatively favorable outcomes in the malnourished group.

	Normal nutritional status (N = 13)	At risk for malnourishment (N = 21)	Malnourished (N = 60)
Risk factors			
Age *(years)*	67 (30 – 85)	71 (48 – 85)	70 (40 – 92)
Gender *(M/F)*	11/2 (85/15)	17/4 (81/19)	45/15 (75/25)
Diabetes Type *(Type 1/Type2)*	4/9 (31/69)	2/19 (10/90)	13/47 (22/78)
HbA1c *(%)*	7.7 (5.9 – 12.2)	6.8 (5.5 – 9.6)	6.5 (3.2 – 15.0)
Albumin *(g/l)*	36 (24 – 42)	34 (21 – 42)	32 (19 – 41)
BMI *(kg/m²)*	25.7[a, b] (23 – 40)	28.5[b] (21 – 43)	29.7[a] (19 – 45)
Smoking status *(Active/Never/Former/missing)*	2/6/5/0 (15/46/39/0)	2/11/7/1 (10/52/33/5)	7/29/23/1 (12/49/38/1)
Cardiac history *(Yes/No)*	3/10[a] (23/77)	14/7 (67/33)	47/13[a] (78/22)
Neuropathy *(Yes/No)*	6/7 (46/54)	14/7 (67/33)	44/16 (73/27)
Peripheral Artery Disease *(Yes/No)*	9/4 (69/31)	16/5 (76/24)	47/13 (78/22)
Chronic kidney Disease *(Yes/No)*	8/5 (62/38)	15/6 (71/29)	47/13 (78/22)
Dialysis *(Yes/no)*	1/12 (8/92)	3/18 (14/86)	5/55 (8/92)
Kidney transplant *(Yes/No)*	0/13 (0/100)	1/20 (5/95)	2/58 (3/97)
Previous DFU *(Yes/No)*	8/5 (62/38)	10/11 (48/52)	40/20 (67/33)
Previous amputation *(Yes/No)*	6/7 (46/54)	9/12 (43/57)	23/37 (38/62)
Wound characteristics			
Wound duration *(days)*	25 (6 – 617)	30 (7 – 365)	50 (1 – 912)
Osteomyelitis *(Yes/No)*	7/6 (54/46)	13/8 (62/38)	40/20 (67/33)
Wagner classification *(grade 1/2/3/4/5)*	0/6/6/1/0 (0/46/46/8/0)	0/8/12/1/0 (0/38/57/5/0)	0/18/39/3/0 (0/30/65/5/0)
Outcome			
Outcome *(healing/no healing/minor amputation/major amputation/death/lost to follow-up)*	5/2/5/0/1/0 (38/15/38/0/8/0)	6/4/10/1/0/0 (29/19/48/4/0/0)	13/12/24/6/3/2 (22/20/40/10/5/3)

Table 1: results

P40.01

Use of Lateral Ankle Stabilization in Midfoot Charcot Beaming and Subtalar Joint Fusion to Prevent Calcaneal Varus: Surgical Technique

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Aim: Ankle varus deformity can occur after midfoot Charcot beaming and subtalar joint fusion, especially with patients with preoperative hindfoot varus and pre-existing ankle instability. Pinzur et al found the rate of ankle neuropathic deformity development to be 3.1% post Charcot reconstruction of non-plantigrade foot after return to weight bearing (1). Charcot osseous reconstruction, including midfoot beaming and subtalar joint fusion, results in increase force going through the ankle joint, especially rotational forces. In hindfoot varus malalignment the ankle undergoes strong inversion forces, leading to further instability by progressive weakening of the lateral ligaments (2). Our primary aim is to introduce a novel surgical technique in the treatment of Charcot with pre-operative hindfoot varus.
Methods: The goal of lateral ankle stabilization is to decelerate the progression of the inverting deforming forces and hold the ankle in a neutral position. The lateral ankle is reconstructed with either a semitendinosus allograft tendon or internal brace, depending on the preoperative stress test for talar tilt. With talar tilt on stress radiographics, the lateral ankle is stabilized using allograft tendon to recreate the ATFL and CFL. With no talar tilt on stress radiographics, primary reconstruction of the lateral collateral ligaments with augmentation using suture anchor as an additional constraint.
Results: The ultimate goal of the Charcot reconstruction is to create a stable, plantigrade, ulcer-free, ambulatory foot. The goal of this novel surgical technique is to retard the deforming forces and prevent progressive deformity at the ankle joint via lateral ankle stabilization.
Conclusion: Hindfoot varus creates severe complications in patients status post beaming and subtalar joint fusion. Progressive attenuation and weakening of the lateral collateral ligaments can result in symptomatic unconstrained lateral ankle instability (Backer). Prior to our surgical technique, no literature has addressed the importance of stabilizing the lateral ankle to stabilize against hindfoot varus in Charcot reconstruction.
References:
1. Pinzur MS. Foot & Ankle International 33:644-646, 2012.
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P40.02

Risks for Failure After Osseous Reconstruction in Non-Diabetic Patients with Charcot Neuroarthropathy

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Aim: This study aims to report the risks of failure for Charcot neuroarthropathy reconstruction in non-diabetic patients. The literature for diabetic Charcot neuroarthropathy is prolific but the literature for non-diabetic Charcot neuroarthropathy remains mostly limited to small case reports and case series of one to two patients. Hyperglycemia is an important risk factor for developing Charcot neuroarthropathy but it is unknown which risks contribute to complication after Charcot reconstruction in the non-diabetic population. Our study is the largest known cohort of non-diabetic Charcot patients

who underwent osseous reconstruction. We sought to evaluate the risks of failure within this cohort.
Methods: A retrospective review was conducted on 26 patients who underwent osseous reconstruction for non-diabetic Charcot neuroarthropathy at a single institution over a 10-year period. Bivariate analysis was performed for post reconstructive outcomes including delayed healing, dehiscence, amputation, delayed or non-union, Charcot recurrence, and new location of Charcot collapse against multiple risk factors. The risk factors for post reconstructive complications included age, BMI, HbA1c, CKD, ESRD, HTN, PAD, smoking history, preoperative ulcer location, Charcot joint breakdown location, and preoperative soft tissue infection or osteomyelitis.
Results: Preoperative soft tissue infection (p=0.0283) and a preoperative ulcer located on the lateral ankle (p=0.0323) were statistically significant risk factors for dehiscence. Dehiscence was 3.750 times more likely in the patients with preoperative soft tissue infection [OR 3.750 (95% CI (0.396-35.54)]. There were no statistically significant risk factors for delayed healing, amputation, delayed or non-union, Charcot recurrence, or new location of Charcot collapse.
Conclusions: We hypothesize neuropathy has the largest effect on post reconstruction complications. Therefore, no statistically significant risk factors were found to result in delayed healing, amputation, delayed or non-union, Charcot recurrence, and new location of Charcot collapse. Both preoperative lateral ankle wounds and soft tissue infection statistically increased the rate of dehiscence. The treatment of soft tissue infections typically involves surgical resection, resulting in a tissue deficit and increased tension across an incision. Similarly, the lateral ankle has minimal soft tissue overlying the bone, leading to tenuous wound closure and resulting in higher rates of dehiscence.

P40.03

One-Year Outcomes of External Fixation Treatment in Infected Charcot Foot Patients

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Aim: Treatment of Charcot neuro-osteoarthropathy (CNO) is mostly conservative by off-loading but a number of case series showed effectiveness of surgical procedures using external or internal fixators leading to foot saving and ability to walk. Use of this method in the case of infected ulceration or osteomyelitis (OM) is subject to ongoing controversy. The aim of our study was to evaluate 12-month outcomes in patients with infected ulcerated CNO treated by external fixation (EF).
Methods: Of 21 patients with CNO (mean age 55±13 years, 15 men, 11 with Type-2 DM) who had had surgery using an external fixation (EF) device between Jan 2015 and Sep 2017, 18 (86%) healed primarily within 6 months and were further followed-up to 12 months after EF application. Prior to surgery, all patients presented with foot ulcer infection (mean duration 17±22 months), severe deformity and/or foot instability without critical limb ischemia (mean TcPO2 54±14 mmHg); OM was confirmed by positive bone cultures in 62%. Mean duration of EF was 11±3 weeks. Healing at 6 months was defined as foot ulcer re-epithelization lasting a minimum of 4 weeks. Postoperative off-loading was performed using a wheelchair progressively replaced by weight-bearing devices. Main outcome measures after 12 months of EF application included re-ulceration, need for additional surgery and ability to walk.
Results: By 6 months, 18/21 (85%) healed. During another 6 months of follow-up, 1/18 patients died from a CV event. Of the remaining 17 primarily healed patients, 7 (41%) re-ulcerated after weight bearing. Additional surgery was required in 5(29%) patients, of these, 3(18%) had orthopedic corrections. Of total 21 patients who underwent ZF, 10 (48%) were ulcer free after one year, 2 (10%) had died, no major amputation was required. At the end of the follow-up period, 12 (71%) patients were able to walk using accommodative devices (footwear or orthoses) while 5 (29%) still used wheelchair.
Conclusion: External fixation in infected CNO is an acceptable treatment option; in our study, 63% of patients were able to walk after one year. Given the high risk of re-ulceration even after primary ulcer healing, intensive life-long podiatric care is necessary.

P40.04

Clinico-Metabolic Factors Determining Severity of Charcot's Neuropathy in Diabetes: a Case-Controlled Prospective Observational Study

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Aim: Charcot neuroarthropathy (CN) is a serious complication of diabetes neuropathy causing progressive destruction of the bones and joints of the foot leading to deformities and increased risk of ulceration. The aim of this study was to identify clinical and metabolic risk factors which could be associated with not only development of but also related to severity of CN in DM.
Methods: A matched case-control study was conducted assessing the association between anthropometric and metabolic variables namely age, gender, BMI, mean blood pressure (mBP), HbA1c, urinary albumin creatinine ratio (uACR), eGFR and lipid indices in acute CN presenting between January 2015 and December 2018. This study compared 30 CN cases of DM with 120 age, gender and type of diabetes-matched DM subjects without CN as controls. Conditional logistic regression was used to estimate matched odds ratios (ORs) and 95% confidence intervals (95% CIs). Within the case group, the same variables were examined to see association with severity of disease.
Results: Our study showed that risk for CN was associated with age (OR=1.09; 95% CI:0.87-1.42; p=0.001), male gender (OR=3.98; 95% CI:1.45-4.15; p=0.01), mBP (OR=1.01; 95% CI:0.87-1.31; p=0.01), HbA1c (OR=1.37; 95% CI:0.1.0-1.62; p=0.001) and triglycerides levels (OR=1.23; 95% CI:1.00-1.51; p=0.01) no risk was

seen with either type of diabetes, BMI, uACR, eGFR and other lipid indices (p=≥0.05).
CN cases were graded using Brodsky classification; 53.3% (n=16) had stage 1, 23.3% (n=7), stage 2, 16.7% (n=5), stage 3a and 6.7% (n=2) had stage 5. After regression analysis the factors associated with increasing severity of CN were male gender (OR=1.28; 95% CI:0.91-1.87; p=0.001) and HbA1c (OR=1.01; 95% CI:0.70-1.37; p=0.003) while no relationship was seen with age, BMI, mBP, lipid indices, uACR and eGFR (p=≥0.05).
Conclusions: This study shows that early identification of specific risk factors is important in the management of CN. It further indicates that apart from specific management of CN, improved glycaemic control and lowering triglycerides could influence onset and progression of the same. Furthermore specific management of these risk factors might lead to improved outcomes in this cohort of patients; however prospective larger studies will be needed to explore this hypothesis.

P41.01

The effectiveness of dialkylcarbamoylchloride (DACC) coated dressings in the management of foot ulceration in people with Diabetes. A case series

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Aim: The primary aim of this case series is to investigate and evaluate the role of DACC coated dressings in the treatment of Diabetic foot ulceration and local infection in 2 sites.
Dialkylcarbamoylchloride (DACC) dressings are composed of acetate swabs or cotton ribbon coated with DACC. DACC binds hydrophobic micro-organisms through the process of hydrophobic attraction. No chemicals are donated into the wound thus increasing the safety profile. The effect of DACC is expected to reduce the bacterial load in the surface of wounds and to prevent infection thus accelerating wound healing. A review of the available evidence shows that such dressings may be beneficial in foot wounds which are complicated by diabetes.
Method: A convenience sample of 16 patients were recruited from the podiatry led diabetic foot clinics in 2 large urban teaching hospitals across an 8 month period. The product was applied at clinicians' discretion and use was continued until the treating clinician felt it was no longer indicated.
Results: Of the 16 patients 10 patients wounds healed completely, 3 patients wounds improved and 3 patients wounds deteriorated and needed further intervention With the heightened awareness of antimicrobial resistance the use of DACC for the management of local bacterial load is worth consideration.
Conclusion: DACC coated dressings may be of use in the management of chronic foot wounds in patients with diabetes. Further studies with controlled variables are now warranted.
References: Haycocks et al (2011)

P41.02

Efficacy of Biological Dressing Based on Collagen-Hyaluronic Acid in Treatment of Non Infected and Non Ischemic Dorsal and Plantar DFU

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Aim: value safe, effectiveness and outcome of new biological dressing based on collagen and hyaluronic acid in treatment of non infected and non ischemic dorsal and plantar diabetic foot ulcers: a prospective non controlled observational study.
Method: Protocol for treatment of out- patients affected by diabetic foot ulcer are characterized by different dressing to be applied during tissue repairing process as described by TIME approach. Since non specific dressing were suggested for remodelling phase we decide to study a new biological dressing consisting of matrix made by native horse collagen Type 1 and Hyaluronic Acid on dorsal and plantar not ischemic not infected diabetic ulcer. We enrolled consecutively , from March 2017 to February 2018, 38 diabetic pts (31 dorsal ulcers and 7 plantar ulcers) with TcPo2 >30 mmHG. Treatment protocol consist of: 1) revascularisation when needed (20/38 52 % TcPo2 post PTA 40±11 2) surgical debridement since bleeding wound bed 3) Collage+Hyaff pad (grease gauze) changed for day 4) post surgical shoes for dorsal ulcer 5) Fiberglas Total Contact Cast for plantar ulcer 6) photo and ulcer measurement at each visit
Results / Discussion: treatment period was 83±68. The healing rate was 4% (21/38) with total healing time of 87±day. Median reduction of wound area was 78%. Healing rate for plantar ulcer treated by TCC 100% with healing time of 93±46 days
Conclusion: Biological dressing can be considered a logical evolution of dressing ulcer protocol moving from TIME to TIMER where R means regenerative approach by biological dressing.

P41.03

Use of Honey Dressings on a Leg Ulcer with Tendon Exposure in a Patient with Type 2 Diabetes: Case Report

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Honey has been used as a wound dressing for hundreds of years by ancient civilizations, but only recently it has acquired scientific interest because of its relevant biological properties. In the last decade, indeed, several trials and observational studies have re-

ported that, compared to conventional treatment (e.g., antiseptics, polyurethane film, paraffin gauze, soframycin-impregnated gauze), honey dressings seem to be better in healing time of different types of wounds, including diabetic foot ulcers. However, to date, information about a potential favorable biological effect of honey dressings on diabetic ulcers with exposed tendon are still scarce. Notably, foot or leg ulcers with exposed tendon are serious complication in patients with type 2 diabetes, as they are associated with an increased risk of adverse outcome. Therefore, the use of effective and safe treatments to bring these lesions to timely healing is very important in clinical practice.
We herein report the case of a Caucasian adult patient with type 2 diabetes presenting a chronic right posterior lower limb ulcer (Texas University Classification [TUC] 2D) with tendon exposure that was successfully treated with honey dressings in addition to systemic antibiotic therapy, surgical toilette and skin graft. In our case, the use of honey dressing for treating exposed tendon tissue probably allowed the timely wound healing. Although further studies are required, such treatment may constitute part of the comprehensive management of diabetic wounds, including those with tendon exposure, and should be considered by clinicians in clinical practice.

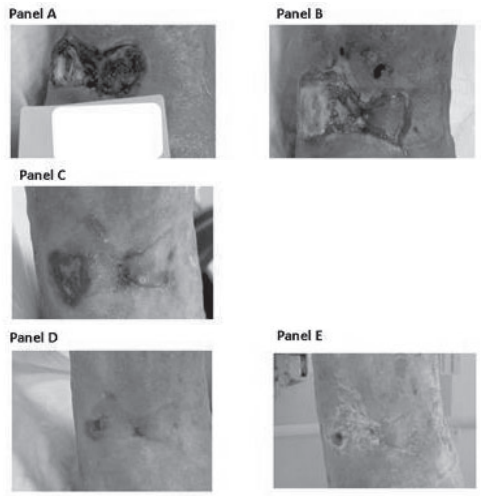

Figure 1. Leg ulcer with tendon exposure in a patient with type 2 diabetes. Panel A, initially the leg ulcer measured 62 × 51 mm and was characterized by tendon exposure, mild perilesional redness and moderate exudate. Panel B, after surgical toilette and the skin graft, the tendon exposure persisted, but it was still vital. Panel C-E, the use of honey dressings started to promote the re-epithelization of the tendon and the healing of the remaining ulcer. The complete healing of the lesion occurred after three months of treatment with honey dressings.

P41.04

Management of Neuropathic Diabetic Foot Ulcers with a Tlc-Nosf Wound Dressing : Results of a Pilot Clinical Trial

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Aim: To evaluate the efficacy, tolerance and acceptability of a TLC-NOSF (TLC-sucrose octasulfate) dressing in the management of neuropathic diabetic foot ulcers.
Methods: A multicentre, pilot, prospective, non-controlled open-label clinical trial. Adult patients with type 1 or 2 diabetes mellitus, suffering from a grade 1A (Texas classification), non-infected neuropathic foot ulcer, 1–15cm2 in size and duration 1–24 months were included in the study. The primary endpoint was the relative reduction of the wound surface area (%) at the end of the treatment period of 12 weeks. Secondary end-points included rate of complete healing, tolerability and acceptability of the dressing. Wound dressing was regularly changed at the investigator's convenience according to the wound status and volume of exudate. Patients were assessed every two weeks for the twelve weeks treatment period. At each visit, patients underwent a clinical assessment with an ulcer surface area measurement (planimetry) and photographs.
Results: Thirty three diabetic patients with a neuropathic foot ulcer were included in this trial. At baseline, the mean surface area of the treated DFUs was 2.7cm2 and mean duration was 6.7 ± 5.2 months. At the 12-week visit, the median surface area reduction was 82.7% (mean reduction 62.7 % ± 49.9) and in
10 of the 33 treated patients (30%), the wound was completely healed. Only two out of the seven documented local adverse events were deemed to be related to the tested dressing. According to the nursing staff, acceptability was considered as very satisfactory, particularly conformability and ease of use.
Conclusions: The use of the TLC-NOSF dressing (UrgoStart Contact), combined with offloading and debridement, looks effective to promote the healing process of the neuropathic diabetic foot ulcers, with a good safety profile and acceptability for patients and nursing staff.

P41.05

Clinical Study on Healing of Foot Ulcers in Diabetic Patients with Medical Collagen

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Aim: To investigate the effectiveness of collagen on the healing of diabetic foot ulcers
Methods: 180 DFU patients who in the Metabolic Disease Hospital of Tianjin Medical University from November 2015 to October 2017 (including Wagner grades 2 to 3 and Wagner grade 4) were admitted to this study. Each patient was given adequate treatment

to improve metabolism,circulation, anti-infection, wound treatment and so on. When the patient's metabolism was stable, the infection was effectively controlled, and the wound bed was ready, then they were randomly divided into a collagen treatment group (90 cases) and a standard treatment group (90 cases). The standard treatment group was given daily wound dressings, if necessary, patients were given debridement and the collagen treatment group was given a medical collagen dressing on the basis of standard treatment.

Results: From the 2nd week, the wound area in the collagen treatment group was significantly reduced, In the fourth week, and 8th week, the wound area in the collagen group was respectively 4.60±1.90cm2 and 3.60±1.85cm2; 5.85±1.76cm2 and 4.96 ± 1.91cm2, P <0.05) .The time of foot ulcer healing in the collagen treatment group was significantly shorter than that in the standard treatment group (78.00±5.43 days) (60.23±5.23 days) (P<0.05). In patients with Wagner grade 2, the healing time in two groups were no difference (18.23±5.56 days vs 20.12±4.23 days ,P>0.05); In patients with Wagner grade 3 and 4,the healing time in two group had difference (Wagner grade 3, 35.16±5.40 vs40.23±6.70, Wagner grade 4, 52.13±2.21 vs 61.01±2.18 Days) (P<0.05). Patients with toe ulcers, there was no significant difference in the healing between the two groups (P>0.05), but in the other three sites(dorsum, sole, heel), the foot ulcer healing of patients in the collagen treatment group was better than the standard treatment group (P<0.05).

Conclusions: After the wound of diabetic foot treating with medical collagen dressing, the wound area was significantly reduced compared with the standard treatment group, the total healing time was shorter, especially in Wagner 3-4 after operation.

P42.01

Comparison of Patient Fears Between Diabetic Patients with and without Diabetes-Related Foot Disease

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Aim: To evaluate patient fears regarding potential adverse outcomes in context of diabetes mellitus (DM) with and without DM-related foot disease.

Methods: Patient medical records and survey responses were collected from multiple institutions and retrospectively reviewed. Patients were asked to grade "Stroke," "Blindness," "Heart Attack," "Death," "Dialysis," "Foot Infection," "Leg Amputation," and "Foot Amputation" on a 5-point Likert scale with a response of "5" corresponding to the highest fear rating and "1" being the lowest fear rating. Patient fears were compared between those with and without DM-related foot disease.

Results: Six hundred fifty-eight patients were included. Of these, 271 (41.2%) had documented DM-related foot disease while 387 (58.8%) had no documented foot problems. Patients with foot disease were significantly younger (57.0±11.5 vs. 62.2±12.5 years, p<0.0001), more likely to be male (65.7% vs. 49.2%, p<0.0001) and had longer duration of DM (17.4±9.7 vs. 13.7±10.6 years, p<0.0001). No differences in body-mass index (BMI) (33.8±8.0 vs. 32.8±7.5 kg/m2, p=0.74), DM type (p=0.14). Among fears, no difference in fear of Stroke (p=0.47) or Heart Attack (p=0.11) was noted between groups. However, patients with DM foot problems rated higher levels of fear for Blindness (p=0.001), Death (0.0003), Dialysis (p=0.0006), Foot Infection (p<0.00001), Leg Amputation (p<0.00001) and Foot Amputation (p<0.00001). The order of patient fears by magnitude are shown in table 1.

Conclusions: Patients with foot disease reported higher fear ratings than those without foot disease. However, the top four greatest fears of both groups were the same: Foot Amputation, Leg Amputation, Foot Infection and Blindness.

Table 1. Patient fears by presence of diabetes-related foot disease ranked in order of highest to lowest fear on a 5-point Likert scale

	DM Foot Disease		No Foot Disease	
	Fear	Avg. Rating*	Fear	Avg. Rating*
1	Foot Infection	3.79	Foot Amputation	2.90
2	Leg Amputation	3.76	Foot Infection	2.84
3	Foot Amputation	3.68	Blindness	2.84
4	Blindness	3.22	Leg Amputation	2.81
5	Dialysis	3.13	Dialysis	2.72
6	Heart Attack	2.79	Heart Attack	2.59
7	Stroke	2.65	Stroke	2.57
8	Death	2.61	Death	2.17

DM = Diabetes Mellitus
*Reported ratings are an average of responses on the 5-point Likert scale. Values closer to 5 indicate greater fear and values closer to 1 indicate less fear.

Patient fears by presence of diabetes-related foot disease

P42.02

To Determine the Prevalence of Psychological Factors in Patients with Chronic Wounds

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Background: Depression, anxiety and stress are associated with widespread impairment of cellular and humoral immunity which causes delayed wound healing. Psychological factors disrupt the activity of macrophages and lymphocytes in the healing process. These factors are exaggerated if these patients are physically or financially dependent or lack family support.

Aim: To determine the prevalence of psychosocial factors in patients with chronic wounds in a tertiary care hospital.

Methods: Medical history was obtained. The participants were administered the DASS 42 (Depression, Anxiety and Stress scale) questionnaire.

Results: Of the 43 patients enrolled with chronic wounds, 28 (65%) were males. The mean age of the patients was 61.8±10.3. Diabetes was present in 39 (91%) patients with the mean duration of diabetes being 11.1±8.8 years. An HbA1c of >7% in the last month was reported in 30 (70%) of these patients. Peripheral vascular disease was found in 6 (14%) patients while 24 (56%) had neuropathy. Of the 43 patients, 28 (65%) were physically dependent for hospital visits, while 33 (77%) were dependent for wound dressing. DASS showed a normal score for depression in 13 (30%) patients, while 30 (70%) had an abnormal score, of which 20 (67%) had a score indicating severe or extremely severe depression. A normal score for anxiety was found in 10 (23%) patients, while 33 (77%) had an abnormal score, of which 21 (64%) had a score in-

dicating severe or extremely severe anxiety. A normal score for stress was found in 20 (47%) patients, while 23 (53%) had an abnormal score, of which 9 (45%) had a score indicating severe or extremely severe stress. A significant linear-by-linear association (p=0.006) was found between the duration of the wound and depression. Pearson chi-square test showed a significant association (p= 0.024) between the duration of the wound and anxiety.
Conclusion: Our results demonstrate a high prevalence of depression, anxiety and stress in patients with chronic wounds. There is an association between duration of wound and development of depression and anxiety. Addressing these psychosocial factors may escalate wound healing.

P42.03

Understanding Patients: a Process Perspective on Diabetic Foot Disease

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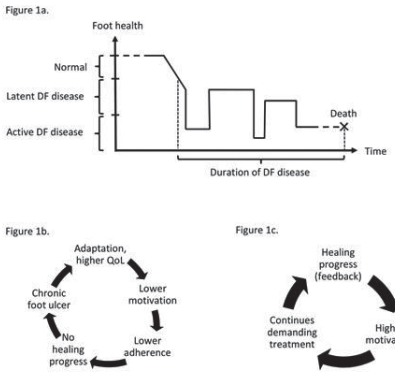
Aim: Diabetic foot self-care activities are often less than optimal and clinicians may find themselves unable to influence them in a positive direction. The aim was to present a novel framework, the process perspective on the diabetic foot, which can explain inadequate self-care behaviors and how they can be improved.
Methods: A literature analysis was conducted.
Results: The central principle of the process perspective is that diabetic foot disease is not a dichotomy (treatment and prevention) but a process over time, including alternating phases of active and latent diabetic foot disease (Fig. 1a). Thus, the patient is standing in the midst of a process, with a history of experiences and expectations for the future, all relevant to the patient's current self-care behavior.
A fictive patient case illustrates how the process perspective can be used to understand patients' situation and how beliefs and behaviors are sometimes self-reinforcing, resulting in stable behavior patterns ('diabetic foot cycles'), which are difficult to understand from a dichotomous perspective. The process perspective can be used to analyze 'vicious' diabetic foot cycles (Fig. 1b) of inadequate patient behavior and to find ways to transform them into 'virtuous' diabetic foot cycles (Fig. 1c), resulting in effective prevention and treatment.
Conclusions: The process perspective on the diabetic foot seems suitable for understanding inadequate patient behaviors not easily understood with a dichotomous perspective, opening up new avenues for clinical practice and research to help patients live a life with long remission phases, few relapses, and a high quality of life.

Figure 1
1a. Diabetic foot (DF) disease last from the onset of latent DF disease (defined as at risk of active DF disease) until death and includes alternating phases of active and latent DF disease.
1b and c. A patient shows decreasing adherence to wearing her therapeutic shoes over time, explained by a vicious cycle (b) of adaptation, higher quality of life (QoL), lower motivation, lower adherence, and chronic ulcer. If we can change the relative costs and gains in QoL implied by treatment and healing, thereby increasing her motivation for a more effective treatment regimen, a virtuous cycle (c) may be reached where her motivation is further increased by giving her feedback on the healing progress.



P42.04

Too Little or Too Much Fear and Avoidance of Activities: Should we Start Learning From the Other Side?

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Aim: Diabetic sensory neuropathy is a frustrating condition as lack of pain and symptoms reduce patients' motivation to avoid activities, such as walking without shoes, that result in foot ulcers and counteract healing. Theoretical developments are needed to better understand patients' situation and develop interventions to change counterproductive behaviors.
Methods: A literature analysis was conducted.
Results: The fear-avoidance model is a cognitive-behavioral account of why some people with acute pain develop chronic pain (1). Intriguingly, the situation of people with chronic pain mirrors the situation of people with diabetic neuropathy and foot ulcers; in chronic pain, counterproductive beliefs and behaviors transform acute pain into a vicious circle of chronic pain (Fig. 1a), in diabetic neuropathy, counterproductive beliefs and behaviors transform acute foot ulcers into a vicious circle of chronic foot ulcers (Fig. 1b). Thus, the situation of people with diabetic neuropathy could be described with a "no fear-avoidance model", which as the fear-avoidance model could be used to guide research, educate patients, and develop interventions.
Conclusions: The "no fear-avoidance model" seems promising for understanding people with diabetic neuropathy and for developing appropriate interventions, building on work on the fear-avoidance model. For example, interventions based on the fear-avoidance model (activity exposure with feedback, patient education using the model with individual beliefs and behaviors as examples, etc.) could be adapted for people with diabetic neuropathy. By this, we may be able to change inadequate beliefs and behaviors, resulting in more effective prevention and treatment of foot ulcers.

References: 1.Vlaeye WS. Pain. 2000;85:317-32.

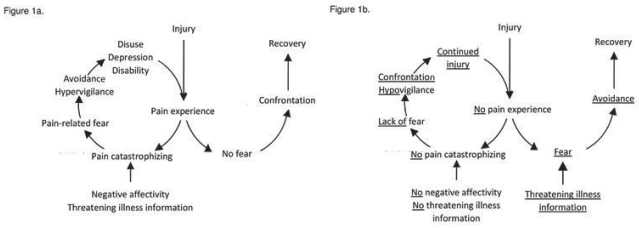

Figure 1. The fear-avoidance model (Fig. 1a, from reference [1]) and the "no fear-avoidance model" (Fig. 1b). Differences between the models are underlined in the figure text.

P42.05

The Experience of Pain in Patients with Diabetes

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Aim: Little is known of the presence of pain in patients with diabetes. The aim of the study was to map the presence and level of pain and health related quality of life (HRQL) in patients visiting a department of prosthetics & orthotics (DPO).
Methods: Patients with diabetes referred to a DPO were asked how they perceived their pain and HRQL. Group 1, n=74, answered the 3 level EQ-5D-3L. Group 2 (n=97) and group 3 (n=111) answered the 5 level EQ-5D-5L. Patients in group 1 and 2 were also asked if they perceived pain in their feet and if yes, at what level (0-100 scale).
Results: In Group 1, more than 70% of the patients reported "I have no problems…" for all domains except for pain/discomfort, in which 40% reported no problems. Result from the EQ-5D-5L in group 2 and 3 is found in Table 1. In G1, 81% of the patients, answered that they had some problems or severe problem with pain. In G2 and G3, (56% and 42% respectively) had moderate to very severe problems with pain. The self-perceived pain in the feet was 10 (±24), range 0-90 in G1. In G2, the self-perceived pain was 26 (±28), range 0-100.
Conclusions: Moderate to severe problems with pain was present in >42% of patients visiting a DPO. A great variation was present in the self-perceived pain in the feet. The HRQL, in general, was good. A large variation existed.

	Mobility		Self-care		Usual activities		Pain/ discomfort		Anxiety/ depression	
Group	G2	G3	G2	G3	G2	G3	G2	G3	G2	G3
Questions (I have…)										
…no problems	46	39	81	73	60	44	21	12	63	5
…slight problems	21	25	11	8	18	27	25	40	25	29
…moderate problems	24	18	8	9	10	14	42	28	4	6
…severe problems	9	7	-	1	11	6	8	10	8	6
I am unable to	-	3	-	0	1	1	4	3	-	0
Missing	8	8	8	10	8	8	8	8	8	8
Total	*97*	*111*	*97*	*111*	*97*	*111*	*97*	*111*	*97*	*111*

Table 1. Results, in percent, of EQ-5D-5L obtained from two cohorts

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P43.01

Development of the Tardivo Algorithm to Predict Amputation Risk of Diabetic Foot

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Diabetes is a chronic disease that affects almost 19% of the elderly population in Brazil and similar percentages around the world. Amputation of lower limbs in diabetic patients who present foot complications is a common occurrence with a significant reduction of life quality, and heavy costs on the health system. Unfortunately, there is no easy protocol to define the conditions that should be considered to proceed to amputation. The main objective of the present study is to create a simple prognostic score to evaluate the diabetic foot, which is called Tardivo Algorithm. Calculation of the score is based on three main factors: Wagner classification, signs of peripheral arterial disease (PAD), which is evaluated by using Peripheral Arterial Disease Classification, and the location of ulcers. The final score is obtained by multiplying the value of the individual factors. Patients with good peripheral vascularization received a value of 1, while clinical signs of ischemia received a value of 2 (PAD 2). Ulcer location was defined as forefoot, midfoot and hind foot. The conservative treatment used in patients with scores below 12 was based on a recently developed Photodynamic Therapy (PDT) protocol. 85.5% of these patients presented a good outcome and avoided amputation. The results showed that scores 12 or higher represented a significantly higher probability of amputation (Odds ratio and logistic regression-IC 95%, 12.2–1886.5). The Tardivo algorithm is a simple prognostic score for the diabetic foot, easily accessible by physicians. It helps to determine the amputation risk and the best treatment, whether it is conservative or surgical management.
note: this abstrac is published at PLoS ONE 10(8): e0135707. doi:10.1371/ journal.pone.0135707

P43.02

Risk Factors for Major Adverse Limb Events after Open Forefoot Amputation in Patients with Critical Limb Ischemia with Tissue Loss

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Objective: Management of patients with critical limb ischemia (CLI) and extensive foot necrosis presents a challenge for limb salvage. Our study evaluates preoperative risk factors that contributed to durability and efficacy of open transmetatarsal amputation (TMA) in patients with CLI. In addition, we analyze risk factors that may contribute to major adverse limb events (MALE).

Methods: Consecutive patients who underwent open TMA at a single institution between 2009-2017 were reviewed. Patient demographics, comorbidities, indications, limb revascularization history, postoperative complications, reinterventions, and functional status data were collected. Descriptive statistics were used for analysis of the entire cohort. Univariate and multivariate analyses were performed to determine predictors of MALE as defined by need for subsequent major amputations or further revascularization procedures.
Results: Thirty-three complete TMAs were performed in 30 patients, including 6 females. The mean age of our cohort was 67 + 11 years. Indications for TMA were dry gangrene in 45% and infection in 55%. Eighty-seven percent of patients had diabetes, 63% had end-stage renal disease (ESRD), and 80% had prior toe amputations. Ipsilteral revascularization was performed on 27 limbs, 19 via open and 8 via endovascular approach. Mean follow-up was 23.4+/- 24 months. All patients maintained their preoperative ambulatory status after their amputation, regardless of healing status. Time-to-healing was available for 14/33 limbs with a mean of 8.7 +/- 13.7 months. Limb salvage was successful in 29 limbs (88%) while 4 major amputation (12%) in the form of a below-knee amputation (BKA) were all seen in ESRD patients (p=0.04). Sixty percent of ESRD-affected limbs (n=20) experienced MALE as compared to 23% of limbs in patients without ESRD (n=13) (p=0.04). Rates of MALE did not vary by demographics of race, age, sex, diabetes, hypertension, and smoking, nor by indication of dry gangrene versus infection (p>0.05).
Conclusions: Open TMA resulted in low rates of transition to BKA in CLI patients overall. However, patients with concomitant ESRD experienced significantly greater risk of MALE. The poor prognosis in this patient population means planning for the next intervention, whether it be amputation or additional revascularization, should be entertained at time of the index operation.

P43.03

Factors Related to Amputation Level and Wound Healing in Diabetic Patients

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Aims: There are no specific criteria to choose the correct level of amputation in persons with diabetes. The objective of this study was to evaluate the influence of clinical and laboratory parameters in the final amputation level of the lower limbs and in the wounds.
Methods: 139 diabetic patients were retrospectively enrolled. They underwent some type of surgical procedure due to infection and/or ischemic necrosis. Type of surgery, antibiotic (ATB) use, laboratory parameters, length of stay and outcome variables were considered in this study.
Results: The most common amputation level was transmetatarsal, in 28 patients (31.1%). The wound closure time increased with statistical significance in individuals who underwent debridement, who did not use preoperative antibiotics and who underwent cardiovascular intervention. Higher level of amputation were statistically related to limb ischemia, previous amputation and individuals who had not used antibiotics preoperatively
Conclusions: Major amputations have as risk factors ischemia and previous amputations and as a protective factor the use ATB preoperatively. The wound healing time declines with the use of preoperative ATB and increases if the patient underwent vascular intervention or has higher leukocyte levels preoperatively and/or had their member preserved, demanding multiple debridement.

P43.04

The Incidence of Further Amputation Following Initial Single Digital Amputation Secondary to Diabetic Foot Disease.

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Aim: The aim of this study is to assess the rate of re-amputation, following an initial digital amputation on the same foot in patients with diabetes and foot disease attending a large multidisciplinary diabetic foot service in Ireland.
Method: Patients who underwent a digital amputation between 2011 and 2016 were identified from hospital databases. Data was collected retrospectively utilizing ICD codes pertaining to further amputation, demographics, additional revascularization procedures, biochemical and clinical findings. Data was cross-referenced with clinical notes to increase the rigour of the data set.
Results: 79 patients were identified for inclusion in the data set. Overall 46% of patients had a second amputation on the ipsilateral side with a mean time to further amputation of only 1.07 years. The mean follow up period was 4.39 years. The adjusted data showed 29% had further amputation within 1 year, 35% in 2 years, 46% within 3 years and 56% within 4 years. No patient had a second amputation more than 4 years after the first in this sample.
Conclusion: A large proportion of patients with diabetes and amputation went on to require subsequent amputation on the ipsilateral side. The mean time to this second amputation was quite short only 1.07 years after the first. This suggests that first amputation is a significant indicator for further surgery. This finding is supported by the data although this is heterogenous. A meta-analysis would be helpful of this data in order to identify any trends.

P43.05

Risk Factors for Re-Amputation Following a Minor Amputation in Patients Hospitalised with Diabetes-Related Foot Disease

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Background and aims: Diabetes is the leading cause of non-traumatic lower extremity amputation (LEA) in Australia with 4,400 amputations performed every year (1). The global incidence for repeat amputations following a minor LEA are reported to be as high as 60% (2), though the exact figures for Australia are not known. We aim to identify factors associated with repeat surgical procedures to manage diabetes-related foot disease (DFD), following an initial minor LEA, during a single hospital admission.
Methods: Data was collected as part of a hospital-based case-control study of patients with DFD admitted to a Melbourne hospital between 2015 and 2016. Patients' demographic and clinical data was collected retrospectively. Stepwise regression was performed to identify factors associated with multiple surgical procedures for management of a single foot ulcer during a hospital admission. Bayesian information criterion was used to select the final model and Bonferroni adjustment was used to control for multiple testing.
Results: A total of 29 (18%) patients required repeat surgeries for management of DFD during a single hospital admission, compared to 136 undergoing a single surgical procedure. The initial amputations that required revision were of the toes (n=13), followed by metatarsal heads (n=5). Of the 31 variables examined, only two were found to be associated with multiple surgical procedures during a single hospital admission. Increasing C-reactive protein (CRP) levels (mg/L) (OR 1.01, 95% CI 1.00-1.02, p=0.047) and presence of bilateral foot ulcers on admission (OR 13.79, 95% CI 2.68-80.99, p=0.002) increase the odds of patients undergoing multiple surgical procedures for management of DFD.
Conclusion: The presence of bilateral foot ulcers and higher CRP levels, which may indicate higher infection severity, increase the odds of multiple surgeries. Presence of peripheral arterial disease and vascular interventions were not found to be associated with multiple surgeries.
Acknowledgments: The abstract and original study were not funded. We acknowledge Dr Karen Van and Dr Andrew Nguyen for their contributions to the project.
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P43.06

Risk of Ipsilateral Re-Amputation Following an Incident Toe Amputation Among Veterans with Diabetes, 2005-2017

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Aim: To determine the extent to which the incidence of subsequent amputations and death following an incident toe amputation has changed over time, by geographic region, and demographic characteristics.
Methods: We conducted a cohort study using national data from the United States Veterans Health Administration (VHA). Eligibility criteria included having diabetes and an incident toe amputation between 2005 and 2016 in VHA as determined by procedure codes. Exclusion criteria included having a prior lower extremity amputation or a bilateral amputation at baseline. We followed patients for 1 year after their toe amputation for subsequent ipsilateral lower extremity amputations and death. Laterality of incident and subsequent amputations were determined based on Current Procedural Terminology (CPT) modifier codes and natural language processing. Key correlates of re-amputation examined included age group, sex, race/ethnicity, marital status, comorbidity burden (based on the Gagne comorbidity index), VHA region, state/territory, and rurality. We calculated means and percentages. Because the sample size was large, we focus our presentation on differences of clinical importance, defined as at least 5 percentage points.
Results: Of 17,849 individuals (98.5% male, mean age = 64.8 years) who met inclusion criteria, 34% (n=6040) had an ipsilateral amputation within 1 year of incident toe amputation and 12% died. Overall, incidence of ipsilateral re-amputation decreased over time. Incidence of ipsilateral re-amputation was more frequent among men (33.9%) than women (28.8%) and among American Indian/Alaska Natives (39.0%), and African Americans (39.3%) compared to Whites (32.4%). Ipsilateral re-amputation rate generally increased with increasing comorbidity burden (from 26.5% in the lowest category to 38.6% in the highest category). Re-amputation was greater among those in urban areas (35.0%) than highly rural areas (26.2%) and intermediate among those in rural areas (31.6%). There was substantial variation across states/territories; Maine had the lowest re-amputation rate (19.0%) and Puerto Rico (46.0%) had the highest.
Conclusions: Ipsilateral re-amputations are a relatively common occurrence following an initial toe amputation. Variations by race and geographic areas merit further examination to try to understand the reasons for the differences.
Acknowledgements: This study was funded by Department of Veterans Affairs Health Services Research & Development (15-372).

P44.01

Analysis of Healing Time and Hospitalization Expense in Diabetic Foot Ulcer Patients with Different TEXAS University Grades

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Aim: According to statistics, in 2000, about 171 million people with diabetes worldwide were expected to increase to 366 million people by 2030. In 2011, China had 90 million diabetics and it is expected to increase to 129 million people by 2030. In China, the medical expenditure for diabetes in 2008 reached US$910 million . The cost of hospitalization for diabetic foot was the highest among all complications and was twice that of patients without foot ulcer. According to reports, about one-third of non-traumatic amputations in the top three hospitals in China are caused by diabetic

foot. Therefore, early recognition of diabetic foot ulcers and timely and effective treatment are particularly important. This study compared the healing time and hospitalization costs of different types of diabetic foot ulcers in order to provide the basis for optimizing the clinical path of diabetic foot.

Materials and Methods: The data of 147 patients with diabetic foot ulcer discharged in Liyuan Hospital of Tongji Medical College of Huazhong University of Science and Technology from May 1,2015 to April 30,2016 were collected and screened out according to the inclusion and exclusion criteria. According to the classification of TEXAS university,patients with diabetic foot ulcer were grouped,TEXAS university grade 1 group(n = 21) : superficial ulcer;TEXAS university grade 2 group(n = 31) : ulcer up to the tendon; TEXAS university grade 3 group(n =95) : ulcer involved bone and joint. The ulcer healing time and hospitalization costs of 3 groups of patients with diabetic foot ulcer were compared. Data were analyzed with the Kruskal-Wallis test.

Results: Among the 147 patients according to the grades of TEXAS university,the healing time of grade 1,2 and 3 patients respectively were 12,22 and 33 days and the hospitalization costs were 13 199. 20,19 572. 81,32 101. 30 RMB,and the healing time and hospitalization costs of different TEXAS university grades patients had statistically significant differences(F =24. 19,24. 04,with P <0. 05).

Conclusions: The ulcer healing time and hospitalization costs in patients with diabetic foot ulcer were positively correlated with the grades of TEXAS university.

P44.02

Comparative Analysis of the Cost-Effectiveness of UrgoStart (TLC-NOSF) Dressing in the Management of DFUs in the UK, France and Germany

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Aim: Diabetes is a growing global epidemic with increasing prevalence in the adult population. A very common side effect of diabetes is the diabetic foot ulcer (DFU), which is associated with a high risk of infection and lower-limb amputation. The TLC-NOSF (TLC-sucrose-octasulfate) dressing, UrgoStart, a new treatment for DFUs has proven efficacy from a randomized, double-blind clinical trial, the EXPLORER, in which it was compared with Advanced Wound Care (AWC) neutral dressings in DFU clinics in France, Spain, Italy, Germany, and the UK.

This report aims to compare the economic impact of using this new dressing from the perspective of three country healthcare Systems.

Methods: Health economic studies of the UK, France and Germany, involving the use of the TLC-NOSF dressing compared to AWC dressings were reviewed. Each study involved a Markov-model cost-effectiveness design. The Explorer trial informed model efficacy parameters, supplemented by estimates from the literature.

All costs were from the country perspectives, adjusted for 2017 prices, and discounted where relevant. Deterministic and probabilistic sensitivity analyses were conducted to assess the robustness of the model parameters.

Results: The studies showed that the use of TLC-NOSF dressing resulted in a significant annual cost savings in all three countries, with superior efficacy being the main cost driver. In all three studies, improved quality of life was also reported in favour of TLC-NOSF dressing, and sensitivity analyses show this dressing to be dominant compared to AWC neutral dressing in every parameter varied in all country models. Furthermore, earlier use of the TLC-NOSF dressing was shown to result in even better efficacy and higher cost savings.

Conclusion: TLC-NOSF dressing compared with AWC neutral dressings is the dominant treatment strategy in the management of DFUs, resulting in cost savings for all three healthcare systems. Furthermore, the earlier the use of TLC-NOSF dressing, the greater the benefits derived.

P44.04

Admission due to Diabetic Foot Ulcer Related Complications May Lead to Increased Self-Care Needs and Changed Home-Situation After Discharge

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Background: Co-morbidities are common in patients with diabetes and foot ulcer, who are not uncommonly require additional medical and nursing interventions in connection with in-patient care and implicates increased demand for assisted self-care after discharge. Registered nurses in home care organizations are responsible for nursing assistance, either at primary health care centers or at municipalities' home nursing service for patients who are not transportable. The aim of this study is to explore nursing needs and home conditions for in-patients with diabetes admitted due to foot ulcers related complications.

Method: A retrospective assessment of medical and nursing records for patients with diabetes consecutively admitted due foot ulcer complications at the department of endocrinology, Skåne University Hospital, Malmö, Sweden, between 1st November 2017 and 30th April 2018. Data on daily self-care needs and skills as well as home situation at admission and discharge were recorded.

Result: Eighty-two patients were included; median age was 71 (38-94) years, 72% were male, and 76% had diabetes type 2. Median admission time was 10 (2-35) days. 39% of patients had leg oedema, 72% had pain, 32% had more than single foot ulcer, 66% of patients had increased fall risk, 23% needed help with elimination, and 49% had treatment for sleep difficulties.

54.9% of patients admitted from own home without external help compared to 41.5% at discharge, 23.1% admitted from own home with home nursing compared to 31.7% at discharge, 3.7% admitted from temporary nursing home compared to 4.9% at discharge, 13.4% admitted from permanent nursing home or home for patients with special support needs compared to 14.6% at discharge, 4.9% had no registered address at admission or discharge, and 2.4% died during admission.
Conclusion: Admission for foot ulcer related complications in this vulnerable patient group with extensive nursing needs seems associated with further changes in home situation and increased dependency after discharge. Care planning before discharge requires to be prepared thoroughly.

P44.05

Resource Utilization Within a Multi-Disciplinary Foot Team Clinic for New Attenders: Evaluation of a Services Care Pathways over Six Months

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Aim: It is well documented that establishment of Multi-disciplinary foot Team (MDfT) clinic helps to decrease amputation rates, but less so the resource requirement. We aim to evaluate the services utilisation upon first visit to an established MDfT clinic.
Methods: A retrospective evaluation of new referrals to the MDfT clinic over a six-month period, for patient demographics, resource utilization and clinical outcome over the subsequent six months of follow-up. Data was extracted electronically with retrospective review of electronic clinical notes.
Results: There were 240 patients attended new visits: mean age 64±15yrs, 60% males, 72% type-2 diabetes, 16% type-1 diabetes, mean HbA1C was 8.4±2.0%, 15% had previous amputation and 40% had previous ulceration. One third of referrals from GPs, 29% other hospitals, 8% community podiatry, 6% diabetologists, 5% emergency department, 3% self-walk-in. Common presentations were ulcerations (55%), osteomyelitis (11%), cellulitis (5%), Charcot (19%), post-operative wounds (14%), and painful neuropathy (4%).
At first attendance, 70% required specialist triage services: 23% joint vascular, 8% joint orthopaedics, 45% diabetologist, 2% dermatologist, and 1% orthotics. 8 patients had complex multi-site debridement, 3 debridement of bone, 1 underwent amputation of toe, 1 had total excision of nail, 2 had drainage of pus, 8 had cast-related procedures, and 3 received vacuum assisted dressing. 4% was admitted on first visit.
The time frame to next follow-up visit was within 2 weeks for 28%, 2-4 weeks (37%), 4-6 weeks (11%), and beyond 6 weeks 6%. Over the following 6 months: 40% of patients needed joint vascular review, 20% orthopaedic, 66% diabetologist, 6% dermatology, and 9% orthotist. 8% received angioplasty and 3% surgical bypass, 40% required vascular arterial duplex investigations, 7% deep vein thrombosis scan, 16% MRI, and 5% bone scan. 10% were discharged from MDfT, 27% had healed ulcers, 4% re-ulcerated at the same site, 4% re-ulcerated at different site, 1% died, and 20% warranted a hospital admission.
Conclusions: Maintaining a functional MDfT clinic needs significant resources with prompt investigations and revascularisation procedures to sustain a low avoidable amputation rates. A regular appraisal of resource utilisation allows the team to plan clinics and determine optimal pathways.

P44.06

Resource Utilisation of Patients with Diabetic Foot Disease in Outpatient Diabetic Foot Clinics

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Aim: To develop and utilise a complexity score to highlight the complexity and resource utilisation of outpatients with acute diabetic foot disease.
Method: A complexity score was developed for patients accessing acute diabetes foot services. This score was based on that proposed by Vas et al (2015) with local adaptations. Each point on the score was considered equivalent to one consultation (approximately 45 minutes of time). In order to capture the complexity of the consultations, services which were provided during the appointment such as total contact casting, imaging and deep tissue samples attracted an additional score. The score was tested in a pilot capacity.
Results / Discussion: The total complexity score during the pilot period of data collection for the 38 patients receiving treatment was 137. This reflects a mean of 3.6 consultations per patient seen during the pilot period. This supports the work of Vas et al (2015) who found a significant correlation between complexity score and resources used. This shows that counting consultations within this complex group of patients is insufficient in reflecting the services provided. Our results support this. This highlights the on-going role of the foot clinic in admission avoidance and delivery of complex interventions to outpatients. Such interventions may have previously only been delivered as inpatients. Further use of the complexity score is ongoing and is being utilised across 2 sites.
Conclusion: In an era of admission avoidance and increasing complexity of interventions delivered to outpatients the use of a complexity score could inform decision makers of the intensity of services provided by the multidisciplinary diabetic foot team and allocate resources appropriately. Further assessment on a wider scale utilising such score systems is warranted.
Reference: Vas et al (2015)

P45.01

The Effect of Sedentary Behaviour on Plantar Skin Inflammation in People with Diabetes: a Feasibility Study

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Aim: Diabetes related foot ulcers (DRFUs) are associated with high morbidity, mortality, social and economic costs. The primary mechanism of DRFUs is repetitive stress over vulnerable bony prominences in the foot of individuals with peripheral neuropathy and vascular disease. DRFUs are notoriously difficult to heal, with high incidence of amputation in individuals with chronic ulcers. Elevated peak plantar pressures and prolonged stance time during gait are associated with risk of ulceration, yet there is evidence to suggest that ulcers occur in individuals are relatively sedentary (1). This study investigated the effects of sedentary (sitting) behaviour on the plantar tissues of people with diabetes compared to healthy controls.
Methods: Eleven participants with diabetes (mean age 55 years) and ten with control participants with no diabetes (mean age 52 years) were enrolled into the study. Plantar pressures were measured at the first metatarsal head whilst patients were seated. Inflammatory markers were recovered from the first metatarsal head using Sebutape pre- and post- seated weight-bearing and analysed for the inflammatory markers IL-1α and IL-1RA by ELISA assay kits.
Results: The average plantar pressure over the first metatarsal head whilst in a seated weight-bearing position (11.16 kPa ± 1.5 (control) and 10.94 kPa ± 0.85 (diabetes)) was not significantly different between the two groups (p=0.89, t-test). It was evident that for both IL-1α and IL-RA, there was a general increase in cytokine ratio in people with diabetes compared to controls on the plantar surface of the foot post-seated weight bearing (p <0.01 and 0.05 respectively by Mann-Whitney U-test).
Conclusion: The present study reveals that pro-and anti-inflammatory cytokine levels are increased in people with diabetes during weight-bearing sedentary behaviour compared to healthy controls. These cytokines have been implicated as precursors to ulcer formation. This pilot work shows that sedentary behaviour may be a risk factor for plantar ulceration in people with diabetes and supports the need to further investigate sedentary behaviours as a cause of DRFU.

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P45.02

Diabetic Neuropathy is Associated with Lower Extremity Arterial Disease but it is not the Case with Isolated Diabetic Retinopathy

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Background and aims: The aim of this study was to examine differences between measures of metabolic control, nephropathy and macrovascular complications in people with diabetes complicated by isolated diabetic neuropathy and isolated diabetic retinopathy.
Materials and Methods: Eyes were examined through dilated pupils. VPT was measured using a semiquantitative tuning fork C128. Sudomotor function was determined using Neuropad®. LEAD was defined with ABPI and Continous wave Doppler. In a fasting blood sample was taken and urinary protein excretion (mg/24h) and the presence of coronary artery disease (CAD) was documented. Hypertension was defined as ≥140/90 mmHg or by antihypertensive therapy.
Results: Of 172 people, 48.2% were male and 65.1% had T2DM. 57 had no evidence of retinopathy and diabetic neuropathy (controls), 40 had DN and 75 had DR. People with DN compared with controls were older (64.8±9.8 vs. 44.9±12.8 years; p<0.01), with higher creatinine (108.3±50.1 vs. 82.38±15.19mmol/L), more frequently prolonged NeuroPad® time (35% vs. 8.8%; p<0.01), diminished ankle reflexes AR (55% vs. 21.1%; p<0.01), CAD (25% vs. 8.8%; p=0.03), LEAD (20% vs. 5.3%; p=0.02), high BP (60% vs. 26.3%), obesity (35% vs. 5.3%), higher waist cicumference WC (99.5±11.08 vs. 92.46±12.8cm; p <0.01), duration of diabetes (16.6±9.2 vs. 10.2±7.4yrs; p<0.01), T2DM (87.5% vs. 43.2%; p<0.01). After multivariable logistic regression analysis (MVRM) significant was the model: age (p<0.01), cretinine clearance CreCle (p=0.01), AR (p=0.05) and LEAD (OR 9.08 [95% CI: 0.88-92.7]; p=0.06). Compared with people without DR and DN, those with retinopathy were more women (62.6% vs. 40.3%; p 0.01), older (54.8±14.5 vs. 44.9±12.8 years; p<0.01), longer duration of diabetes (17.1±7.6 vs. 10.2±7.4y.; p<0.01), with higher PrU (554.3±1527 vs. 157.8±120.3; p=0.03) and lower CreCle (77.92±25.27 vs. 102.53±9.41 ml/min/1.73m2; p<0.01), longer Neuropad® time (6.8±5.1 vs. 5.1±5.4min.; p=0.06) diminished AR (2.5±1.4 vs. 1.6±1.5; p<0.01) After MVLR model with age (OR 8.7) and diabetes duration (OR 9.7) persisted (p<0.01).
Conclusion: Our data showed associations between the presence of isolated peripheral neuropathy and isolated diabetic retinopathy with diabetic nephropathy. LEAD was associated only with isolated diabetic neuropathy supporting the IWGDF classification. In these groups of people effects of SGLT2 inhibitors and antitrombotic therapies should be prospectively followed.

P45.03

Systemic Musculoskeletal Effects of Diabetes are Evident in the Relationships Within and Between Foot/Ankle and Upper Extremity Dysfunction

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Aim: This project examines relationships between foot/ankle and upper extremity dysfunction as evidence of diabetes mellitus (DM) related systemic musculoskeletal changes.
Methods: We studied 60 people with type 2 DM and peripheral

neuropathy [mean (standard deviation); age=67 (6) yrs, body mass index= 35 (7) kg/m2, DM duration 14 (10) yrs, and 57% female]. The following measures were collected; 1) Self-reports of function: Foot and Ankle Ability Measure (FAAM-higher indicates better function) and Shoulder Pain and Disability Index (SPADI, lower indicates less pain and better function), 2) Range of motion (goniometry): ankle dorsiflexion and shoulder flexion, and 3) Strength: unilateral heel rise height (UHR, 3D kinematics) and hand grip (hand dynamometer). Pearson correlations examined associations within and between foot/ankle and upper extremity functional measures, p<.05.

Results (see table): Significant within extremity correlations: Lower FAAM with lower UHR and higher SPADI with lower shoulder flexion. Highlights of significant between extremity correlations: lower FAAM and higher SPADI, lower ankle dorsiflexion range of motion and lower shoulder flexion range of motion, and lower UHR and lower hand grip strength.

Conclusion: Foot/ankle strength relates to lower foot and ankle function while lower shoulder range of motion relates to higher shoulder pain and dysfunction. Interrelationships between upper extremity and foot/ankle self-reports of function, range of motion, and strength impairments indicate the potential of a systemic impact of diabetes on the musculoskeletal system. These results provide insights into possible treatment interventions for the systemic and often disabling musculoskeletal problems associated with DM and peripheral neuropathy.

	Ankle/Foot			Upper extremity	
	FAAM	Ankle Dorsiflexion (deg)	Unilateral Heel Rise Excursion (cm)	SPADI	Shoulder Flexion (deg)
Ankle Dorsiflexion (deg)	.14				
Unilateral Heel Rise Excursion (cm)	.48**	.05			
SPADI	-.42**	-.39**	-.32*		
Shoulder Flexion (deg)	.26**	.30*	.31*	-.44**	
Hand grip (kg)	.33*	.16	.39**	-.11	.23

Table: Correlation matrix for ankle/foot and upper extremity variables. Shaded cells are the between extremity correlations. *p<.05 **p<.01

P45.04

Are the Left and Right Limbs Unequally Affected by Diabetic Foot Complications?

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Aim: There is some debate about laterality for diabetic foot complications, that is, whether the left and right limbs are unequally affected. Coxon and Gallen (1) found that more amputations were performed on the right limb than the left. Evans et al. (2) found that most foot ulcers occurred on the dominant limb (which for most people is the right limb) and speculated that the dominant limb may be more exposed to mechanical stresses and injuries. However, Demetriou et al. (3) did not find any laterality in foot ulcer location. The aim was to investigate laterality for foot ulcers and amputations.

Methods: A questionnaire was posted to 1245 people who had diabetes, experience of using therapeutic shoes, and who had attended one of two prosthetics and orthotics clinics during a 12 months' period. The number of ulcers and amputations on the left and right limbs were compared with a two-sided chi-square test.

Results: 469 (37.7%) questionnaires were returned. 118 (25.2%) participants reported unilateral foot ulcers, 54 (11.5%) reported unilateral minor amputation, and 21 (4.5%) reported unilateral major amputation. There were no statistically significant differences between the left and right limbs in terms of foot ulcers, minor amputations or major amputations (Table 1, p-values 0.713-1.000).

Conclusions: Our results do not support the hypothesis about laterality for foot ulcers and amputations.

References:

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	Left	Right	P-value[a]
Current foot ulcer, n (%)	61 (13.0)	57 (12.2)	0.713
Minor amputation, n (%)	27 (5.8)	27 (5.8)	1.000
Major amputation, n (%)	11 (2.3)	10 (2.1)	0.827

[a]Two-sided chi-square tests.

Table 1. Comparison of unilateral foot ulcers and amputations between the left and right limbs

P45.05

Plantar Fascia of a Patient with Type 2 Diabetes Contained Chondrocytes: a Case Report

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Aim: The aim was to study the morphology of plantar fascia of a patient with type 2 diabetes mellitus, who underwent foot amputation due to complicated foot ulcers.

Methods: The patient was a 57 year-old male who has had type 2 diabetes for 20 years. Plantar fascia of 4.5x2.0x0.5cm size (excluding the fat tissue) was removed after the surgical amputation of the foot, with informed written consent of the patient. The sample was fixed in 10 percent neutral formalin solution and embedded in paraffin. For routine histology tissue slices were stained with hematoxylin and eosin, and a histochemical staining with periodic acid Schiff reagent was applied.

Results: Plantar fascia of the patient was composed of dense regularly arranged connective tissue: parallel bundles of thick collagen fibers, fibroblasts and fibrocytes; also the tissue contained multiple chondrocytes arranged in parallel arrays along the collagen fiber

bundles that indicate fibrous cartilage structure. Chondrocytes were numerous in the proximal end and in the middle part of the plantar fascia. Chondrocytes were clearly distinct from fibroblasts and fibrocytes due to rounded nucleus and obvious lipid inclusions as well as the PAS-positive territorial matrix, surrounding the chondrocytes.
Conclusions: Presence of fibrous cartilage in the plantar fascia may indicate that the metabolic changes associated with diabetes might have induced biological alterations of cellular phenotype as well as changes in the mechanical properties of the patient's foot.

P45.06

Regional Anesthesia Does not Affect Hospital Length of Stay After Ankle Fracture Fixation in Patients with Diabetes Mellitus

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Aim: To assess the relationships between regional anesthesia, hospital stay and diabetes mellitus (DM) in patients with ankle fractures.
Methods: Patient data from the American College of Surgeons-National Surgical Quality Improvement Program (ACS-NSQIP) database was retrospectively reviewed. 4,289 patients with non-electively treated ankle fractures in the inpatient setting were identified. Patients were grouped by general, regional and general + regional anesthesia.
Results: The average time from operation to discharge was 2.8±4.0 days. The regional only group had significantly longer time to discharge than the regional + general anesthesia group (3.7±6.1 days vs. 2.6±3.2 days p = 0.046), but no differences were appreciated between general versus regional + general anesthesia (2.8±4.1 days vs. 2.6±3.2 days, p = 0.106) or general versus regional only (2.8±4.1 days vs. 3.7±6.1 days, p = 0.244). Among non-DM patients, regional anesthesia was associated with longer hospital stay than general (p=0.024) and general + regional anesthesia (p=0.048). However, no differences were found among patients with DM. In the multivariate linear regression, older age (p < 0.0001), greater body-mass index (p < 0.0001), insulin control (no diabetes vs. insulin, p = 0.003; non-insulin vs. insulin, p = 0.018), steroid use (p = 0.040), dependent functional status (p=0.003) and American Society of Anesthesiologists class ≥ 3 (p < 0.0001) were significantly associated with increased time to discharge. Anesthesia method was not independently associated with length of stay.
Conclusion: Patients with DM, particularly those on insulin control, have longer length of stay and time to discharge after surgery than patients without DM. Regional anesthesia alone was associated with increased time to discharge after ankle fracture fixation in non-DM patients, but no difference was seen in DM patients. Although it is unclear whether the addition of regional anesthesia helps with post-operative pain control in DM patients, the results of this study appear to show no difference with time to discharge whether surgery is performed under general or regional anesthesia.

P46.01

A Multicenter Study on Influencing Factors of Pre-Hospital Treatment Effect of Patients with Diabetic Foot

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Objective To investigate pre-hospital treatment effect of patients with diabetic foot and analyse the influencing factors by a multicenter approach.Method A total of 340 patients with diabetic foot from 13 centers were included in this study to investigate pre-hospital treatment effect (improved, unchanged or worsening). Influence of patient demographics and clinical data on wound healing was detected using multivariate logistic regression analysis. Results Of the 326 patients with diabetic foot, 34 (10.4%) were improved, 101 had no significant change (31.0%) in wounds, and 191 patients (58.6%) worsened. In multivariate logistic regression analysis,the monthly income, the concept of whether the diabetic foot was known, and the location of pre-hospital care were factors influencing the effect of pre-hospital treatment.Conclusion The effect of pre-hospital treatment of patients with diabetic foot is related to the monthly income of the patient, whether the concept of diabetic foot is known, and the location of the pre-hospital treatment.
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A multicenter study on influencing factors of pre-hospital treatment effect of patients with diabetic foot

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P46.02

Diabesity and the Foot: a Truck on Scooter's Wheels

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Aim: To evaluate the distinct contribution of obesity and diabetes (DM) to the skin modification in metabolic diseases.
Methods: we analysed all patients admitted for bariatric surgery in our Hospital with BMI between 38 and 47 kg/m2, with (Group 1) or without (Group 2) DM and compared them with a group of non obese diabetic patients (Group 3) and healthy volunteers (Group 4). The following features were evaluated: skin hardness, skin temperature, ultrasound (US) skin and subcutaneous thickness alongside with anthropometric measures of foot and leg.
Results: Between march and September 2018, 120 patients (30 for each Group) respected all inclusions and exclusions criteria and were enrolled. For the general characteristics patients differed in age and body mass index. As predictable all circumferences (dorsal foot, sovramalleolar and under the knee) were significantly higher in obese with no differences depending on DM (all parameters: p<0.01 in Group 1 and Group 2 vs Group 3 and Group 4). Skin temperature was significantly higher in all obese, irrespectively from the presence of DM (1st metatarsal head: p=0.02 Group 1 and Group 2 vs Group 3 and Group 4; 5th metatarsal head: p<0.01 Group 1 and Group 2 vs Group 3 and Group 4). Skin hydration score showed increased anhydrosis both in diabetics and in severe obesity with a synergistic effect (p<0.01 Group 1 and Group 3 vs Group 2 and Group 4). US revealed in heel region and under the scaphoid an increase in thickness of skin and subcutaneous tissues (at heel p<0.01 Group 1 and Group 2 vs Group 3 and Group 4 and under the scaphoid p=0.03 Group 1 and Group 2 vs Group 3 and Group 4) and plantar fascia (in both regions p=0.02 Group 1 and Group 2 vs Group 3 and Group 4) in all obese patients, with or without DM.
Conclusions: Severe obesity significantly affect both shape and structure of the foot possibly exposing these patients to a higher risk of biomechanical stress. On such a background, DM modifying skin hydration and protective mechanisms, exerts a synergistic role further increasing the risk of trauma and ulcers.

P46.03

The Potential Cost Benefits of Using a Smart Insole System in the Diabetic Foot

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Aim: To clearly demonstrate the use of an FDA-cleared foot plantar pressure sensing technology[1], in decreasing the recurrence of diabetic foot ulcers (DFUs).
The device[1] relays alerts to a smartwatch using plantar pressure monitoring. When dangerous pressure and time thresholds have been surpassed, alerts are provided to the patient with offloading instructions allowing the patient to modify their behavior and relieve the pressure.
Method: Decision tree analysis to compare cost-effectiveness and outcomes between standard of care and the smart insole device[1] as an adjunct to standard of care (control and intervention). Total of 84 patients with 42 in each group were enrolled.
Results: Interim analysis: 84 patients were assessed with 42 in the control group and 42 in the intervention group. The intervention group has shown to limit the recurrence of DFUs, with the control group having a DFU recurrence rate of 1.63 times higher. Cost-savings of $2,079 per year was estimated per intervened patient. There are currently 99 patients enrolled in the study.
Conclusion: Through plantar pressure monitoring the smart insole system[1] is currently being used in the Accelerating Innovations into Care (AICE) study in which ulcer recurrence rates are investigated. Patients were randomized to either receive standard of care or the smart insole device[1] as an adjunct to standard of care. An interim analysis demonstrated cost effectiveness and promising correlation trends in decreasing ulcer recurrence rates in the intervention group. An estimated net cost savings per patient of $2,079 is expected per year with the use of the device. This innovation supports health system transformation where patients are encouraged to become involved in the management of their own disease. This not only stimulates compliance, but participation in reducing the impact of morbidity. Further verification of these trends will be available upon completion of the study with full analysis.

[1]SurroSense Rx® smart insole system (Orpyx Medical Technologies Inc., Calgary, AB, Canada)

P46.04

Do Shoe Lifts Immediately Improve Gait? – Gait Function and Symmetry in Patients Wearing Offloading Footwear for Diabetic Foot Ulcers

Ms. Erica Ling[1], Dr. Brian Lepow[1], Dr. He Zhou[1], Ms. Ana Enriquez[1], Ms. Ashley Mullen[1], Dr. Bijan Najafi[1]
[1]Baylor College Of Medicine, Houston, United States

Aim: Patients with diabetic foot ulcers (DFU) require offloading footwear, which could induce limb length discrepancy (LLD). This study assessed the negative impact of unilateral DFU's and offloading footwear on gait function and symmetry. This study also evaluated how prior offloading wear duration influences immediate benefits on gait symmetry when provided with a contralateral shoe lift to correct for an offloading-induced LLD.
Methods: Eighty subjects were recruited in 3 groups: 47 non-diabetic controls (ND, age=62.9±16.1years, BMI=29.0±6.0kg/m2), 27 with diabetic peripheral neuropathy (DPN) (DPN, age=64.3±7.7years, BMI=30.9 ± 5.4kg/m2), and 6 with unilateral DFU's wearing offloading footwear (Offloading, age=57.0 ± 10.3years, BMI=28.7 ± 2.3kg/m2). Duration of prior offloading use was collected for the Offloading group. 4 subjects had worn offloading footwear more than one month (experienced user) and 2 subjects had worn it less than one month (new user). A habitual gait test was performed. Subjects in the Offloading group were tested under two conditions: (1) without a contralateral shoe lift and (2) with a contralateral shoe lift.

Results: Without a contralateral shoe lift, the Offloading group had significant deteriorated gait function and symmetry. They had reduced stride velocity ($p<0.001$, Cohen's effect size $d=1.43$) and stride length ($p<0.001$, $d=1.08$), and increased left-right step asymmetry ($p=0.017$, $d=1.03$), even when compared to the DPN group. Results also showed that with a shoe lift, new offloading users had immediate improvement in gait symmetry (77% improvement), whereas gait symmetry decreased for experienced users (121% deterioration).

Conclusions: This study highlighted the negative effects that DFU's and offloading footwear have on gait function and symmetry. It also demonstrated that using a shoe lift to correct for an offloading-induced LLD immediately improves gait symmetry in new offloading users. On the other hand, gait symmetry decreased when a shoe lift was added for experienced users. This suggests that while a shoe lift may improve gait symmetry, experienced offloading users may need to acclimate to correcting the LLD they became accustomed to. This needs to be verified in future studies.

Plenary Lectures

PL1.01

How Do I Cope With a Recurrent Foot Ulcer? A Patient's Story

Prof. Nicolaas C. Schaper[1], Frans Tempel
[1]Maastricht University Medical Center, Maastricht, The Netherlands

Abstract not available.

PL1.02A

New Trends in Diabetic Foot Ulcer Research: From Biology to Psychology

Prof. Andrew Boulton[1], Dr. Loretta Vileikyte
[1]University of Manchester, Manchester, United Kingdom

In the first half of this presentation I will cover developments in three areas of research in diabetic foot disease in the last decade. As mentioned by Mike Edmonds in a recent editorial, there has been a renaissance in diabetic foot care, particularly in the diagnosis and management of infection, new evidence-based treatments for foot ulcers and the use of "smart" technology in the monitoring of high-risk feet and the prevention of ulceration.

a) Infection: First, the CODIFI study clearly demonstrated the superiority of tissue specimens vs wound swabs for diagnosing infecting organisms. RCTs have shown that antibiotics are non-inferior to local surgery in diabetic foot osteomyelitis, and most recently, the OVIVA study confirmed equal efficacy for oral vs intravenous antibiotics. Lastly, a study from China suggested that platelet-rich plasma plays an anti-bacterial role in an in-vitro model for infected diabetic foot wounds.

b) Evidence-based treatments for DFUs: Whereas the latest Cochrane review on negative pressure wound therapy could only provide low-certainty evidence to support its use in diabetic foot wounds, there have been a plethora of trials supporting the use of new therapies in the treatment of foot ulceration. Examples include the use of continuous infusion of oxygen, of a nitric-oxide generating medical device and most recently, the LeucoPatch system.

c) Smart technology: It is well known that high foot pressures predict ulceration in the neuropathic foot and that the foot heats up before it breaks. The advent of the internet of medical things has permitted smart sensors to be used to identify repetitive stress due to high pressure and local heat under the foot that can feed back to patients and health care professionals to warn of imminent ulceration. This may well represent the dawn of a new era in preventative foot care in diabetes.

PL1.02B

New Trends in Diabetic Foot Ulcer Research: From Biology to Psychology

Dr. Loretta Vileikyte[1]
[1]University of Manchester, Manchester, United Kingdom

Diabetic foot ulcers (DFUs) are a source of physical dysfunction, emotional distress and diminished quality of life. Although DFUs are not independently predictive of depression, they generate specific emotional responses, which either facilitate (fear of amputation) or inhibit (anger at health care providers) preventive foot self-care. Moreover, patients appraise their DFU risk by creating their own models of this medical condition, which are largely inconsistent with the clinician's view, resulting in a lack of foot self-care. Intriguingly, while DFU-specific beliefs and emotions shape preventive foot self-care, it is depression that is associated with the development of first DFUs, the link that does not appear to be accounted for by poor foot self-care. Diabetic neuropathy-related unsteadiness is emerging both as an important determinant of depression in patients at high DFU risk and as a predictor of non-adherence to offloading in those with active DFUs. While there is a general agreement that the psychological stress (PS)-induced immune suppression is associated with an impaired wound healing, its effects have been studied almost exclusively in acute, experimental wounds. DFUs are fundamentally different from the acute wounds: they present with an excessive inflammation, increased proteolysis and delayed re-epithelialization. Thus, the mechanisms by which PS affects acute wound healing may not be relevant to DFUs. Studies that examined the psychological stress and DFU healing link have invariably focused on depression, thereby producing inconclusive results. Latest body of evidence indicates that DFU patients exhibit high levels of fear of amputation which, in turn, impairs DFU healing. However, the potential mechanisms linking PS and DFU healing are yet to be elucidated. Until recently, systemically released cortisol and epinephrine were recognized as the only mechanism through which stress hormones influenced wound healing. However, the skin has been found to be an extra-adrenal site for glucocorticoid synthesis that modulates local inflammation. A novel finding that local, tissue-specific cortisol synthesis enzymes are implicated in DFU non-healing was recently discovered and could potentially serve as a future target for therapeutic interventions.

PL1.03

Prevention of Diabetic Foot Ulcers: Guidance and Beyond

Dr. Jaap J. van Netten[1]
[1] Amsterdam UMC, location AMC, Amsterdam, The Netherlands

Prevention has long been recognized as key in reducing the burden of diabetic foot disease. However, 40% of patients will get a new ulcer in the first year after healing, and prevention is still under-represented in clinical trials and multidisciplinary treatment.

During this presentation, I will present the updated IWGDF Guidelines on Prevention. This includes discussing the most important interventions, and the evidence these recommendations are based on.

But the Guideline only presents state-of-the-art, whereas some major changes in healthcare in general and ulcer prevention specifically can be foreseen. During the second part of this presentation, I will discuss the directions ulcer prevention can (and should) take in the years to come. This includes a shift from ulcer prevention to safe activity promotion, and from stratified healthcare to personalised medicine.

PL2.01

Microangiopathy: Is It Relevant For Wound Healing?

Prof. Gerry Rayman[1]
[1]The East Suffolk and North East Essex University Foundation Trust, Ipswich, United Kingdom

Abstract not available.

PL2.02

Cardiovascular Risk Management in a Patient With Diabetic Foot Complications

Prof. Naveed Sattar[1]
[1]Institute of Cardiovascular and Medical Sciences, University of Glasgow, Glasgow, United Kingdom

Abstract not available.

PL2.03

Which Diagnostic Tests in Everyday Clinical Practice are (Not) Useful?

Prof. William Jeffcoate[1]
[1]Nottingham University Hospitals Trust, Nottingham, United Kingdom,

The intention is not to come up with a lists of tests which are either good or not good for all the myriad diagnostic decisions that need to be made in everyday practice. Instead, testing will be considered under four main headings: (1) tests to assess risk of ulceration, (2) tests to diagnose an ulcer, (3) tests used in defining ulcer type and the impact this has on clinical decisions and (4) tests to assess the response to treatments and how their results might change practice. While neither the choice of tests nor the interpretation of results is straightforward, one clear message should emerge and this is that it is not the tests themselves which vary in their usefulness but the ways in which they are used by clinicians.

PL3.01

When to Call for a Vascular Consultation

Prof. Ed Boyko[1]
[1]University of Washington, Seattle, United States

This talk will provide guidance on the indications for seeking a vascular consultation in the care of a patient with diabetes and a lower limb complication. Typically, the lower limb complication will be a nonhealing or complicated diabetic foot ulcer where ischemia is thought to be a contributing factor. The expected benefit from a vascular intervention will be improvement in arterial perfusion of the lower limb thereby increasing the probability of ulcer healing. Identification of patients with a nonhealing diabetic foot ulcer who might benefit from a vascular consultation is based both on clinical course and history and physical examination. Factors that indicate presence of ischemia and potential for revascularization success will be described. The value of the physical exam will be outlined including the sensitivity and specificity of commonly used clinical findings that suggest diminished arterial flow, such as symptoms or examination findings such as absent pedal pulses, delayed capillary refill time, delayed venous filling time, or atrophic, blue, or hairless skin. The value of sensitivity and specificity when combined to form likelihood ratios in revising probability of ischemia will be described, and the information gained from their application will be discussed. Assessment of tests for ischemia measured on a continuous scale using ROC curves will also be presented and a practical interpretation regarding the area under the ROC curve provided. The importance of clinical course in decision-making regarding the need for vascular consultation will also be presented. Special challenges complicate the assessment of arterial perfusion in patients with diabetes mellitus, particularly the problem of elevated ankle-brachial index due to arterial calcification causing vessel incompressibility. Alternate methods to assess arterial flow in this instance will be discussed. Although diabetic neuropathy may be the most important factor in the pathogenesis of foot ulcer, poor arterial perfusion may play a more important role in the occurrence of amputation among persons with a foot ulcer. Thus, restoration of arterial perfusion may be a key intervention in the prevention of amputation in persons with a diabetic foot complication.

PL3.02

Foot Infections in Diabetes: Tribulations, Trials and Triumphs

Prof. Benjamin Lipsky[1]
[1]University of Washington, Seattle, United States

In this lecture I will review key aspects of the history of the infectious complications of the diabetic foot, a subject in which I have been engaged as a clinician, researcher and guideline writer for

over 30 years. I will highlight the state of the (rather sorry) art three decades ago, the beginning of the era of scientific research on the causative pathogens and antibiotic treatments, the development of guidelines and principles of antimicrobial stewardship. I will discuss the problems and joys of clinical trials, and a few that have helped improve knowledge about and management of these difficult infections. This will include discussions about biofilm, antibiotic resistance, topical therapies, new antimicrobial and non-antimicrobial treatments. I will also discuss what I believe are the major areas of controversy currently and some potential ways to address these issues.

PL3.03

Artificial Intelligence for the Next Generation of Healthcare Interventions

Dr. Tingting Zhu[1]
[1]*University of Oxford, Oxford, United Kingdom*

Communication devices and connectivity are increasingly ubiquitous, contributing to a rapidly-expanding infrastructure. This development promises to tackle some of the most challenging issues facing society today - how healthcare is delivered to an aging and expanding population. Each year, millions of people worldwide suffer from chronic long-term diseases, such as diabetes, heart disease, and kidney malfunction, with limited access to appropriate treatment. Machine learning plays a key role in determining how effective healthcare will be delivered to future generations. Reliable continuous tracking of patient health can provide accurate early warning of health deterioration. “Big data” (e.g.: electronic health records and data from wearable devices for monitoring chronic diseases and well-being) are now being collected, which cover the entirety of patient care, throughout the life of a patient. It is therefore necessary to develop novel machine learning methods to exploit the contents of these large complex datasets by performing robust, automated inference at very large scale.

PL4.01

What are the Most Cost-Effective Treatments in Different Countries?

Prof. Jan Apelqvist[1]
[1]*Skåne University Hospital, Malmö, Sweden*

There is an increasing awareness of the economic burden to heal DFU. Most estimates in the literature for the economic cost of treating a diabetic foot ulcer (DFU) are from industrialized countries. The increasing demand for quality outcome data as part of the economic decision-making process turns our attention to resource utilization efficiency and assessment of consequence rather than simplistic cost arguments. The impact of current models of care that are often fragmented in their delivery and reflect on intervention vs cost over time.

While it is important to identify interventions and strategies early to avoid complications and facilitate healing, these often have cost implications. Clinicians need to be able to present robust economic arguments to fund holders. A major problem in the analysis of the cost of disease states is the wide variation in the cost criteria used by studies. Difficulties in comparing cost analyses are compounded by variations in care protocols and the economic status of different countries, eg variations in rates of pay to healthcare staff. Significant efforts will be required to identify a series of standardized criteria for cost analyses that can be used to further identify the most economically effective ways to treat hard-to-heal wounds and to aid useful comparisons between different care protocols and healthcare systems. A number of reports have indicated the cost-effectiveness of different new technologies and dressings used for the treatment of hard to heal wounds. Although many of these products are more expensive than the compared treatment, the use of them may be cost- effective if they result in less frequent dressing changes and/or if they result in more effective or faster healing It is important to be aware that a treatment could be cost-effective in one group of patients or for one type of wound but not in another type. An intervention could also be cost-effective when used in one setting or country but not in another.

When assessing use of resources, it is important not to focus on individual items such as dressings or procedures but to adopt a broader view of total resource use.

PL4.02

What Does a Clinician Need to Know About the Microbiome?

Prof. Bonnie Hurwitz[1]
[1]*University Of Arizona, Tucson, United States*

Chronic wounds represent a significant clinical burden in the US, that also directly impact a patient’s quality of life. Poor outcomes in DFU are in part due to inaccurate diagnosis, wherein standard microbiological techniques provide no results in 50-80% of cases. Lack of diagnosis leaves clinicians with no choice but to use empirically-based antibiotic regimens that can be ineffective and contribute to the rise of antibiotic resistance with worldwide health implications. Developing strategies for faster diagnosis and directed treatment of microbial infection is fundamental to improved wound healing and effective patient care. The advent of low-cost next-generation sequencing makes it possible to accurately quantify bacterial-species present, but also genes of clinical importance (e.g. antibiotic resistance and virulence factors). Moreover, emerging cloud-based computing enables efficient data mining to convert large-scale sequence datasets and clinical factors into specific diagnoses. These advances make a molecular-based clinical diagnosis of polymicrobial infection possible. Here I describe state-of-the-art techniques in computational metagenomics and their application in understanding the microbial ecology of wounds towards diagnostic development.

PL4.03

Surgery to Prevent a Foot Ulcer?

Prof. Lawrence Lavery[1]
[1]*The University of Texas Southwestern Medical Center, Dallas, United States of America*

Abstract not available.

Workshops

WS01

Difficult Diabetic Foot Infection Cases

Prof. Benjamin Lipsky[1], Prof. Eric Senneville[2]
[1]University of Washington, Seattle, United States, [2]Gustave Dron Hospital, Tourcoing, France

Diabetic foot infections are now the most frequent diabetes-related reason for hospitalization and cause substantial morbidity, including being the proximate cause of most lower extremity amputations in persons with diabetes. Proper treatment of these infections requires an understanding of diagnosing skin/soft tissue as well as bone infection, obtaining appropriate specimens for culture, selecting optimal empiric and definitive antimicrobial therapy, determining which patients need surgical interventions and possibly other adjunctive treatments. While many cases are straightforward, some present particular difficulties; these often require consultation with specialists.
Out workshop will begin with asking the audience to tell us which issues related to the infectious aspects of the diabetic foot they would most like to learn about. We will list these on a flipchart and during the session will attempt to answer each. We will also present some difficult cases with which we have been involved that we think offer useful teaching points.
We look forward to seeing you at our workshop!

WS02

Prevention and Education: Challenges and Opportunities in Empowering Patients and Improving Diabetic Foot Outcomes

Prof. Jeffrey Gonzalez[1], Ms. Anne Rasmussen[2]
[1] Yeshiva University and Albert Einstein College of Medicine, New York, United States of America, [2] Steno Diabetes Center Copenhagen, Copenhagen, Denmark

This workshop will deal with patient education and prevention of poor diabetic foot health outcomes. Dr. Gonzalez will provide the perspective of a clinical health psychologist focused on diabetes care and Dr. Rasmussen will provide that of a podiatrist with extensive experience in diabetic foot care and research. After a brief overview of the issues involved, the session will focus on an interactive discussion of cases that highlight problems and promising interventions to improve education and prevention.

WS03

"How it's Made" Total Contact Cast and Other Casting Techniques

David G. Armstrong[1,2], Ron Sleegers[3]
[1] Southwestern Academic Limb Salvage Alliance (SALSA), [2] Keck School of Medicine of University of Southern California (USA), [3] University Hospital Maastricht, department of Internal Medicine, Maastricht, The Netherlands.

In literature and daily practice, casting techniques are frequently recommended for treating diabetic foot problems. Plantar ulcers and Charcot foot form the indications for these techniques. Nevertheless, many professionals do not use casts in their patient care. For an effective and safe utilization of casting techniques in patients with diabetes sufficient knowledge, skills and facilities are required. This workshop aims at an exchange of these aspects of expertise. And at the end of the workshop you know how a Total Contact Cast is made and hope to stimulate you to use it in your setting.
Practical 'ins-and-outs' of the organization and facilities of incorporating casting into a clinical setting will be presented. One of the lecturers works in The Netherlands, the other in the USA. Differences in approaches will be shown and discussed. Attention will be paid to specific conditions which form indications, or on the other hand, contra-indications for the application of a cast. The lecturers will exchange their experience with facilities and materials needed, choices in different techniques and alternatives (cast walker, (orthopaedic) shoes), required instructions to the patients and frequency of policlinic visits. Next to interactive comprehensive Powerpoint presentations and discussion with the audience, prefabricated demonstration models will be present and a live demonstration of the manufacturing of a total contact cast (TCC) will be given. A handout, composed by the lecturers with practical recommendations concerning the casting techniques will be presented to the audience.
The educational style will be characterized by the following keywords: practical, ins-and-outs, lively, interactive, stimulating.

WS04

Diabetic Foot Emergencies

Prof. Lawrence Lavery[1], Prof. Eric Senneville[2], Dr. Sjef van Baal[3]
[1]The University of Texas Southwestern Medical Center, Dallas, United States, [2]Gustave Dron Hospital, Tourcoing, France, [3]Ziekenhuisgroep, Twente, Almelo, The Netherlands,

Several diabetic foot presentations are considered as acute , usually surgical, conditions Often a limb or life threatening infection plays an important role During this workshop, some cases are presented, for which the authors will try:
– To explain the diagnostic approach,
– The treatment with all its implications like surgery and antibiotic therapy
- The outcome
Interactive participation of the audience will be stimulated.

WS05

When to Stop treatment

Dr. Zulfiqarali Abbas[1], Prof. William Jeffcoate[2], Prof. Alberto Piaggesi[3]
[1] MUHAS / AMC, Dar es Salaam , Tanzania, 2Foot Ulcer Trials Unit, Nottingham, United Kingdom, [3]University of Pisa, Pisa, Italy, [3]Diabetic Foot Section - Pisa University Hospital, Pisa, Italy

The aim of this workshop is that the presenters and the participants will together air topics that are rarely formally discussed. It is unlikely that we will reach many conclusions but the aim is simply to trigger thought.
Most teaching is based on the initiation of investigations and treatments but we do not usually have clear policies for care when treatments don't produce a rapid cure.

Our aim is to discuss three broad topics: the use of antibiotics, revascularisation and special dressings.

WS06

Charcot: Diagnosis and Medical Treatment

Prof. Michael Edmonds[1], Prof. Edward Jude[2]
[1]King's College Hospital, London, United Kingdom, [2] Tameside Hospital NHS Foundation Trust, Manchester, United Kingdom

Learning Goals
- To understand the natural history of the Charcot Foot
- To diagnose the Charcot Foot early using modern imaging techniques

To be aware of casting and pharmacological treatments.
It is important to have a high index of suspicion when a patient presents with a hot swollen foot. There may be diagnostic radiological changes. However, if the X-ray is normal, two further investigations may be performed: technetium methylene diphosphonate bone scan and MRI scan. Prompt casting treatment is vital and various pharmacological treatments can be considered.

WS07

Radiology in the Diabetic Foot: Pearls and Pitfalls

Dr. Richard Whitehouse[1], Prof. Mario Maas[2]
[1]Manchester Royal Infirmary, Manchester, United Kingdom, [2]Amsterdam Medical Centre / University of Amsterdam, Amsterdam, The Netherlands.

Workshop format: Short presentations on imaging of diabetic foot complications, concentrating on plain radiography and MR scanning, then a simulated MDT with audience participation. This will be an educational, fun experience.
Please submit imaging of a case that caused you difficulty. (PPT presentation, anonymised, no more than 5 slides, workshop date included). Send to Richard.whitehouse@mft.nhs.uk before 30 April. We will select cases for discussion in each workshop.
Objectives: Insight into the uses and limitations of radiology. Both infection/ osteomyelitis and morphological degradation (Charcot deformity) will be discussed.
Possible Imaging Strategies are discussed. When to use MRI, which protocol, which problems may occur. Which clinical information is mandatory for optimal protocol choice. Which information is necessary in radiological report.
To consider developing service enhancements, if not already used: Clinico-radiological meetings (MDT), Optimizing tailored radiography, Repeat radiography.

When to use MR
To consider developing service enhancements, if not already used:

WS09

Podiatry: a Live Diabetic Foot Clinic

Ms. Ingrid Ruys[1], Ms. Lian Stoeldraaijers[2]
[1]Maxima Medisch Centrum, Veldhoven, The Netherlands,
[2]Diabetes Podiatrists, Valkenswaard, The Netherlands

Especially diabetic feet are at risk for ulceration. The diabetes podiatrist is the Dutch specialized professional in screening, examination and treatment of the diabetic foot and his complications. The diabetes podiatrist identifies the risk factors for foot ulceration, which include peripheral neuropathy,peripheral arterial disease, limited joint mobility, foot deformity, abnormal biomechanics or shoes. But is also trained in wound care and offloading, and is working in a multidisciplinary network.
In the Netherlands there is a preventive foot check system for all patients with diabetes. At least every year every patient with diabetes will be signed up for an a foot screening. Depending on the risk factors they get a control visit every 3, 6, or 12 months. All professionals in the field of the diabetic foot should be aware of all the risk factors of the diabetic foot, properly screen for risk factors, have knowledge of the current (inter)national consensus guidelines and its emphasis in daily practice in diabetic clinics, but also in family care clinics, nursing homes and general hospitals.
During this workshop you will be shown how to screen a diabetic foot for risk factors and how to treat a foot at risk by a diabetes podiatrist. Some diabetic patients will be present in this workshop and their feet will be screened, examined and treated by two Dutch diabetes podiatrists.
Recurrence of plantar foot ulcers is also a common and major problem in diabetes, ulcers often recur. There is a serious risk for infection and amputation. Foot biomechanics and patient behaviour are important. This 'live' foot clinic will be shown to you on a big screen and comments and xplanations will be made by experts. As the 'live' foot clinic is presenting the daily practice of of a diabetes podiatrist, discussion about treatments and therapeutic plans with the participants will be stimulated. Prevention of ulceration is important to decrease the economic burden of diabetic foot disease and the quality of life. Let's work together to reduce these footulcers!

WS10

Diabetic foot Ulcers and Skin Disorders: the Importance of the Dermatologist in the Diabetic Foot Team

Dr. Miriam Loots[1], Ms. Birgitte Visch[2]
[1]Franciscus Gasthuis & Vlietland, Rotterdam, The Netherlands,
[2]Rijnstate Hospital, Arnhem, The Netherlands

To prevent diabetic foot ulcers and amputation of the foot, all kind of effort is made by several clinicians, podiatrists and woundnurses. A lot of attention is paid to treat arterial disease and infection, have a normoglycemic patient, treat comorbidities, off-loading and management of the wound. The skin it self with mycosis, eczema and edema are often neglected or not treated. The importance for these aspects and other skin disorders is discussed in this workshop.

WS11

Pitfalls in Peripheral Arterial Disease

Prof. Joseph Mills[1], Dr. Kim Christian Houlind[2]
[1]Baylor College of Medicine, Houston, United States of America,
[2]University of Southern Denmark, Odense, Denmark

Along the course of care for patients with diabetic foot ulcer (DFU), ischemia is surprisingly a frequently missed diagnosis. Thus, unless perfusion assessment is mandatory and routinely incorporated into the evaluation and management algorithm, ischemia will continue to be missed. It is evident that all patients with DFUs should be referred to a multi-disciplinary clinic, which should include specialists who can manage the foot, the metabolic issues, and assess for and correct perfusion abnormalities. The most commonly available perfusion tests are: ankle-brachial index, toe pressure, transcutaneous oxygen and skin perfusion pressure.
The evaluation of a patient with a DFU should begin with a careful pulse and continuous wave Doppler evaluation, but perfusion needs to be objectively measured in every case. Based upon the WIfI framework, if perfusion is deemed inadequate to heal the given wound, then the anatomy should be assessed with angiography, recognizing distinct patterns of disease which are more common in diabetic patients, particularly tibial and pedal artery occlusive disease. We prefer to obtain duplex imaging in clinic to assess the inflow and map the infrainguinal arteries, which helps select the angiographic approach. Detailed arteriography is performed to the level of the toes and after either endovascular or open revascularization, perfusion should then be objectively re-assessed to ensure that is adequate. All patients after such vascular interventions should be subjected to noninvasive surveillance with the type and frequency of testing dependent upon the type of intervention and its predicted failure modes.
In this workshop, we will review the limitations of reliance on physical examination alone to assess for ischemia and the pitfalls and utility of simple hemodynamic and perfusion measurements. We will also present and walk through clinical cases in which the assessment, the decision to revascularize and the means selected for revascularization were based on a combination of patient risk factors, good clinical judgment and an algorithmic approach grounded in the SVS WIfI (Wound, Ischemia, foot Infection) Classification.

WS12

Shoes: From Art to Science

Prof. Klaas Postema[1], Mr. Rob Verwaard[2]
[1]Univerity Medical Center Groningen, Groningen, The Netherlands,
[2]Wittepoel, Rotterdam, The Netherlands

In this workshop Rob Verwaard will present about the arts in pedorthic footwear and Klaas Postema will present an update of science about footwear for DM patients.
There is ample time for discussion for next and other questions:
Which knowledge about footwear should be published in the DM community?
How should this knowledge be made available?
Registration of patient outcomes, related to footwear; how to collect data?
Please send other questions via the app!

WS13

Diagnosing and Treating (Painful) Neuropathy

Prof. Andrew Boulton[1], Prof. Rayaz Malik[2]
[1]University of Manchester, Manchester Royal Infirmary, Manchester, United Kingdom, [2]Weill Cornell Medicine, Doha, Qatar

The diabetic neuropathies are the most prevalent of the chronic complications of diabetes. They comprise the heterogeneous group of conditions that afflict different parts of the nervous system both somatic and autonomic. This workshop will cover aspects of the diagnosis and management of diabetic neuropathy and also focus somewhat on the autonomic neuropathies (ANs). There will be initial presentations by the two speakers for the first 20-30 minutes, followed by 30-45 minutes to give ample time for discussion with the audience.

It must be remembered that the diabetic neuropathies are diagnoses of exclusion: there is no test that can diagnose the neuropathy in your patient as being due to diabetes. A careful clinical history and examination remain pivotal to the overall diagnosis and management of the condition. The most recent Position Statement of the American Diabetes Association will form the basis for this discussion and can be downloaded free of charge from Diabetes Care (Pop-Busui R, Boulton AJM, Feldman EL, Bril V, Freeman R, Malik RA, et al. Diabetes Care 2017; 40: 136-154). The commonest variety of the neuropathies, chronic sensorimotor peripheral diabetic neuropathy, is common affecting up to 50% of older type 2 diabetes. Half of these patients may be asymptomatic hence the importance of a careful clinical examination. Having excluded other causes of neuropathy, the first approach to the management of painful diabetic neuropathy is to obtain optimal stable glycaemic

control. Thereafter there are a number of evidence-based treatments available including anti-depressant drugs such as the tricyclics (eg., amitriptyline) and the duel inhibitors (serotonin- norepinephrine reuptake inhibitors, eg., duloxetine). The other main group of drugs used in the treatment are the anti-epileptics such as gabapentin and pregabalin. For those whose pain remains unresponsive to these two groups of drugs, there is evidence to support the use of opioid or opioid-like drugs such as tramadol and for very severe cases controlled release oxycodone.

The commonest of the ANs are those affecting the cardiovascular system although these are often asymptomatic. The question of potential screening will be discussed during the workshop. Erectile dysfunction (ED) is probably the most commonly symptomatic of the ANs and although there are multiple causes of ED, autonomic dysfunction is common in such patients. There is evidence to support the use of the PDE5 inhibitors. Treatments are also available for some of the gastrointestinal autonomic neuropathies and the sweating disorders. These will be discussed during the workshop. The most important message for both somatic and autonomic neuropathies is that they may be silent in their early phases hence the need for screening particularly for evidence of sensory loss in the lower limbs.

WS14

Treatment of Diabetic Foot Infections in the Era of Multi Drug Resistant Organisms

Dr. Edgar Peters[1], Prof. Kavita Bhavan[2]
[1]Amsterdam UMC, Location VUmc, Amsterdam, The Netherlands, [2]UT Southwestern Medical Center, Dallas, United States of America

The worldwide burden of multidrug antimicrobial resistance is rising. Multidrug resistant pathogens could well lead to poor outcomes of diabetic foot infections, because commonly used antibiotics are ineffective. Goals of the workshop are that the audience can name some different types of antimicrobial drug resistance, the epidemiology of resistance, antibiotic strategies and non-antibiotic options to treat infections with resistant organisms and strategies to reduce the number of infections with resistant organisms.

WS15

Surgical Management of the Charcot Foot (in collaboration with the Association of Diabetic Foot Surgeons)

Mr. Venu Kavarthapu[1] Dr. Armin Koller[2], Prof. Dane Wukich[3], Dr. Thomas Zgonis[4]
[1]King's College Hospital, London, United Kingdom, [2]Mathias-Spital and Jakobi Hospital, Hamburg, Germany, [3]UT Southwestern Medical Center, Dallas, United States of America, [4]University of Texas, San Antonio, United States of America

Charcot Midfoot reconstruction is considered if the deformity is not amenable to offloading and is associated with midfoot instability. Surgical correction should be aimed at achieving a stable and plantigrade foot that can take normal weight bearing loads in a surgical shoe. Full deformity correction is achieved by soft tissue balancing procedures, combined with bone wedge resections. In order to achieve full bone fusion, the fixation construct should follow a 'durable long-segment rigid fixation with optimal none opposition' principle.

WS16

From Scientific Evidence to Daily Practice

Prof. Dr. Frances Game[1], Prof. Ed Boyko[2]
[1]University Hospitals of Derby and Burton NHS Foundation Trust, Derby, United Kingdom, [2]University of Washington, Seattle, United States of America

This workshop will develop skills in the identification and evaluation of evidence to guide clinical decision-making by focusing on clinical questions regarding diagnosis, prognosis, or treatment. Participants will consider the process of finding and evaluating evidence to answer the questions, including effective literature searching and assessment of information for evidence of benefit and absence of bias. Tools for assessing research quality will be presented including hierarchy of study designs and the metrics for assessment of diagnostic tests and prognostic models.

WS17

Debridement and Choice of Dressing

Prof. Dr. John Steinberg[1], Prof. Jan Apelqvist[2]
[1]Georgetown University School of Medicine, Washington, United States of America, [2]Skåne University Hospital, Malmö, Sweden

Debridement is a key part of advanced wound repair therapies and must be understood as a process, in conjunction with other treatments with regard to indications, methods ,benefits and limitations Debridement refers to deeply removing adherent, dead or contaminated tissue from a wound and must be clearly separated from the act of cleansing, defined as the removal of dirt (loose metabolic waste or foreign material). Debridement is the act of removing necrotic material, eschar, devitalized tissue, infected tissue, hyperkeratosis, slough, pus, hematomas, foreign bodies, debris, bone fragments or any other type of bioburden from a wound with the objective to promote wound healing.
Debridement can range from the excision of excessive callus to early debridement of superficial dead tissue and release of pus; through to the specialized early recognition of underlying osteomyelitis and dead bone which needs skilled surgical interventions to reduce the need for extensive amputation.
Key factors to recognize in the choice of debridement technique are infection, ischemia and the extent of tissue loss/involvement
The choice and timing of debridement techniques in the diabetic

foot can be described in the terms of initial damage control to save the leg and life of the patient, secondary eradication of devitalized tissue to improve or facilitate wound healing and finally to achieve a foot that can maintain ambulation.
An appropriate diagnosis must first define the problem (necrosis, eschar, slough, sources of infection) and secondly, define the exudate levels of the wound bed ranging from dry to wet.
The following need and choice of type of debridement is dependent on the level of decreased perfusion to the foot and the extent of tissue loss, not only to achieve healing of an ulcer. Additional parameters which have the capacity to influence the decision for debridement and the choice of the appropriate method comprise pain, the patient's environment, patient's choice, comorbidities , skill and resources of the care giver, patient's quality of life, regulations and guidelines.

Several methods of debridement and many techniques have been introduced; primarily applying physical principles and forces to promote the development from acute inflammatory phase to the reparative condition.

WS18

Endovascular Revascularisation for Diabetic Limb Salvage: Tips/Tricks and Updates

Prof. Dr. Jim Reekers[1], Dr. Edward Choke[2]
[1]Academic Medical Center, University Of Amsterdam, Amsterdam, The Netherlands, [2]Singapore General Hospital, Singapore, Singapore

This workshop will be a hands on and interactive session focussing on the endovascular treatment for diabetic limb salvage. There will be talks on endovascular strategies (including angiosome concept and overall aims of endovascular treatment), updates on new technologies for below the knee endovascular treatment (drug coated balloons, stents) and tips and tricks on successful endovascular treatment for below the knee and ankle arteries (Options on wires, microcatheters and retrograde or pedal-plantar loop techniques).

WS19

How to Deal with Diabetic Foot Disease in Tropical, Warm and Humid Areas

Dr. Neil Baker[1], Dr. Zulfi Qarali Abbas[2]
[1]Muzaini Vascular and Diabetic Foot Clinic, Jabriya, Kuwait, [2]Muhas / AMC, Dar es Salam, Tanzania

Diabetic foot problems especially ulceration cause considerable suffering and morbidity. Commonly diabetic foot problems are multifactorial and are not always easy to manage requiring an array of skills knowledge and expertise. In tropical, hot, humid and climatic hostile conditions diabetic foot pathologies are fraught with even greater challenges. Additionally in these environments other pathologies and conditions arise that are not often discussed or addressed. This workshop will look at some of these situations but will also provide a forum for debate, support and exchange of expertise and knowledge. Perhaps even provide a network for clinicians working with these problematic and often devastating conditions.

WS20

MRI and Nuclear Medicine in Diagnosis and Follow-up

Dr. Jan Dening[1], Dr. Andor Glaudemans[2]
[1]Martini Ziekenhuis, Groningen, The Netherlands, [2]University Medical Center Groningen , The Netherlands

Imaging of a diabetic or a Charcot foot can be difficult and complex with the possibility of mimicking of certain imaging features. It usually requires a multimodality approach to the diagnostic problem to properly identify the problem and its potential complications. During this workshop, we aim to demonstrate the strengths and weaknesses of especially MRI and Nuclear medicine in the diagnosis and follow-up of diabetic and Charcot foot.

WS21

Screening the diabetic foot for risk factors and simple treatments

Dr. Margreet van Putten[1], Ms. Miranda van Mol[2]
[1]Fontys Paramedische Hogeschool, Eindhoven, The Netherlands, [2]Fontys University of Applied Sciences, Eindhoven, The Netherlands

This practical workshop informs you about the simple techniques to detect the diabetic foot at risk for ulceration. This includes neuropathic tests, tests to determine peripheral arterial disease, including measuring toepressures and the toe-arm index, as well as checking if your patient is able to inspect her/his own foot (visus check). Also simple techniques will be shown how to achive off-loading using felt paddings.
After a short introduction you are free to walk around and visit the different stations to inform yourself, even perform the tests yourself on available feet of students. The different materials and methods for off-loading will be shown.
From all tests protocols in English will be available.
Note that the workshops on Thursday and Friday are identical!

WS22

Treatment of infection and Osteomyelitis (in collaboration with the Association of Diabetic Foot Surgeons)

Dr. Klaus Kirketerp-Møller[1], Prof. Alberto Piaggesi[2], Prof. Luca Dalla Paola[3], Dr. Katherine Raspovic[4], Dr. Chiara Goretti[5]
[1]Copenhagen Wound Healing Center, Bispebjerg University Hospital, Copenhagen, Denmark, [2]University of Pisa, Pisa, Italy, [3]Maria Cecilia Hospital, Cotignola, Italy, [4]University of Texas Southwestern Medical Center, Dallas (TX), USA, [5]University Hospital of Pisa, Pisa, Italy

Foot and ankle surgery in diabetic patients is frequently associated to impaired wound healing. Diabetic people with uncontrolled hyperglycemia have a four times higher risk of developing surgical complications when compared with patients with tighter glycemic control, such as prolonged wound healing, deep infection and major amputation, or even mortality. So it is important implementing a multidisciplinary approach to the postoperative management of diabetic foot patients, avoiding surgical site infections, deischences, getting faster healing byprimary or secondary intention.

Mini Symposia

MS1.01
Indications for Preventive Surgery

Prof. Lawrence Lavery[1]
[1] *The University of Texas Southwestern Medical Center, Dallas, United States of America*

Abstract not available.

MS1.02

The Surgical Ladder for Prevention

Mr. Venu Kavathapu[1]
[1]*King's College Hospital NHS Trust, London, United Kingdom*

Prevention of recurrence of ulceration is important to reduce the risk of a major limb loss in a patient with diabetes. An ulcerated diabetic foot warrants a through assessment, focusing on the presence and extent of local infection, vascular status and presence of any deformity. The surgical treatment ladder for such ulcerated diabetic feet include surgical debridement of the ulcer, surgical debridement of diabetic foot attack, revascularisation, soft tissue balancing procedures, minor amputations, exostectomy, minor and major deformity corrections.

MS1.03

Surgery of Osteomyelitis

Prof. Luca Dalla Paola[1]
[1]*Maria Cecilia Hospital, GVM Care&Research, Cotignola, Italy*

Foot infection is a major risk factor for limb loss in diabetic population. Over half of foot ulcers become infected and at initial presentation, diabetic foot osteomyelitis complicates approximately 20% of foot ulcers. Osteomyelitis is the natural evolution of chronic wounds being present approximately in 15% of moderate and in 50-60% of severe infection disease. The presence of osteomyelitis localization increases morbidity, health care costs, and increase significantly the risk of minor and major amputations.
Lesions complicated by osteomyelitis often require surgical approach associated to antibiotic therapy. There are several indications for the surgical management of osteomyelitis. Patients who have failed medical antibiotic treatment or patients with evidence of abscess formation, necrotizing fasciitis, or gangrene should undergo surgical treatment.
Debridement is defined as the surgical removal of infected or necrotic tissue from below and/or around a wound with underlying osteomyelitis. Conservative surgery is defined as the removal of infected bone and surrounding soft tissues while amputation is the removal of a portion of the foot.
Whether one treats an osteomyelitic focus with a surgical or non-surgical approach, all infected ulcerations should be debrided with the drainage of any obvious purulence.
There are some key concepts that a surgeon must keep in mind when surgically treating a patient with osteomyelitis of the foot. The surgeon should debride to bleeding viable bone, resecting all infected and necrotic bone
Wide excision of bone with margins >5 mm has been shown to reduce the recurrence rate in chronic osteomyelitis as opposed to marginal or limited resection <5 mm. Clinically infected surgical sites should be left open, and repeat debridements may be necessary. Once bleeding and clinically evident infectious components are under control, the use of negative pressure wound therapy may be appropriate.
If the infected bone is resected along with all soft tissue involvement, primary closure could be an option. If delayed primary closure is not possible, negative pressure wound therapy followed by the use of dermal substitutes and/or skin grafts or flaps could be scheduled.

MS1.04

Surgical Offloading

Dr. Thomas Zgonis[1]
[1] *University of Texas, San Antonio, United States of America*

Abstract not available.

MS1.05
Minimally Invasive Surgery

Dr. Armin Koller[1]
[1]*Mathias-Spital and Jakobi Hospital, Hamburg, Germany*

Abstract not available.

MS1.06

Surgical Therapy in Low Income Countries

Dr. Arun Bal[1]
[1]*Association of Diabetic Foot Surgeons, Mumbai, India*

Diabetes is a major public health problem in low income countries. One of the dreaded complications of diabetes in these countries is Foot Ulcer. In India annually 200000 higher level amputations are done for infected foot ulcer. A patient of infected diabetic foot ulcer spends 50% of his/her annual income for treatment. In majority of low income countries the main challenge is delayed reference to specialized center for treatment. Also lack of awareness about dia-

betic neuropathy and annual preventive examination of the foot in diabetes caused delay in the treatment. Training of paramedic for annual preventive foot examination is sporadic. However over the last decade there are concerted efforts in many countries to form a network of organization for training and upgrading knowledge of graduate and post graduate doctors for optimal management of diabetic foot ulcers. Countries like Myanmar, Tanzania, Fiji have made significant strides in this direction. In India Step by Step program has shown encouraging results. Online courses for family physicians are being conducted in many countries for training family physicians. Newer resource materials are easily available and more training courses are being conducted for paramedics. The scenario which was fairly bleak a decade ago is changing rapidly with even complicated vascular procedures and surgical correction for Charcot foot being made available for patients in many countries

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MS1.07

Podoplastic Surgery

Dr. Christopher Attinger[1]
[1]MedstarGeorgetown University Hospital, Washington, United States

A diabetic limb salvage team is critical to preserving diabetic limb function. Ideally, it should include vascular surgery, orthopedic surgery, plastic surgery (microsurgery and peripheral nerve), podiatric surgery, infectious disease, rheumatology, dermatology, endocrinology, hyperbarist, hospitalist, physiatrist, psychiatry, physical therapy, prosthetists, and social worker. We have found that surgical algorithms work more rapidly and effectively to solve diabetic limb salvage problems. While more expensive in the short run, correcting the biomechanical abnormality when healing the wound leads to better long-term outcomes. Whether the limb is salvaged or amputated is not the critical question. One has to strive to give the patients the most functional limb (preserved or amputated) given their medical condition, physical potential and personal goals. New advances in major amputations and peripheral nerve surgery has increased the possibility of optimizing function and decreasing mortality.

MS2.01

Neuro-Immune Interactions: Interplay Between the Autonomic Nervous System and Immunity

Dr. Matthijs Kox[1]
[1]Intensive Care Medicine, Radboud University Medical Centre, Nijmegen, Netherlands

Neuropathy, inflammation, and infection play important roles in diabetes in general, and in the diabetic foot in particular. The autonomic nervous system (ANS) innervates virtually every organ in the body, and performs a plethora of functions. The most well-known function of the sympathetic branch of the ANS is the so-called 'fight or flight' response, whereas the parasympathetic part, predominantly represented by the vagus nerve, is known for its 'rest and digest' effects. In the 90s of the previous century, effects of the sympathetic nervous system on the immune response were established, and in the year 2000, a novel pathway was discovered via which the vagus nerve can reflexively attenuate the immune response. In this lecture, an overview of ANS-immune interactions is provided, including recent work on this interplay in the context of diabetes.

MS2.02

Will Smart Technologies Make Our Treatment Smarter?

Prof. Dr. Bijan Najafi[1]
[1]Interdisciplinary Consortium on Advanced Motion Performance (iCAMP), Michael E. DeBakey Department of Surgery, Baylor College of Medicine, Houston, United States

In light of the impending diabetes epidemic and high provenance of diabetic foot ulcer (DFU) and its associated complications, the need for enhanced prevention of DFUs is clear. Thanks to new "smart" sensors and communications technology available today, new opportunities have opened to smartly manage DFUs with personalized screening and timely intervention. With the help of automation, patients can even be prompted to check their feet, glucose level or weight, and enter results into mobile patient portals. Even better: They can transmit the results to their doctors in real time. These fast growing, low cost, and widely available resources, can help predict one's risk for foot ulcers, infections, peripheral arterial disease, frailty, and other diabetes associated complications, ultimately saving limbs and prolonging lifespan and healthspan. The speaker will overview and discuss promises and barriers toward implantation of technology to promote management and prevention of DFUs.

MS2.03

Diabetes and Non-Infectious Bone Disease

Prof. Peter Vestergaard[1]
[1]Aalborg Universitetshospital, Aalborg, Denmark

Diabetes and bone health are connected in a number of ways. Patients with type 1 diabetes (T1D) have a decreased bone mineral density (BMD), while patients with type 2 diabetes (T2D) may have an increased BMD, but an increased risk of fractures. The risk of fractures may depend on the skeletal site, the increased fracture risk being especially prominent for proximal hip fractures. The discrepancy between BMD and fracture risk in T2D points at a decreased bone biomechanical competence not reflected by the calcium content. BMD is a reflection of the calcium content of the skeleton, but does not reflect the inorganic matrix. Bone turnover is generally low in diabetes both expressed as biochemical markers of bone turnover and as histomorphometry of bone biopsies. The

changes in bone turnover may be related to glycation of collagen, which may impair bone formation, decreased adherence of collagen fibrils through formation of advanced glycation end products (AGE), and changed excretion of calcium from osmotic effects of hyperglycemia in the kidneys. Altered ratios between mineralized and organic matrix as well as changes in hydroxyapatite crystal formation may also impair bone biomechanical competence. Obesity and altered feeding pattern leading to obesity, may also influence fracture risk and bone turnover. Hypoglycemia only seems to play a minor role in fracture risk. Altered vision from diabetic retinopathy, sequelae from strokes, and decreased postural balance from neuropathy may also increase risk of falls. Drugs against diabetes have varying effects on fracture risk. Thiazolidinediones may increase fracture risk by diverting mesenchymal stem cell differentiation towards adipocytogenesis rather than osteoblastogenesis. Other antidiabetic drugs may have minor effects on fracture risk.

MS2.04

Size Does Not Matter: Relevance of Small Fibre Neuropathy

Professor Rayaz Malik[1,2]
[1]Department of Medicine, Weill Cornell Medicine-Qatar, Doha, Qatar, [2]Cardiovascular Medicine, University of Manchester, Manchester, UK

The current approach to the diagnosis of diabetic neuropathy is flawed. The focus is on symptoms and the simple, but inadequate assessment of neurological deficits using loss of vibration sensation and monofilament testing. There are currently no FDA approved treatments and we have the enviable record of 100% failure rate in clinical trials of diabetic neuropathy.
The focus of diagnostic and clinical trial endpoints is on the large fibres, instead of the more abundant and clinically relevant small fibers, which mediate pain, tissue blood flow and inflammation, all key to the genesis of foot ulceration.
The assessment of small fibres has mainly relied on thermal thresholds, but they are not commonly available and lack sensitivity for detecting repair. Sudomotor dysfunction is an important measure which has relevance to foot ulceration, but is again not commonly assessed. Skin biopsy is a potential alternative for imaging small fibers and has been advocated as an end point for trials of diabetic neuropathy. However, it is an invasive and time-consuming technique, which requires laboratory expertise. However, several recent trials deploying IENFD have failed. We have pioneered the novel ophthalmic technique of corneal confocal microscopy (CCM) that allows a rapid, non-invasive means to identify early sub-clinical small fibre damage, even in subjects with IGT and predicts the development of diabetic neuropathy, foot ulceration and Charcot. It also shows an improvement in corneal nerve morphology following pancreas and kidney transplantation, multiple risk factor intervention and ARA290, a first in class erythropoietin analogue.

MS2.05

Innovations in Footwear Technology

Dr. Sicco Bus[1]
[1]Amsterdam UMC, location AMC, Amsterdam, The Netherlands

Footwear plays and important role in the development, prevention, and healing of foot ulcers in patients with diabetes. International guidelines from the IWGDF report on the importance of custom-made footwear and insoles to prevent recurrence of plantar foot ulcers in patients in remission. For the prevention of the first-ever foot ulcer, footwear also seems an important cornerstone of treatment and footwear advice for different levels of ulcer risk is given in the guidelines. However, very little data is available on the effect of footwear in reducing risk of first-ever ulceration in diabetes.
Innovations in footwear technology include the use of plantar pressure measurements to guide modifications to the footwear that optimize the pressure relieving properties of the shoe. The efficacy of this approach has been tested in several trials. These trials show that barefoot or in-shoe plantar pressure measurements can improve the footwear of high-risk patients with diabetes, and can lead to better clinical outcomes in prevention. Further innovations include the development of scientific-based protocols to help in clinical decision-making for the right type of footwear and for the design of custom-made footwear for different levels of foot complications. Other innovations include the testing and comparison of scientific-based pressure-based footwear design on plantar pressure relief, of which the results can help in moving towards designing the most optimal shoe for diabetic foot prevention. Other innovations will also be presented during this lecture.

MS3.01

Diagnosis of osteomyelitis

Prof. Eric Senneville[1]
[1]Gustave Dron Hospital, Tourcoing, France

Bone infection is associated with infection of a diabetic foot ulcer in 20 to 60% of the cases according to the infection severity. Suspicion of diabetic foot osteomyelitis (DFO) is based on clinical and imaging arguments. DFO corresponds to the class 3 (moderate) infection according to the IWGDF/IDSA classification. DFO is considered certain in case of positive culture of a bone sample associated with histopathological findings consistent with the diagnosis of osteomyelitis (i.e. acute or chronic inflammation and necrosis).
The absence of healing despite appropriate wound care and offloading on a foot with good blood supply, bone exposure, toe involvement particularly when it is erythematous and indurated (the so-called “sausage toe”), a positive probe to bone test and ulcer area larger than 2cm2 all make osteomyelitis more likely. Erythrocyte sedimentation rate (ESR) has been identified as a biological marker associated with the presence of an osteomyelitis underlying a diabetic foot wound when it is elevated more than 60-70mm/h. C-reactive protein and procalcitonin may also be predictive of the presence of osteomyelitis while elevated white blood cell count

does not influence the likelihood of osteomyelitis.
The microbiology of DFO is usually polymicrobial and due to the poor concordance between bone sample and any other tissue sample cultures, bone biopsy obtained during surgery or percutaneously when surgery is not necessary is considered the gold standard when obtaining a reliable documentation is of importance. The main advantage of bone biopsy is to provide reliable data on the organisms responsible for the infection and to determine their profile of susceptibility to antimicrobial agents.
Despite a low negative predictive value due to the delay of 2 to 4 weeks for the onset of osteomyelitis to become visible, plain-X ray is the first imaging examination recommended in these settings. Other more sophisticated imaging techniques such as magnetic resonance imaging (MRI), radioisotope scans (leukocyte or antigranulocyte scan), and as magnetic resonance imaging (MRI) scan, 18F-FDG- positron emission tomography (PET)/computed tomography (CT) or leukocyte scintigraphy (with or without CT) show better sensitivity and specificity but their interest in the daily practice is limited by their availability and cost.

MS3.02

How to evaluate response to therapy for the treatment of diabetic foot infections

Dr. Edgar Peters[1]
[1]Amsterdam UMC, Location VUmc, Amsterdam, The Netherlands

A diabetic foot infection (DFI) is a frequent reason for a lower extremity amputation. Adequate therapy of DFIs is therefore of crucial importance to prevent amputations. Overtreatment of infections can lead to treatment complications, e.g. increased antimicrobial resistance, Clostridium difficile associated diarrhea, and acute kidney injury. Treating infections too short will increase the likelihood of amputation. Current guidelines recommend treating soft tissue infections for 1-2 weeks, and osteomyelitis for 6 weeks. Individualized treatment might be possible using clinical signs of inflammation, laboratory biomarkers for inflammation, and possibly by using imaging techniques.
In this presentation, the presenter will discuss the background behind the guideline recommendations, and the possibilities (or impossibilities) to use clinical, laboratory and imaging features of patients to individualize treatment duration.

MS3.03

Peculiarities of Diabetic Foot Infection in the Low-Income or Medically Underserved Communities

Dr. Zulfiqarali Abbas
[1]MUHAS, Dar es Salaam, Tanzania, 2AMC, Dar es Salaam, Tanzania

Diabetes mellitus is one of the most common non-communicable diseases in industrialized and economically undeveloped countries across the globe. This increasing trend is well recognized in Africa, where it is predicted by epidemiologists that by 2045 rates diabetes will increase by 156%. Not surprisingly, with this increase in diabetes prevalence, rates of diabetes complications are increasing in parallel, especially diabetic foot disease. The burden of diabetic foot complications cannot be addressed without a discussion of infection. Foot infections are common, complex and serious problem in diabetics. In less-developed countries, diabetic foot complications commonly have an underlying infectious etiology superimposed on existing peripheral neuropathy or peripheral arterial diseases. Diabetic foot infection in Africa usually leads to prolonged hospital inpatient stays and is associated with substantial morbidity and mortality. Typically, patients often present to health centres after gangrene and infection have developed, or after foot infection has progressed to systemic infection. In many resource-poor countries where podiatry services are unavailable, the progression of diabetic foot infections to life-threatening sepsis is very common for the following reasons: delays in appreciating there is a problem or ignoring a lesion till it has worsened and causes systemic symptoms; after unsuccessful home therapies, such as application of herbal medication and other unproven remedies; bathroom surgery; soaking in water; or seeking assistance from a faithhealer in the first instance. In Africa, delayed presentation, for whatever reason, is invariably associated with significant morbidity, loss of limb, or systemic infection, and death.
In conclusion, additional complications on existing diabetic foot disease are preventable and can be reduced through proper foot care and cost-effective educational programmes on prevention and management of diabetic foot complications, targeted at both healthcare providers and patients. For developing countries, this pragmatic approach is exemplified by The Step by Step Foot Program educational program that was first piloted and carried out in Tanzania and India and includes implementation of sustainable training programmes for health care professionals, focusing on the management of all aspects of the diabetic foot, and dissemination of information to other health care professionals and patients.

MS3.04

Everything You Need to Know About Biofilms (But Were Afraid to Ask)

Associate. Prof. Trine Rolighed Thomsen[1]
[1]Technological Institute and Aalborg University, Aarhus C, Denmark

Aim: 60% of all infections are estimated to be biofilm related and to cost more than 1 billion dollars per year in USA alone, emphasizing the importance of the field. The biofilm community, its spatial distribution and activity play an important role in the prolongation of treatment and healing of chronic infections and is clearly different from acute infections by planktonic microorganisms. The purpose of this presentation is to describe different aspects and challenges of biofilms. How to improve sampling, diagnosis and treatment of chronic infections, especially considering the biofilm issue, will be presented.
Methods: Systematic and optimized sampling of various specimen types from patients with chronic biofilm infections was performed. Extended culture and a panel of molecular biological tools were applied on the different types of specimens for improved diagno-

sis. For further investigation of the microbial pathogenesis, in situ transcriptomics and metabolomics were applied.
Results: In chronic biofilm related infections, molecular techniques detected a larger diversity of microorganisms than culture based methods in several patients. A heterogeneous distribution of bacteria in various specimens from the same patient was evident. In non healing wounds, multiple biopsies from the same ulcer showed large differences in the abundance of fx P. aeruginosa and S. aureus at different locations. Transcriptomic and metabolomic analyses indicated the important virulence genes and nutrient acquisition mechanisms of S. aureus in vivo and showed a capability to survive under severe oxygen limitation.
Conclusion: Our studies showed that improved diagnosis and understanding of chronic biofilm related infections required multiple specimen types, standardized sampling, extended culture and molecular biological analysis. The use of a well-designed diagnostic algorithms, big data and personalized diagnosis and treatment has large potentials and will be discussed during the presentation.

MS3.05

Self-Administered Outpatient Parenteral Antibiotic Therapy (OPAT) for Diabetic Foot Infections

Prof. Kavita Bhavan[1]
[1]UT Southwestern Medical Center, Dallas, United States of America

Abstract not available.

MS4.01

Wound Healing in Diabetes: Basic Principles

Prof. Dr. Frances Game[1]
[1]University Hospitals of Derby And Burton Nhs Foundation Trust, Derby, United Kingdom

The management of foot disease in diabetes remains a major financial and therapeutic challenge throughout the world. Whilst the most feared complication for patients with foot disease is amputation of part of the foot or leg, the majority of the costs to health care systems are incurred in the management of ulcers. Even though there is good evidence of the benefit of providing integrated multidisciplinary care, the outcome of chronic ulcers of the foot in people with diabetes is not good with only about half reported to heal within 3 months and two-thirds within 6 months. There is an urgent need therefore for treatment strategies to enhance healing, and for good evidence of effectiveness and cost effectiveness of those already available to clinicians. During this session we will explore basic principles of wound healing, with particular reference to pathologies that may be responsible for prolonging healing in people with diabetes. By examining these pathologies we can then look at the rationale for existing management strategies and the potential for future therapeutic targets.

MS4.02

Wound Healing: an Update on the Latest Trials

Dr. Robert Frykberg[1]
[1]Diabetic Foot Consultants, Fountain Hills, Az, United States

Aim: To critically discuss several recent wound healing trials
Methods: Literature review and ClinicalTrials.gov
Results: Several trials and designs will be explained, including strengths and weaknesses
Conclusions: Overall, Diabetic Foot Wound Healing studies suffer from methodological design weaknesses including lack of double blinding or inhomogeneous patients and outcomes. However, we can be encouraged that such studies have improved over the years.

MS4.03

Advanced Surgical Techniques to Heal a Wound

Prof. Dr. John Steinberg[1]
[1]Georgetown University School Of Medicine, Washington, United States

This session will provide an overview of the functional limb salvage principles utilized by our team at Georgetown University Hospital in Washington DC. This will review the multidisciplinary approach and surgical aspects of wound healing, biomechanical correction, and limb salvage. Videos will be used to illustrate surgical procedures commonly used by our team to include tendon lengthening and transmetatarsal amputation.

MS4.04

Stem Cells to Improve Wound Healing

Prof. Franco Bassetto[1]
[1]Clinic of Plastic and Reconstructive Surgery, Department of Neurosciences, University of Padova, Padova, Italy

In order to impreve wound healing stem cells have been considered as a great promise. In these years our experience brought us to believe that adipose derived stem cells can be the ideal stem cell because they are autologous, abundant and easy to accessible. The adipose derived stem cells have multiple effects: 1) adipogenic differentiation; 2) neoangiogenesis; 3) modulation of immunoresponses and inflammation; 4) modulation of granulation tissue and fibrosis; 5) antioxidant effect; 6) secretion of lymphangiogenic factors; 7) recruitment of systemic endogenous stem cells to the area of injury. Here we present our clinical experience.

MS4.05

Optimising Peri-Operative Glycaemic Management for the Diabetic Foot

Prof Ketan Dhatariya[1,2]
[1]Norfolk And Norwich University Hospitals NHS Foundation Trust, Norwich, United Kingdom, [2]Norwich Medical School, Norwich, United Kingdom

There are now a large number of data to show that poor peri-operative glycaemic control - glucose or HbA1c - is associated with post operative harm. These harms can be of any sort, including pneumonia, wound infection, sepsis, urinary tract infections, acute coronary syndrome, acute renal failure and death.
These risks are significantly higher if pre-operative hyperglycaemia is not identified early, and is associated with most harm, if the hyperglycaemia persists post operatively. Thus identifying who is at risk and communicating this between all members of the team along the peri-operative patient journey is paramount.
This talk will summarise some of the available data showing the evidence that poor peri-operative glycaemic control is associated with harm - for all types of surgery, not just for the diabetic foot. The talk will also touch on the difficulties encountered by teams trying t address this subject. It will also go through some of the newest guidance available for how to manage this situation - from an organisational point of view as well as for the individual with diabetes. Most importantly it will help you, the person looking after the individual with diabetes, improve the care they receive during their peri-operative journey

The peri-operative journey

MS4.06

Which Treatments in Everyday Clinical Practice are Useless?

Prof. Jan Apelqvist[1]
[1]Skåne University Hospital, Malmö, Sweden

Ongoing controversy surrounds the value of various approaches to wound management and care. The question is: which interventions, technologies and dressing materials are the best from those available ?
There is fundamental confusion over the best way to evaluate the effectiveness of interventions in this complex patient population. This is illustrated by reviews of the value of various treatment strategies for non-healing wounds, which have highlighted methodological inconsistencies in primary research. This situation is confounded by differences in the advice given by regulatory and reimbursement bodies in various countries regarding both study design and the ways in which results are interpreted.
The nature and extent of the problem for wound management is different from various pespective : clinical perspective vs the policy maker and health-care system perspectives , an industry perspective ,the care givers perspective and patients perspective.
From the clinical research perspective there is a need to be aware of the strengths and limitations of
different study designs if they are to effectively evaluate which health-care practices are worth considering for different patients in different health contexts. Key issues are, for example, use of a study protocol, problems related to heterogeneity of the study population and underlying conditions.
From an industry perspective, external evidence needs are set by the requirements of national regulatory and reimbursement authorities, and other payers. When focusing on payment or reimbursement for a new product, the key issue will often be budgetary impact and/or cost-effectiveness, rather than healing
The question for wound care practitioners is: which interventions, technologies and dressing materials are the best from the point of view of a single patient or group of patients, where the primary focus is healing and the absence of complications in the environment in which the patient and the physician/ care givers are meeting. From the patient perspective additional factors above the condition of the wound is added such as priorities such as living condition and quality of life issues. It is essential in that perspective to identify which treatment does not meet expectations in a particular patient , wound or environment.

MS5.01

The Diabetic Foot Attack

Prof. Alberto Piaggesi[1]
[1]University of Pisa, Pisa, Italy

The Diabetic Foot Syndrome (DFS) is a life-long pathology which affects 25% of diabetic patients.
DFS has different clinical patterns, all part of a chronic worsening process which, for its severity, tendency to relapse and mortality rates, has been compared to cancer.
The typical clinical course of DFS is characterized by long intervals of chronic manifestation of the disease (i.e. deformities, ulceration, oedema, mild ischemia) alternated with acute episodes (i.e. infection, critical ischaemia, acute inflammation) which dramatically change the scenario, suddenly trasforming a chronic medical disease into an iperacute critical condition; these episodes have recently been defined Diabetic Foot Attacks (DFAs).
DFAs increase the velocity of progression of the patology, and expose the patient to a consistent increase in the risk for major amputaion (MA) and even death.
In general, even after they have been treated, DFAs leave the patient in a condition which is worse than the previous one and that represents a further step in the evolution of DFS with an increased risk for MA and recurrences.
DFAs need to be promptly and adequately treated, and their treatment implies a substantial increase in the allocation of resources compared to the chronic phases of DFS, involving the multidisciplinary team as a whole.
It has been demonstrated that, when promptly and aggressively treated, DFAs have a better outcome compared to conventional

treatment; unfortunately, due to the presence of neuropathy, DFAs are often sudden and subtle in their presentation and most likely underestimated by the patients and by their caregivers, leading to a delayed referral to the specialized team.
This is why the awareness and preventative education of the patients and caregivers is so important in avoiding the underestimation of DFAs and their late referral, reducing the risk of negative outcomes: the pivotal experiences in some European Countries have produced positive data in this perspective.
We look forward to a novel approach to DFAs that will put them on the same level of the other medical and surgical emergencies, like the heart attack or the acute abdomen, with dedicated and precise referral protocols and procedures, in a time-dependent network.

MS5.02

Internal Pedal Amputations and Two-Stage Procedures for the Infected Diabetic Foot

Dr. Armin Koller[1]
[1]Mathias-Spital and Jakobi Hospital, Hamburg, Germany

Abstract not available.

MS5.03

Level of Amputation

Dr. Robert Frykberg[1]
[1]Diabetic Foot Consultants, Fountain Hills, Az, United States

Aim: A discussion of limb-salvaging partial foot amputations that allow for pedal weight bearing.
Methods: A review of techniques successfully used by the author over forty years with literature review.
Results: Clinically illustrated discussion of useful foot-sparing amputations for diabetic foot gangrene.
Conclusions: Knowledge of various successful amputation levels in the diabetic foot can avoid unnecessary limb loss

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MS5.04

Debridement, Drainage and Biofilm Management

Dr. Klaus Kirketerp-Møller[1,2]
[1]Copenhagen Wound Healing Center, Bispebjerg University Hospital, Copenhagen Nv, Denmark, [2]Steno Diabetes Center Copenhagen, Copenhagen, Denmark

In daily practice, debridement and biofilm management and drainage are considered an essential part of the wound treatment. Biofilm management is incorporated in many guidelines, but is this term valid and is it supported by science? The knowledge of bacterial biofilm is origins from the laboratory doing in-vitro experiments. Biofilms are obligatory findings in chronic wounds, yet the impact on healing is debated. This lecture will present a different view on bacterial biofilms and claim that standard debridement techniques may be the ultimate biofilm management.

MS5.05

The Burden of Lower Extremity Amputation

Prof. Dane Wukich[1]
[1]UT Southwestern Medical Center, Dallas, United States of America

Abstract not available.

MS6.01

D-Foot International: Our Global Mission and Clinical Implementation

Dr. Kristien van Acker[1]
[1]D-Foot International, Edegem, Belgium, 2Diabetologist in Centre de Santé des Fagnes, Chimay, Belgium

D-Foot International is an international charity and a global network of diabetic foot care experts. Our goal is to reduce amputations caused by complications of diabetes. We have nearly 200 national representatives from more than 150 countries working together to raise the global profile of diabetic foot prevention and care, standardise treatment guidelines and offer training and development opportunities for podiatrists and other foot care professionals.

In this session we want to share some news about our projects.

Our Train-the-Foot-Trainer project took the momentum we built with the Step-by-Step programme and transformed it into an advanced course that has trained 300 experts in Latin America, the Caribbean, the Western Pacific and French-speaking Africa. The training given to these experts is then leveraged into continuing professional development training at the local level. In Latin America, for example, 4000 additional healthcare providers participated in the three years following the Train-the-Foot-Trainer course. In 2019, we will give the course in the Middle East.

D-Foot works hard to identify care gaps and work together with partners (WHO, IFP-FIP, ICRC) to find solutions. Our POINT document, created in 2018, outlines our vision to bring podiatry to countries where there are currently no practitioners.

The FLIRT-Bird Project (Footwear in Low Income Regions all Together) is dedicated to developing and distributing low-cost, long-lasting, fit-for-purpose footwear for diabetic foot patients in low-resource countries. 80% of people with diabetic foot ulcers have no access to even basic foot care, so even something as simple as getting the footwear to the patients remains a challenge.

We will also talk about our e-learning modules, our DIAFI tool for data collection and our newsletter Footnote.

www.d-foot.org

MS6.02

Diabetic Footwear for Low Resource Countries; the "FLIRT-bird" Project

Associate Professor Gulapar Srisawasdi[1]
[1]Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand

When a patient has problems with their feet, they have problems with mobility. In low-resource countries this is especially difficult, as it means patients can't work, take care of their home or look after their children. Treatment for a non-healing ulcer can cost the equivalent of nearly six years' wages. Preventive care is not only the most cost-effective way of managing diabetic foot, but also the best strategy for minimising the knock-on effects of immobility on resource-poor patients.

D-Foot International is addressing this problem with our FLIRT (Footwear for Low Income Regions all Together) programme, which aims to provide low-cost, long-lasting, fit-for-purpose footwear to diabetes patients all over the world regardless of ability to pay.

Research has made clear that protective shoes and orthoses prevent lower-limb amputations. It is a simple fix, but one that is out of reach for most patients in middle and lower income countries because of lack of knowledge, funds, materials and basic resources like electricity. Our FLIRT programme aims to identify standard specifications for therapeutic footwear, train local people to build the shoes using local materials, support manufacture by providing technology to improve systems, and raise awareness in the local area about the positive impact therapeutic footwear has on quality of life.

The FLIRT concept of low-cost, long-lasting, fit-for-purpose footwear was adapted by the Pakistan team and, with the support of the World Diabetes Foundation, transformed into the local initiative "Footwear for Every Diabetic."

Action plans need to be customised to remain sustainable system in each country. To this end, D-Foot works with organisations such as WHO, ISPO, ICRC, our corporate partners and local support. With proper footwear, our patients will be free to live their lives like a flirt bird.

MS6.03

Global Alignment with Podiatry for All: The POINT Project

Dr. Neil Baker[1]
[1]Muzaini Vascular And Diabetic Foot Clinic, Jabriya, Kuwait, 2D.Foot International

Foot complications are the most common of all diabetes-related long-term pathologies. The most serious is foot ulceration, which frequently leads to lower-limb amputations. Identification, prevention and effective management rely on clear guidelines and well-structured multi-disciplinary teamwork. Podiatry skills are central to this process but currently not available in 90% of countries. Where there are trained podiatrists, there is a wide variance in scope of practice, competencies and training. Even the name of the profession itself varies widely from country to country. While D-Foot International was delivering the Step-by-Step and Train-the-Foot-Trainer programmes it became clear that the most common problem was a lack of trained foot professionals.
To address this, using an existing published competency framework the expert group, analysed, modified and with consensus developed the POINT* (POdiatry for INTernational diabetic foot teams) Project in collaboration with the International Federation of Podiatrists (FIP-IFP).
The resultant POINT documents, launched in the Spring of 2018, identify the skills needed to provide podiatry care across four levels, basic to expert. POINT supports clinicians globally by:

- acting as a benchmarking tool for existing teams;
- helping clinicians highlight the podiatry skills needed to establish a diabetic foot team;
- giving national and local decision makers the information, they need to identify which skills podiatrists can offer; and
- standardising the term podiatry both to address the current confusion and to unite and promote the specialty.

The next step is to work together to ensure consistent delivery, with the aim of further improving patient treatment outcomes and quality of life.
The Point documents provide a tool to benchmark, develop and initiate diabetes podiatry worldwide.
*The Diabetic Foot Journal 2018; 21(2):84-88
*J Wound Care 2018; 27(sup 11):1-32

MS6.04

Train the Foot Trainer Courses in Europe, Latin America and Western Pacific

Prof. Nalini Campillo[1]
[1]Plaza De La Salud General Hospital, Santo Domingo, Dominican Republic Nalini Campillo Vilorio, MD, Diabetologist.
Plaza de la Salud General Hospital, Santo Domingo, Dominican Republic

In 2003, D-Foot International develop Step-by-Step, an in-country diabetic foot training course with the help of the World Diabetes

Foundation. By 2012, the programme had evolved into a regional Train-the Foot-Trainer course, which gave trainers support in designing course structure, delivery methods and developing evaluation skills.
To date, we have supported Train-the-Foot-Trainer courses in Latin America (2012), the Caribbean (2013), Central and Eastern Europe (2015), Western Pacific (2017) and French-speaking Africa (2018). In November 2019, we will offer the programme in the Middle East.
The goals of the Train-the-Foot-Trainer courses are:

- integratingtheInternationalConsensusGuidanceDocumentontheDiabeticFootand other guidelines into local foot care programmes;
- buildingalocaliseddiabeticfootcareframeworkthatincludessustainabilityof service, continuing education, service development and referral pathways, local and regional networks and study/working groups;
- providingsupportmechanismforlocalchampionsandencouragingthedevelopment of further national training programmes; and
- collectingdatatodrivechange,supportresearchandmeasuretheimpactthe training has had on local service provision and clinical outcomes.

As of 2018, we have trained over 300 trainers. This Train-the-Foot-Trainer format has been immensely successful and we now have the challenge of finding the money and manpower needed to scale delivery.
Participants leave the 5-day course with a clear national and regional implementation plan based on their specific treatment barriers, needs and priorities. They also have access to three years of coaching with D-Foot experts.This support further motivates trainers to develop more detailed training implementation plans to improve diabetic foot treatment outcomes in their local area.
In this presentation, we will present some of the data we have collected over the last seven years and lay out our D-Foot Train-the-Foot-Trainer vision for the coming years.

MS7.01

Prioritization in PAD treatment in Low- and Middle- Income Countries

Prof. Gerry Fowkes[1]
[1]*University of Edinburgh, Edinburgh, United Kingdom*

AIM. Lower extremity peripheral artery disease (PAD) is increasing in prevalence in low- and middle-income countries creating a large health care burden. Clinical management may require substantial resources but little consideration has been given to which treatments are appropriate for less advantaged countries. The aim of this review was to prioritise treatments for use in such settings.
METHODS. A systematic appraisal was conducted of published data on the costs and effectiveness of PAD treatments used commonly in high-income countries. An international consensus panel reviewed the information and proposed a hierarchy of treatments relevant to low- and middle-income countries.
RESULTS. Pharmacotherapy for intermittent claudication was found to be expensive and improve walking distance by a modest amount. Exercise and endovascular therapies were more effective and exercise the most cost-effective. For critical limb ischaemia, bypass surgery and endovascular therapy, which are both resource intensive, resulted in similar rates of amputation-free survival. Substantial reductions in cardiovascular events occurred with use of low cost drugs (statins, ACE inhibitors, anti-platelets) and smoking cessation.
CONCLUSIONS. The panel concluded that, in low- and middle-income countries, cardiovascular prevention is a top priority, whereas a lower priority should be given to pharmacotherapy for leg symptoms and revascularisation, except in countries with established vascular units.

MS7.02

Advanced Endovascular Options

Prof. Roberto Gandini[1]
[1]*University of Rome Tor Vergata, Rome, Italy*

Interventional Radiologists play a crucial role in the management of diabetic patients, treating Peripheral Arterial Disease (PAD) and preventing diabetic foot amputation.
Indeed, vascular interventions are related with better clinical outcomes, reduced patient mortality, morbidity, improved quality of life and patient satisfaction.
If on the one hand, over the last decades, Diabetes Mellitus (DM) prevalence increased worldwide, on the other hand the evolution of devices allow IRs to face new challenges.
The PAD of diabetic patients is not usually a short femoro-popliteal disease but otherwise it is related with long complex calcific lesions, involving most of the times the below-the-knee and below-the-ankle vessels.
Actually these lesions can be treated thanks to improved operator'skills, new devices, with different approaches, providing better outcomes.
Among advanced endovascular options, subintimal angioplasty, first described by Bolia et al., can be now optimized by smart re-entry devices.
If in the past long CTO were considered as an exclusion criteria for an endovascular approach, now newer Atherectomy devices represent an effective solution to debulk atherosclerotic plaque from diseased arteries.
Even simple angioplasty and stenting has been improved by the advent of new drug-eluting technologies, like drug-eluting balloons, and drug-coated stents, increasing long term outcomes and reducing in-stent restenosis.
Anyway, when wires and catheters fail to cross highly calcified vessels, micropuncture set and new wires have evolved to obtain retrograde access of the pedal, tarsal or calf collateral vessels to perform the SAFARI technique: the Subintimal arterial flossing with antegrade-retrograde intervention (SAFARI) for subintimal recanalization of chronic critical limb ischemia.
New advanced endovascular techniques are also available to treat intraprocedural complications. Indeed, the wider spectrum of PAD being treated by IRs is necessarily related with a higher percentage of plaque embolism during procedure that can be rapidly managed with thromboaspiration devices.
Finally, new technologies allow to monitor real-time and continuously diabetic foot TCpO2, assessing indirectly microvascular blood flow, and providing Patients a tailored follow-up.

MS7.03

Advanced Open Surgical Techniques

Prof. Dr. Kim Houlind[1]
[1]University of Southern Denmark, Kolding, Denmark

The paper reviews infrequently performed surgical techniques for preservation of the diabetic foot.
Distal bypass surgery performed to perigeniculate arteries and to an isolated ”blind” popliteal segment with visible collaterals can be performed with limb salvage rates close to what can be achieved with standard bypass to crural arteries. This is also the case when performing bypass to the dorsal pedal artery. Bypass to the medial or lateral plantar artery or to the lateral tarsal artery is associated with a relatively high rate of early occlusion, but in the patients who have persistently open grafts, limb salvage is common. The use of an arteriovenous fistula as an adjunct to distal bypass surgery does not seem to improve prognosis. Venous arterialization, either creating retrograde perfusion of the superficial or of the deep veins of the foot has been successful in many cases although it is difficult to predict which patients will benefit.
Reconstructive surgery is often performed in a multidisciplinary team including plastic surgeons. Use of split skin grafts is a relatively minor procedure that may reduce healing time in patients with diabetic wounds. In patients with need of more extensive cover of defects, the transplant of muscular or fasciocutaneous free flaps has provided good results in the few centers that have applied this technique.
A majority of the described techniques can be implemented in most vascular centers and they should be considered in complicated cases when standard methods of revascularization and reconstruction do not suffice.

MS7.04

When to Apply Stem Cells in Peripheral Artery Disease

Prof. Dr. Sigrid Nikol1
1Asklepios Klinik St. Georg, Angiology, Hamburg, Germany

Amputation rates and cardiovascular events including death is high in critical limb ischemia, frequently as a complication of diabetes. The amputation rate in diabetics is far higher compared to non-diabetics. Particularly, in distal disease options for endovascular or surgical revascularisations are limited requiring alternatives. Besides diabetics, this is also true for patients with Burger’s disease.
Another group of patients seeking for regenerative therapy are claudicants with very long occlusions and short walking distances in whom long bypasses below the knee are not indicated, yet, walking training not effective.
Angiogenic gene therapy and autologous cell therapy have failed for various reasons. Allogenic cell therapy is promising, however, still in the phase of clinical evaluation in randomised trials.

MS7.05

Patient Selection Based on Micro-Circulation Functionality

Prof. Dr. Jim Reekers[1]
[1]Academic Medical Center, University Of Amsterdam, Amsterdam, The Netherlands

Abstract not available.

MS8.01

Supporting Adherence and Relieving the Burden: What Can a Psychologist Offer?

Prof. Jeffrey Gonzalez[1]
[1]Yeshiva University and Albert Einstein College of Medicine, New York, United States

Aim: This lecture will provide a psychologist’s perspective on the goals of supporting patient adherence and disease self-management and reducing the burdens of diabetic foot and its treatment on emotional well-being and quality of life.
Methods: A review of selected qualitative, quantitive and clinical trials psychosocial and behavioral science research.
Results: Treatment recommendations increasingly emphasize the importance of increased attention to psychosocial aspects of care and patient-reported outcomes. Research on the measurement of treatment adherence and the development and evaluation of interventions to improve disease self-management and reduce risk for poor health outcomes provides a useful guide for improvements in evidence-based practice for psychosocial care of individuals living with diabetic foot complications. However, important gaps remain in diabetes care in general and in the care of individuals living with diabetic foot complications in particular.
Conclusions: Psychologists can make research and clinical contributions to improving the clinical outcomes of treatment and to ensuring that treatment prioritizes patient-centered outcomes in diabetic foot care. Greater interdisciplinary collaboration is needed to advance these goals.

MS8.02

Shared Decision-making – Relevant to the Management of the Diabetic Foot?

Prof. Frank J. Snoek[1]
[1]Amsterdam UMC, Amsterdam, the Netherlands

Abstract not available.

MS8.03

The Impact of What I Do on the Quality of Life of My Patients

Prof. Dane Wukich[1]
[1]UT Southwestern Medical Center, Dallas, United States of America

Abstract not available.

MS8.04

How Good Communication Can Increase Therapy Compliance and Improve Quality of Life

Dr. Kristien van Acker[1]
[1]D-Foot International, Edegem, Belgium, [2]Diabetologist, Centre de Santé des Fagnes, Chimay, Belgium

Communication between doctor and patient is a central clinical function that cannot be delegated. Therapeutic communication, as outlined by WHO, promotes two-way interaction in which the healthcare professional and the patient contribute to the dialogue on equal footing.

As healthcare professionals, we must try to walk into our patients' shoes. We need to make sure we really understand devastating impact nerve damage has on day-to-day life as well as the cumulative effect of constantly worrying about losing a limb.

Let's dare to look in the mirror. Do we take enough time to listen to patient concerns instead of watching the clock? Are we sure our patients understand their diagnosis and are able to remember and carry out our instructions? Do we show enough warmth and friendliness? Perhaps the blame for low patient compliance also lies at our feet.

This presentation looks at a few basic communication techniques that, when incorporated into patient consults, are likely yield an immediate improvement in how patients feel about conversations with their doctor.

We'll look at the factors that affect compliance - daily life situation, background, patient anxiety and other issue that affect motivation - and discuss improving decision-making processes and developing other simple communication tools that take all these factors into consideration.

Hippocrates, the Father of Medicine said: "Cure sometimes, treat often, comfort always." These ancient words still hold true. While we are often tempted to treat first and talk later, more and more research is showing that the optimal doctor-patient relationship is based on dignity, respect and communication, and encourages active patient participation in care decisions. The cost is perhaps a bit more time, but the result is a massive increase in quality of life.

MS8.05

Diabetes and Depression: an Unhappy Marriage

Prof. Frans Pouwer[1]
[1]University of Southern Denmark, Odense, Denmark, 2STENO Diabetes Center Odense, Odense, Denmark, 3Deakin University, Geelong, Australia

Aim: The aim of this invited lecture is to give an overview of the research into diabetes and depression
Methods: Narrative review
Results: Depression is a burdensome and common co-morbid health problem in people with type 1 or type 2 diabetes. Depression has a strong negative impact on quality of life, not only in those who are depressed, depression also impacts their family members. Important risk factors that explain why depression is more common in people with diabetes are demanding self-care tasks and the diabetes complications, including neuropathic pain or discomfort, and diabetic foot problems (ulcer, amputated too, foot or limb) or cardiovascular disease. Meta-analyses of longitudinal studies have shown that the associations between diabetes and depression are bi-directional, with diabetes increasing the risk of depression and vice versa. Moreover, depression in people with diabetes is associated with less favourable health outcomes. Systematic reviews have concluded that depression in diabetes is associated with less optimal self-care behaviours, higher HbA1c levels and a higher risk to develop diabetes complications. Depression in diabetes is also associated with higher mortality rates in longitudinal studies. Effective treatments are available. Results from various randomised controlled trials have shown that depression in diabetes can for example be treated with cognitive behavioural therapy (CBT), mindfulness-based cognitive therapy, web-based CBT or anti-depressant medication. An important clinical barrier is the fact that depression is often overlooked in busy clinics. International guidelines therefore recommend the use of short screening or monitoring questionnaires, which should be embedded in a stepped care or a collaborative care approach for depression (which appeared to be cost effective). Whether intensive and successful treatment of depression prevents diabetes complications or lowers mortality rates is unclear.

Conclusions: It is important that a psychologist is a standard member of the diabetes team, as other psychological problems such as fear of hypoglycaemia, disturbed eating, disturbed sleep and needle phobia or blood phobia can hamper diabetes self-care and negatively impact quality of life. High quality studies should be conducted to test the effectiveness of new psychological interventions that could help people to cope with neuropathic pain and discomfort.

MS9.01

Everything a Clinician Needs to Know About Functional Anatomy of the Foot

Dr. Robert Frykberg[1]
[1]*Diabetic Foot Consultants, Fountain Hills, Az, United States*

Aim: To briefly discuss the biomechanics and functional anatomy of the diabetic foot for the non-specialist clinician.
Methods: Review of anatomy, literature, and clinical illustrations.
Results: Functional anatomy and pertinent Biomechanics of the Diabetic Foot with emphasis on pressure concentration are discussed. Simple methods to isolate such anatomical alterations also discussed.
Conclusions: The attendee will have a basic understanding of functional anatomy and biomechanics that can predispose to foot ulceration.

MS9.02

Foot Pressure: Measure for Measure

Dr. Sicco Bus[1]
[1]*Amsterdam UMC, location AMC, Amsterdam, The Netherlands*

Plantar pressure measurements have since long been used in research on the diabetic foot, mainly to assess risk for diabetic foot ulcers and effect of treatment in healing and prevention of foot ulcers. Since the early 1980's, plantar pressure measurements have been related to the important component of offloading, as a means to heal and prevent foot ulcers. While pressure measurements have been around for a while, only recently they have gained interest from the clinical community. This is probably influenced by a significant recent improvement in our understanding of the role of plantar pressure reduction and the value of pressure measurements in the prevention of foot ulcers, by the completion of two multicentre trials on footwear efficacy and by an implementation project on the use of in-shoe plantar pressure measurement in clinical footwear practice. These trials show that barefoot or in-shoe plantar pressure measurements can improve the footwear of high-risk patients with diabetes, and can lead to better clinical outcomes in prevention. The implementation projects show that these methods of pressure measurement are becoming more widely integrated in diabetic foot practice and the 2015 and 2019 IWGDF guidelines on the diabetic foot report in detail on the value and use of pressure measurement in the prevention and healing of foot ulcers in diabetes. Few new innovations in plantar pressure measurements have been introduced. Most innovation occurs in taking the plantar pressure measurement out of the lab for continuous pressure monitoring and as feedback tool to identify possible harmful above-threshold pressures for the patient. Commercial pressure measurement systems still lack the option to measure shear, while we think this is an important factor in ulcer development. The lecture will discuss the current state of art in plantar pressure .

MS9.03

Shoes and Offloading in Low-Income Countries

Prof. Vijay Viswanathan[1]
[1]*M V Hospital for Diabetes, Chennai, India*

Aim : Providing shoes and offloading in Low Income countries
Methods: Patients who have Diabetic Foot infection and who underwent a wound debridement were provided with different types of offloading devices like TCC ,posterior cast and pre fabricated offloading devices
Results: TCC could not be used in many patients as they had infected wounds requiring frequent wound dressing.Posterior cast was found to be an ideal way to offload the foot with the wound as the cast could be taken off and dressing done .The posterior cast was strapped to the foot with a roller bandage to prevent the patients from removing them. Pre fabricated offloading devices were not affordable to many patients as they were imported and expensive
Conclusions :TCC is the most effective way to offload the foot when infection was not present and frequent wound dressing was not required.Posterior cast was effective and affordable to most patients in the developing world.

MS9.04

Mobility Advice to Help Prevent Re-Ulceration

Dr. Michael Mueller[1]
[1]*Washington University School of Medicine In St Louis, St Louis, United States*

Current guidelines are silent on how best to resume walking following a foot ulcer and subsequent healing. The objectives of this talk will be to review the patient's prognosis following ulcer healing for ulcer recurrence and mortality; general activity levels of this population; effect of physical activity and exercise on selected foot related outcomes; and suggest advice to progress weight-bearing activities following diabetic foot wound healing.

A diabetic foot ulcer may be likened to "the canary in the mineshaft", an indicator of grim things to come. Indeed, rates of ulcer recurrence and mortality are high and activity is low following a diabetic foot wound. Medical and rehabilitation approaches have emphasized protection of the insensitive, fragile foot with the hope to prevent subsequent harm to the foot and person. In particular, the 1 to 2 months following wound unloading and "healing" have the greatest risk for ulcer recurrence. During this time, the foot should be carefully protected and activity slowly progressed. While early protection should be emphasized, a growing body of evidence suggests that over-protection of the foot and limited walking can be harmful, presumably because of the negative effects of prolonged immobility and stress protection. Multiple studies, and recent reviews (1-3) report the ability of exercise and walking to have a positive effect on various diabetic foot outcomes, including the num-

ber of steps taken without additional harm. Much less is known about how an ulcerated foot can resume walking after the wound is healed. This talk will integrate available guidelines, evidence, and precautions to suggest advice on how best to resume and progress walking in this population at high risk for ulcer recurrence (3).
Funding: National Center of Medical Rehabilitation Research, National Institutes of Health.
References:
1. LeMaster JW, et al, Effect of weight-bearing activity on foot ulcer incidence: Feet First RCT. Physical Therapy, 2008
2. Matos M, et al, Physical activity and exercise on diabetic foot related outcomes: a systematic review. Diabetes Research and Clinical Practice, 2018
3. Kluding PM, et al, Physical Training and Activity in People with DPN: Paradigm Shift. Physical Therapy, 2017

MS9.05

Strategies to Improve the Consequences of Diabetic Neuropathy for the Lower Limb

Prof. Neil D. Reeves[1]
[1]Research Centre for Musculoskeletal Science & Sports Medicine, Manchester Metropolitan University, Manchester, United Kingdom

Diabetic neuropathy is associated with changes to gait and foot loading that serve to increase unsteadiness, heighten the risk of falls and increase the likelihood of developing a diabetic foot ulcer. Some aspects of altered gait have been shown to be evident even before the onset of significant diabetic neuropathy, whereas many other aspects such as marked unsteadiness, are either only present, or much more pronounced with diabetic neuropathy. Diabetic neuropathy is a major risk factor for diabetic foot ulceration and the complete loss of sensation removes the patient's capacity to self-adjust their gait to modify foot loading, requiring innovative strategies to help prevent ulceration.

This presentation will describe a number of gait-related studies conducted to investigate the influence of diabetes and diabetic neuropathy on lower limb biomechanics, foot function and unsteadiness. It will also explore some recent developments to address the consequences of diabetic neuropathy, including exercise and visual gaze interventions to address gait and unsteadiness. The presentation will also describe the use of smart insole technology, measuring plantar pressure throughout daily life to provide pressure feedback to the patient and allow them to modify foot loading with the aim of reducing foot ulcer risk.

Gait studies have shown how diabetic neuropathy is associated with altered lower limb loading compared to people with diabetes and those with diabetes but without neuropathy. The major muscles groups of the lower limbs have been shown to develop lower forces as part of a strategy to cope with the high demands of daily activities and compensate for muscle weakness with diabetic neuropathy. Novel mechanisms have been uncovered to help explain how people with diabetic neuropathy alter these demands during gait. Altered neuromuscular function during everyday activities contributes to gait impairments and serves as a target for appropriate interventions. Exercise interventions have shown promise for improving gait and some of the contributing factors underpinning unsteadiness in patients with diabetic neuropathy. Smart insole technology has been shown to reduce the risk of plantar ulceration in a high-risk cohort of patients.

MS10.01

The National Diabetes Foot Care Audit of England and Wales

Prof. William Jeffcoate[1]
[1]Nottingham University Hospitals Trust, Nottingham, United Kingdom

The National Diabetes Foot Care Audit of England and Wales (NDFA) has analysed data on almost 40,000 episodes of DFU presenting between July 2014 and March 2018 (www.digital.nhs.uk/pubs/ndfa1418). The report shows highly significant associations between the time from first presentation to first expert assessment and ulcer severity when assessed, as well as highly significant associations between both elapsed time and ulcer severity and each of four clinical outcomes: healing (being alive and ulcer-free) by 12 weeks and the incidences of foot-related hospital admission, major amputation and death within 6 months. There isevidence of widespread variation in outcomes between different localities as well as links between measures of outcome and the structure of foot care services. The data have also been used to explore the clinical details of both patient and ulcer which link to the chosen outcomes and to establish models to use for case-mix adjustment of populations.

Participation in audit is an essential part of routine practice and is key to improving the outcomes of clinical care.

MS10.02

Venous Arterialisation

Drs. Daniël van den Heuvel[1]
[1]St. Antonius Ziekenhuis, Nieuwegein, The Netherlands

Abstract not available.

MS10.03

The Role of MicroRNAs in Diabetic Wound Healing and Microvascular Disease

Dr. Mark Feinberg[1]
[1]Brigham & Women's Hospital/ Harvard Medical School, Boston, United States

Diabetic wound healing is an incompletely understood pathophysiological state. It comprises a range of potentially devastating and common complications of diabetes mellitus (DM) leading to intractable infections, lower extremity amputations, and associated cardiovascular morbidity and mortality. MicroRNAs (miRNAs) have emerged as important regulators in various physiological processes in health and disease through their ability to fine-tune cellular responses. Herein, we summarize the versatile roles of miRNAs implicated in diabetic wound healing in key stages including inflammation, angiogenesis, re-epithelialization, and remodeling. In this talk, I will highlight current evidence through which miRNAs exert control of gene expression and angiogenic signaling pathways in the reparative response that may provide opportunities for therapeutic intervention for this devastating disease state.

MS10.04

Bone Marrow as a Target and Accomplice of Vascular Complications in Diabetes

Prof. Paolo Madeddu[1]
[1]*University of Bristol, Bristol, United Kingdom*

Diabetes mellitus is a systemic disease causing adverse processes and complication in many vital organs. The impact of diabetes and associated ischemic complications on the bone marrow has not been fully appreciated. An alteration of bone marrow derived cell release, named mobilopathy, has been recently reported. This phenomenon is attributed to the failure to modulate the chemokine gradient across the bone marrow vasculature. In addition, microvascular disease and sensory neuropathy disturb stem cells and progenitor cells viability. The accumulation of ROS and activation of inflammatory mediators induce the accumulation of adipocytes, which in a vicious cycle stimulate mesenchymal cells to differentiate in additional adipocytes. Progenitor cells in the circulation of complicated diabetic patients show a distinct microRNA profiling which can negatively influence the vasculature upon homing to peripheral tissues. As a consequence, a normal homeostatic mechanism is converted in an adverse response, resulting in worsened cardiovascular outcome. In line with this, the migration of CD34 progenitor cells correlated with a higher risk of cardiovascular mortality in a cohort of diabetic patients with limb ischemia at 6 year follow up after revascularization.

MS10.05

Gazing at the Foot Through a Futuroscope

Prof. David Armstrong[1]
[1]*University of Southern California, Los Angeles, 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 blurl the line between consumer electronics and medical devices whether stationed in the home, the clinic, and on (or in) the patient.

MS11.01

Are there differences in Outcomes Between Diabetic and Non-Diabetic Patients with Chronic Limb-threatening Ischaemia?

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Approximately one half of patients presenting with a diabetic foot ulcer (DFU) have peripheral arterial disease (PAD). The presence of PAD is significantly associated with delayed wound healing and likelihood of major amputation.

The assessment of the severity of PAD in patients (diabetic and non-diabetic) presenting with foot ulceration and/or sepsis can be challenging for the managing clinician.
Recently, the major international vascular societies formed a collaboration to develop Global Guidelines for Chronic Limb-threatening Ischaemia (CLTI). The working group felt that the previously used diagnosis of critical limb ischaemia was inadequate to deal with the profile of patients (particularly those with diabetic foot disease) currently seen.
CLTI describes patients with either ischaemic rest pain of greater than 2 weeks duration, or tissue loss of the foot of at least 2 weeks duration in which there is a perfusion deficit which will potentially delay wound healing and/ or increase the risk of major amputation. This guideline supports the concept that there is a significant range of perfusion defects that will impair wound healing, depending on the stage of the foot pathology (as assessed by WIfI).

An assessment and management algorithm for patients with CLTI has been proposed (“PLAN”) in which the Patient’s risk is estimated, the Limb is staged (using WIfI), and the Anatomical pattern of arterial disease is assessed for potential endovascular or open surgical intervention.
Diabetic patients tend to have more distal arterial disease (particularly infrapopliteal occlusive disease) compared to smokers, who frequently present with aorto-iliac and femoral artery disease. In addition to the more challenging anatomy, diabetic patients more frequently have co-morbidities such as chronic kidney disease and ischaemic heart disease. Diabetic patients are also more likely to present with sepsis in addition to tissue loss.

The literature regarding the influence of diabetes on the outcomes of patients requiring revascularisation is conflicting. This is likely to be due to the level of adjustment for the co-morbidities which do have a major impact on wound healing and survival, rather than diabetes per se.

MS11.02

Treatment of Limb Ischemia in Diabetes

Dr. Edward Choke[1]
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Abstract not available.

MS11.03

How to Predict Outcome in an Ischemic Diabetic Foot Ulcer

Prof. Robert Hinchliffe[1]
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The ischaemic diabetic foot ulcer comprises a heterogeneous group of pathologies. In some patients ischaemia or a severe perfusion deficit is the dominant factor that prevents ulcer healing, whilst in others a poor blood supply plays a peripheral role, being a mere bystander. Many aspects of a diabetic foot wound influence outcome, notably the presence of infection and the size or depth of a wound. In that regard classification systems such as WIFI are helpful. However, systemic factors such as severe co-morbidities and patient behaviour will also impact on the outcomes of ulcers. To date there have been sparse data on the overall factors that predict outcome for individual patients and therefore the management of patients including the decision to perform revascularization is rather haphazard.

MS11.04

The WIFI Classification as a Tool for Predicting Benefit and Outcomes of Revascularization

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In response to changing patient demographics due to the global epidemic of diabetes and broadening treatment options for Chronic Limb Threatening Ischemia (CLTI), the Society for Vascular Surgery (2014) published a new classification system for threatened limbs, which blended previous classification systems intended for use only by vascular surgeons with those focused on diabetic foot ulcers. The system, WIfI, grades the components of wound, ischemia and foot infection because these factors drive the risk of amputation. Based on objectively grading these factors, 4 clinical stages are created. A free “SVS IPG” app is available to help individuals and limb salvage units calculate the WIfI grades and clinical stages.
Since its publication, WIfI has been widely adopted by many societies and is being used throughout the world. WIfI was intended to be applied much as TNM is for cancer. The initial WIfI clinical limb stage strongly correlates with intermediate and long-term prognosis. WIfI has been shown to predict the one-year risk of amputation in patients with CLTI as well as those with diabetic foot ulcer. There is a striking contrast between the one-year amputation rates for WIfI clinical stage 1 (< 3%) versus clinical stage 4 limbs (> 20%), even with revascularization. WIfI stages have also been shown to correlate with other important clinical end-points such as wound healing time, wound healing rate, major adverse limb events after revascularization, hospital length of stay and hospital cost.
Routine WIfI baseline assessment of the patient and after initial therapy, analogous to restaging patients with cancer, is a major step forward in the treatment of patients with CLTI and DFU. It should be noted that WIfI is a limb staging system. It incorporates aspects of the wound, modified from the International Working Group and the UT classifications. The infection component is based upon the IDSA classification. The ischemia component is graded objectively; in patients with diabetes, toe pressures and waveforms are preferred due to falsely elevated ABIs, but alternative measures of perfusion are also useful when available, including skin perfusion pressure, transcutaneous oxygen pressure and indocyanine green angiography.
It would potentially be a major step forward to mandate an assessment of all three of these major limb factors whenever evaluating patients with DFU and limb threat for the potential benefit of revascularization. Recent data compiled from 10 centers across the globe shows that specific WIfI stage subsets benefit greatly from revascularization. WIfI is a clinical impactful tool to be utilized by limb salvage centers as it allows stratification of amputation risk, predicts the need for revascularization and allows comparison of outcomes between centers and after alternative modes of treatment.

MS11.05

Hyperbaric Oxygen: Useless or Useful? A Battle

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Abstract not available.

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