DFSG2020
VIRTUAL

Diabetic Foot Study Group

of the EASD

16th Scientific Meeting

18 - 19 September 2020
Virtual meeting

Abstracts

		FRIDAY 18 SEPTEMBER 2020	
Time	**Abstract**	**Title**	**Speaker**
12:00		**Welcome speech**	DFSG Chairman Klaus Kirketerp-Møller
12:10-13:30		**Oral abstracts session 1: Biomechanics**	Moderator 1: Frances Game Moderator 2: Raju Ahluwalia
	O1	*Predictive values of Foot plantar pressure assessment in patients with rocker bottom defomity secondary to Charcot Neuroartrhopathy*	Mateo López Moral, Spain
	O2	*Association of foot biomechanics, weight-bearing activity and device adherence with ulcer development and ulcer healing in diabetes: a systematic review*	Chantal Hulshof, Netherlands
	O3	*Plantar pressures and adherence of indoor and regular custom-made footwear for people with diabetes at high risk of foot ulceration'*	Tessa Busch-Westbroek, Netherlands
	O4	*Can we reduce high foot pressures in patients at risk of DFU using daily monitoring through smart insole technology?*	Katie Chatwin, United Kingdom
	O5	*Plantar shear stress in foot ulcer pathomechanics: challenging the status quo*	Metin Yavuz, United States
	O6	*Predictors of therapeutic footwear adherence among people with diabetes*	Gustav Jarl, Sweden
13:45-14:45		**Oral abstracts session 2: Basic and clinical science, classification and epidemiology**	Moderator 1: José Luis Lázaro-Martínez Moderator 2: Roberto Anichini
	O8	*The association between plantar skin microcirculation and the indicators of Peripheral Arterial Disease in patients with Diabetes*	David Allan, United Kingdom
	O9	*Verification of Yearly Incidence of Foot Ulcers in Patients with Diabetes Mellitus at Diabetologic Centre and Recommendation of Preventive Measures (Foot Screening, Education and Monitoring) for At -Risk Diabetics in Clinical Practice*	Johana Venerová, Czech Republic
	O10	*Multivariable clinical prediction models for foot ulcer recurrence in high-risk people with diabetes*	Wouter aan de Stegge, Netherlands
	O11	*Midfoot amputations in diabetic patients: a tertiary referral hospital experience*	Andrea Michelli, Italy
	O12	*The enormous impact of Covid-19 in the diabetic foot, end stage renal failure patients*	Elizabeth Pendry, United Kingdom
15:00-15:30		**Paul Brand Award Presentation**	Moderator 1: Klaus Kirketerp-Møller Moderator 2: Nikolaos Papanas
	Paul Brand Award Oral	*Analysis of plantar pressure pattern after metatarsal head resection. Can plantar pressure predict reulceration?*	Marta García-Madrid Martín de Almagro, Spain
15:40-16:00		**Industry sponsored session: Mölnlycke**	
		Empowering patients to play a role in the care of diabetic foot ulcers	Paul Chadwick, United Kingdom
16:15-16:30		**Industry sponsored session: Söring**	
		Neuroischaemic DFU - Evidenced based recommendations for use of low-frequency contact ultrasound debridement (LFCUD)	José Luis Lázaro Martínez, Spain
16:40-17:10		**DFSG Prevention of the First Ulcer Study Group session**	Moderator 1: William Jeffcoate Moderator 2: Sicco Bus
		Welcome and introduction	Anna Trocha
			Jarmila Jirkovska, Czech Republic
			Daina Walton, United Kingdom
			Johan Røikjer, Denmark
			Elisabetta Iacopi, Italy
			Matilde Monteiro-Soares, Portugal
		SATURDAY 19 SEPTEMBER 2020	
	Abstract	**Title**	**Speaker**
10:00-10:45		**Industry sponsored session: URGO: Put your patients with diabetes back on their feet sooner - DFU management from clinical evidence to real life efficacy**	Moderator: Ralf Lobmann
			Raju Ahluwalia, United Kingdom
			Marco Meloni, Italy
			Chris Manu, United Kingdom
			José Luis Lázaro-Martínez, Spain

11.00-12:15		**Oral Award Presentations**	Moderator 1: Nikolaos Papanas Moderator 2: Anna Trocha
	Prize Oral 1	*The effectiveness of at-home foot temperature monitoring in reducing the incidence of ulcer recurrence in people with diabetes: a multicentre randomized controlled trial (DIATEMP)*	Sicco Bus, Netherlands
	Prize Oral 2	*Development of a diabetic foot navigator role across a large diabetic foot network allows continued provision high-quality diabetic foot care during the COVID19 pandemic: The South East London Diabetic Foot Network experience.*	Prash Vas, United Kingdom
	Prize Oral 3	*A Prognostic Model to Predict the Risk of Diabetic Foot Ulceration. A Prospective Cohort Study of Patients with Diabetes in Tanzania*	Roozbeh Naemi, United Kingdom
12:20-13:40		**Oral abstracts session 3: Outcome**	Moderator 1: Enrico Brocco Moderator 2: Maureen Bates
	O13	*Outcomes of a digital wound imaging and data management system for the integration of community and secondary care based multidisciplinary diabetic foot clinics.*	Doreen Bunting, United Kingdom
	O14	*Systematic Review of Surgical Outcomes Using Intramedullary Fixation for Midfoot Charcot Reconstruction*	Katherine Raspovic, United States
	O15	*Results of a multicentre, prospective, observational study on the healing properties of TLC-NOSF poly-absorbent dressing in chronic wounds. Focus on the Diabetic Foot population*	Claas Lüdemann, Germany
	O16	*Cost-effectiveness analysis of a TLC-sucrose octasulfate dressing in comparison to a neutral dressing within the treatment of diabetic foot ulcers*	Ralf Lobmann, Germany
	O17	*Effectiveness of Fast-track pathway for diabetic foot ulcerations: preliminary data from Italy*	Marco Meloni, Italy
	O18	*Randomized controlled clinical study to elucidate effects on cellular proliferation and dermal repair in complicated diabetic foot ulcers (DFU) debrided with low frequency ultrasound (UAW) compared to DFU receiving standard wound treatment*	Yolanda García Álvarez, Spain
13:45-14:00		**Industry sponsored session: Trigocare**	
		Dryness of foot skin assessed by the visual indicator	Nikolaos Tentolouris, Greece
14:15-15:00		**Business Meeting and Assembly**	Speaker/moderator 1: Klaus Kirketerp-Møller Speaker/moderator 2: Nikolaos Papanas Speaker/moderator 3: Maureen Bates
		For members of DFSG only	

[O1] PREDICTIVE VALUES OF FOOT PLANTAR PRESSURE ASSESSMENT IN PATIENTS WITH ROCKER BOTTOM DEFOMITY SECONDARY TO CHARCOT NEUROARTRHOPATHY

Mateo López Moral[1], Aroa Tardáguila García[2], Marta García-Madrid Martín de Almagro[3], Raúl Molines Barroso[4], Esther Garcia Morales[5], José Luis Lázaro Martínez[6]

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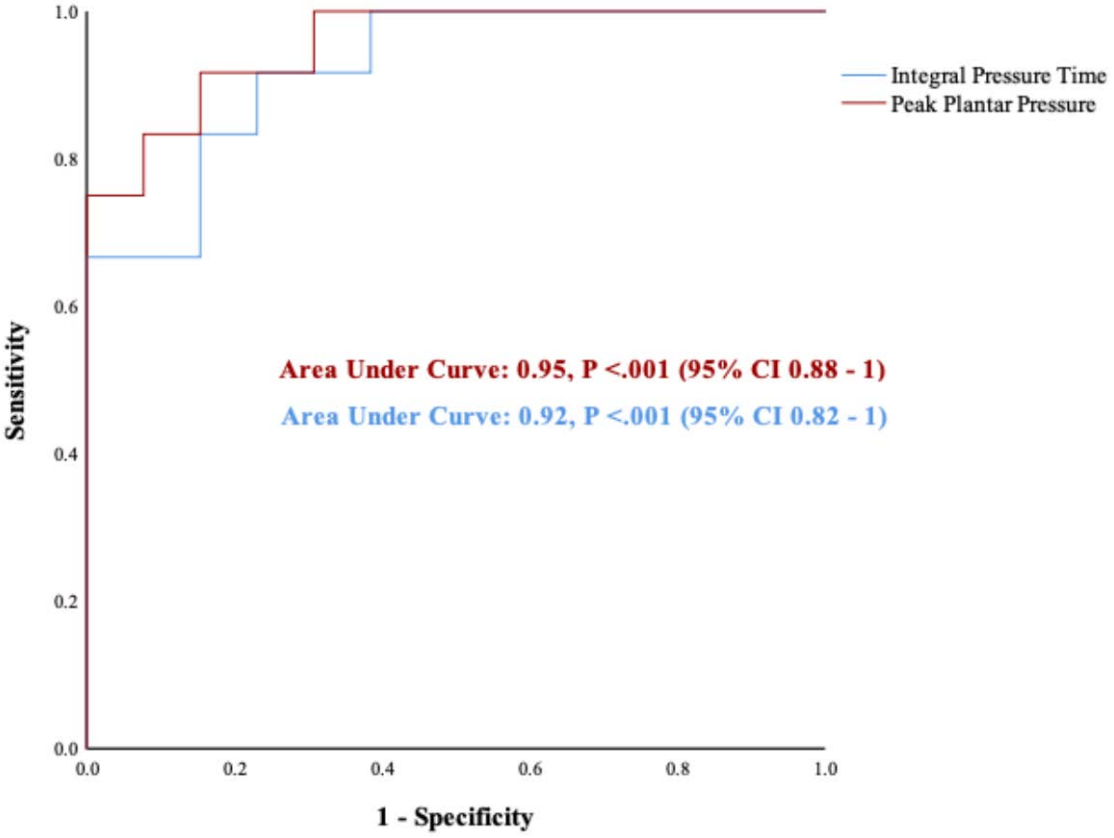
[6]*Complutense University Madrid, Diabetic Foot Unit, Clínica Universitaria de Podología, Madrid, Spain*

Aim: The principal aim of this study was to identify a cut-off point along the spectrum of peak plantar midfoot pressure that has an optimum combination of sensitivity and specificity to screen for neuropathic ulceration, in patients with Charcot Neuroarthropathy (CN).

Method: A longitudinal 1-year outcome study was performed in a specialized diabetic foot unit between December 2018 and January 2020. Twenty-five patients with diabetes, affected with CN stage 3 according to the Eichenholtz classification and rocker bottom deformity were included. Peak plantar pressure (PPP) and pressure/time Integral (PTI) in the midfoot region were registered by Foot Scan 7.x Gait Interface (Rsscan International, Olen, Belgium). All patients were followed-up in the outpatient clinic at intervals from 1 month based on the IWGDF recommendations, in addition, all patients wore an extra-depth footwear with a semirigid outsole and a custom-made multilayer insole to offload the plantar surface of the foot. Ulcer occurrence was assessed by the same clinician, who was blinded from the plantar pressure measurement. For selecting the optimal diagnostic cut-off points on the scale of pressure measurement, ROC curves were used.

Results / Discussion: Of the entire population, twelve (48%) patients developed a plantar midfoot ulcer. As expected, baseline PPP (24.04 ± 6.33 Vs 12.85 ± 3.29 N/cm^2) and PTI (11.89 ± 4.60 Vs 5.42 ± 2.26 N/cm^2/s) were significantly higher in the ulcerated group ($p<.001$ and $p<.001$ respectively). Using ROC analyses, for the optimal cut – off point for PPP, was 16.45 N/cm^2, yielding a sensitivity of 92% and a specificity of 85%; and for PTI, was 7.2 N/cm^2/s, yielding a sensitivity of 92% and a specificity of 77%.

Conclusion: Patients with rocker bottom and CN with cut-off values for PPP of 16.45 N/cm^2 and PTI of 7.2 N/cm^2/s showed an elevated risk of neuropathic ulceration in the plantar area of the midfoot. To implement dynamic barefoot plantar pressure measurement in the clinical practice could help clinicians to discriminate patients at risk of ulcer occurrence and then implement preventive and corrective therapies.


Integral Pressure Time
Peak Plantar Pressure
Area Under Curve: 0.95, P <.001 (95% CI 0.88 - 1)
Area Under Curve: 0.92, P <.001 (95% CI 0.82 - 1)
Sensitivity
1 - Specificity
0.0
0.2
0.4
0.6
0.8
1.0

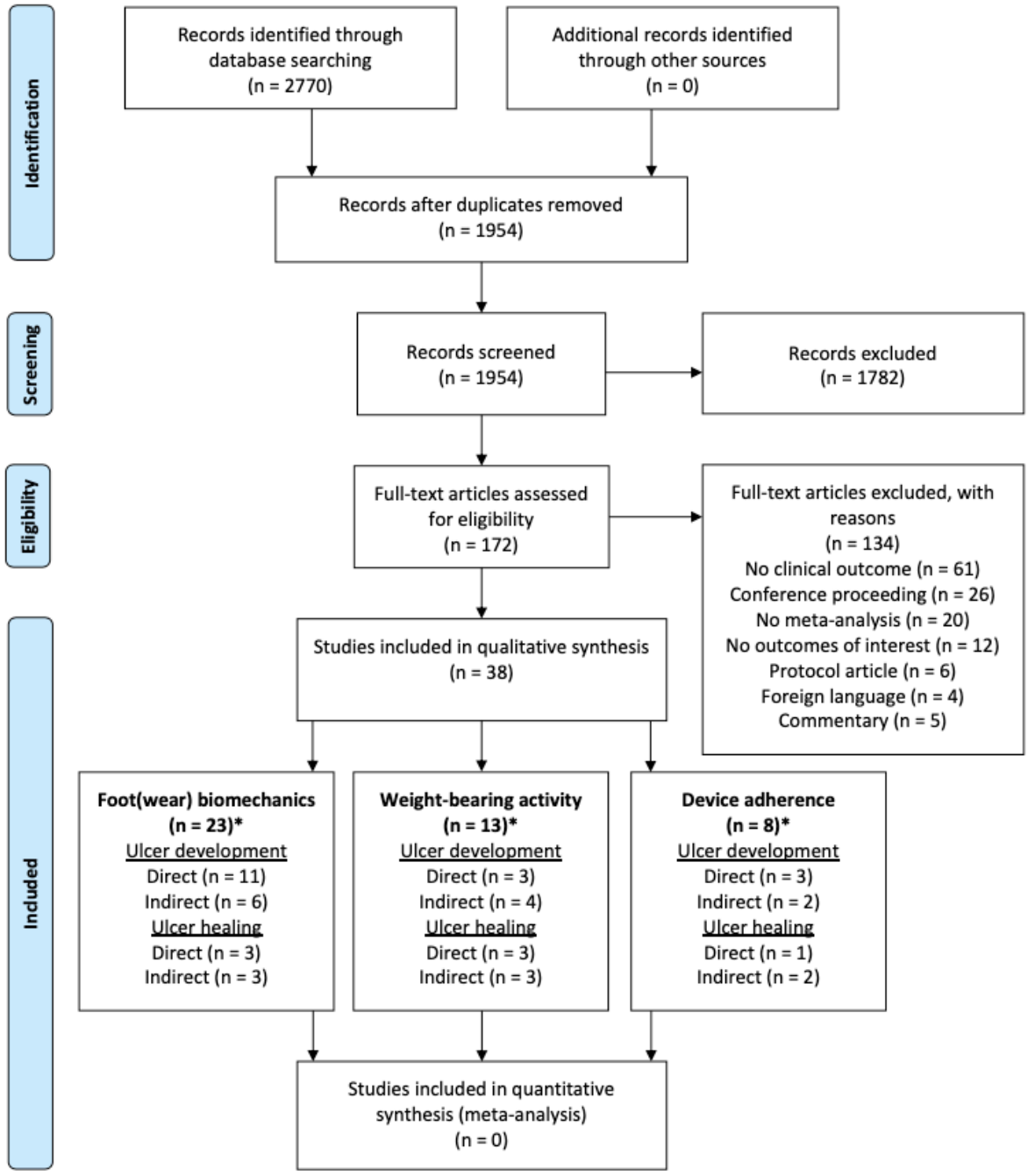
[O2] ASSOCIATION OF FOOT BIOMECHANICS, WEIGHT-BEARING ACTIVITY AND DEVICE ADHERENCE WITH ULCER DEVELOPMENT AND ULCER HEALING IN DIABETES: A SYSTEMATIC REVIEW

Chantal Hulshof[1], Jaap J. van Netten[1], Sicco A. Bus[1]

[1]*Amsterdam Umc, Department of Rehabilitation Medicine, Amsterdam Movement Sciences, Amsterdam, Netherlands*

Aim: Foot-loading is an essential concept in diabetic foot ulcer prevention and healing. Three factors play an important role in foot-loading: foot(wear) biomechanics, weight-bearing activity and device adherence; together, they determine the cumulative plantar tissue stress on the foot. These three factors are associated with ulcer outcomes, but that has never been systematically reviewed. Insight in these associations can help improve treatment in diabetic foot care. Therefore, our aim was to systematically review peer-reviewed literature on foot(wear) biomechanics, weight-bearing activity and device adherence and their associations with ulcer outcomes.
Method: A systematic literature search was performed on March 18, 2020 in PubMed and EMBASE without date restriction. We included studies if foot(wear) biomechanics, weight-bearing activity or device adherence was objectively measured and associated with foot ulcer outcomes (either development or healing) in people with diabetes. We included studies that reported a direct association on an individual level or an indirect association on group level. This review was prospectively registered in PROSPERO (CRD42020170945).
Results / Discussion: Out of a total of 1954 records, 38 studies were included and qualitatively analyzed (Fig. 1). For foot(wear) biomechanics, we found that people who stayed ulcer-free had lower barefoot and in-shoe plantar pressures. The direct association between ulcer healing and lower plantar pressures was less clear, although indirect evidence was available. For weight-bearing activity, we found that improved ulcer healing was associated with a lower level of walking activity. The association between ulcer development and level of or variation in activity was unclear. For device adherence, we found that people with better ulcer outcomes spent more time in their devices. Assessment of cumulative plantar tissue stress based on more than one foot-loading factor was investigated only twice, once each for ulcer development and healing: lower cumulative plantar tissue stress resulted in better ulcer outcomes, albeit not statistically significant.
Conclusion: We found supporting evidence for associations between ulcer outcomes and some foot-loading factors, but not between foot(wear) biomechanics and ulcer healing and between weight-bearing activity and ulcer development. Cumulative plantar tissue stress is hardly studied in association with ulcer outcomes and requires more comprehensive investigation in people with diabetes, to provide patients and clinicians with more tailored advice on foot off-loading.

Figure 1: PRISMA Flow Diagram



* The total number of studies of the three foot-loading factors together is higher than the total number of included studies, because some studies reported more than one foot-loading factor.

[O3] PLANTAR PRESSURES AND ADHERENCE OF INDOOR AND REGULAR CUSTOM-MADE FOOTWEAR FOR PEOPLE WITH DIABETES AT HIGH RISK OF FOOT ULCERATION

Tessa Busch-Westbroek[1], Renske Keukenkamp[2], Jaap van Netten[3], Sicco Bus[4]

[1]*Department of Rehabilitation, Academic Medical Center, Amsterdam, Netherlands*
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[3]*Amsterdam Umc, Department of Rehabilitation Amsterdam Umc, Amsterdam Umc, University of Amsterdam, Department of Rehabilitation, Netherlands*
[4]*Department of Rehabilitation, Location Amc, Department of Rehabilitation, Amsterdamumc, Amsterdam Umc, University of Amsterdam, Department of Rehabilitation, Netherlands*

Aim: Adherence to wearing custom-made footwear is a known problem in people with diabetes who are at high ulcer risk, especially inside their homes. Therefore, we designed and manufactured special offloading footwear for indoors that is easy to use, low in weight, more comfortable and easy to don and doff, so it might improve adherence. Importantly, this indoor footwear needs to have similar capacity as someone's regular custom-made footwear to offload repetitive stress in order to provide optimal ulcer protection. The aim was to compare plantar pressures of indoor and regular custom-made footwear for people with diabetes at high risk of foot ulceration.
Method: Custom-made indoor footwear was provided to 35 persons with diabetes, a previous foot ulcer and in possession of regular custom-made footwear. Indoor footwear was made on the shoe last of the regular footwear, with similar rocker profile and insole characteristics, but with softer materials for the vamp and the upperpart. Plantar pressures were measured with Pedar-X (Novel, Munich, Germany) in the participants' indoor footwear and their regular custom-made footwear. If necessary, the footwear was modified until peak pressures were clinically acceptable. Differences between footwear conditions were compared using paired samples T-tests, with Bonferroni correction for multiple comparisons.
Results / Discussion: Thirty participants completed all plantar pressure measurements (mean(SD) age: 70(10) years; females: n=12; type 2 diabetes: n=25; mean(SD) BMI: 30(6) kg/cm^2). Peak plantar pressures were similar between footwear conditions (0-7% difference) for the different anatomical regions, except the heel (7-10% lower in the indoor footwear); no statistically significant differences were found (Table 1). In a per-foot analysis, we found peak pressures <200kPa for 32 indoor shoes (53%) and 25 of the regular shoes (42%).
Conclusion: Custom-made indoor footwear for people with diabetes at high risk of foot ulceration has similar offloading quality compared to their regular custom-made footwear. Therefore, this indoor footwear is safe to use at home. Because patients will likely prefer to wear a pair of lighter-weight and easier-to-use indoor footwear over their regular footwear, we expect this to increase adherence indoors and satisfaction and ultimately prevent foot ulceration.

Table 1: Peak plantar pressures for indoor and regular custom-made footwear

		Indoor footwear[†]	Regular footwear[†]	Mean difference (95%CI)	% difference	p-value*
Hallux	Left	121 (46)	122 (53)	-1 (-12; 11)	-1%	0.908
	Right	124 (47)	128 (66)	-4 (-18; 9)	-3%	0.525
MTH1	Left	141 (40)	145 (60)	-4 (-21; 14)	-3%	0.653
	Right	146 (40)	153 (72)	-8 (-28; 13)	-5%	0.467
MTH2-3	Left	145 (36)	151 (56)	-6 (-22; 10)	-4%	0.460
	Right	157 (43)	157 (52)	-1(-13; 12)	-1%	0.916
MTH4-5	Left	121 (39)	124 (45)	-3 (-15; 9)	-2%	0.599
	Right	124 (48)	123 (52)	0 (-9; 10)	0%	0.972
Midfoot	Left	117 (38)	115 (35)	2 (-8; 12)	2%	0.634
	Right	112 (29)	115 (36)	-4 (-12; 4)	-3%	0.343
Heel	Left	187 (52)	201 (76)	-14 (-33; 3)	-7%	0.112
	Right	185 (58)	209 (69)	-24 (-47; -1)	-10%	0.046

Note: [†]: Peak plantar pressure values are provided as mean (standard deviation) kPa. MTH: metatarsal head.
*: Bonferroni-corrected level of significance: alpha = 0.05/12 = 0.004.

[O4] CAN WE REDUCE HIGH FOOT PRESSURES IN PATIENTS AT RISK OF DFU USING DAILY MONITORING THROUGH SMART INSOLE TECHNOLOGY?

Katie Chatwin[1], Caroline Abbott[2], Prabhav Nadipi Reddy[3], Frank Bowling[4], Andrew Boulton[5], Neil Reeves[2]

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[2]*Manchester Metropolitan University, School of Healthcare Science, Faculty of Science and Engineering, Manchester, United Kingdom*
[3]*University College London, Dept. of Medical Physics and Biomedical Engineering, London, United Kingdom*
[4]*University of Manchester, Dept. of Vascular Surgery, Manchester, United Kingdom*
[5]*University of Manchester, Manchester, United Kingdom*

Aim: High plantar pressure is a major risk factor in the development of diabetic foot ulceration (DFU). Recent evidence shows that continuous plantar pressure monitoring and dynamic offloading guidance can lead to reduced DFU recurrence. The aim of this study was to investigate whether continuous daily use of an innovative smart insole system over 18-months can reduce foot pressures in patients at risk of DFU.
Method: Forty-six patients, recruited from two UK outpatient diabetic foot clinics, with diabetic peripheral neuropathy and a history of plantar DFU, were randomized to intervention (IG) or control group (CG). All patients received their own smart insole system, consisting of pressure-sensing insoles and a smartwatch. Patients were instructed to wear the smart device throughout all daily activity for 18-months or until re-ulceration. The device provided high-pressure feedback to IG only, via audiovisual-vibrational alerts when a new bout of high-pressure was detected. CG received no pressure-feedback; however, the device recorded integrated pressure continuously for all patients. Minutes of high pressure and the number of high pressure bouts per hour were averaged every 4-weeks and compared between IG and CG across the 18-months. Total pressure for the wholefoot, forefoot and rearfoot were assessed for patient-feet independently, with multilevel binary logistic regression analysis.
Results: CG experienced significantly more high-pressure bouts over time than IG across all areas of the foot (wholefoot p=0.003, forefoot p=0.048, rearfoot p=0.001). Differences between groups became apparent from 16 weeks of wearing the pressure device. Analysis of minutes of high pressure did not yield any significant differences between groups over time.
Conclusion: For the first time, this study showed that daily foot pressure feedback reduced the number of bouts of high pressure in patients at high risk of DFU. The findings indicate a potential learning response, which appeared to take effect after 16-weeks of wear. A reduction in the number of high-pressure bouts over time suggests patients were pre-emptively offloading through learning the activities that generated this high pressure. High variation in pressure outputs between patient-feet likely contributed to lack of any significant differences in minutes of high pressure. This study establishes proof-of-concept for the use of daily foot pressure feedback in reducing pressure and DFU risk.

SurroSenseRx, Orpyx Medical Technologies Inc., Calgary, Canada

[O5] PLANTAR SHEAR STRESS IN FOOT ULCER PATHOMECHANICS: CHALLENGING THE STATUS QUO

Metin Yavuz[1], Lawrence Lavery[2]

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[2]*University of Texas Southwestern Medical Center, Department of Plastic Surgery, Ut Southwestern, Dallas, United States*

Aim: Recent data indicates that DFU-related lower extremity amputations have been on the rise in the USA. DFU is known to have a biomechanical pathology; “DFU occur due to repetitive mechanical stress.” Foot pressure has been extensively studied and labeled as a “poor tool” in predicting DFU by Lavery and Armstrong. Only 38% of DFU develop at peak pressure locations and ulcers can develop at low pressures. Plantar shear may be the missing key in better understanding DFU pathology as well as effective prevention. We have reviewed the studies conducted on plantar shear from our own lab.
Method: Our group has had the technology to quantify plantar shear, demonstrated by 8 articles on shear and its relevance to DFU. A review of these reports is provided here.
Results / Discussion: Our results indicated that shear stress is a major causative factor in DFU since;

- Shear is twice as repetitive as pressure, as the foot experiences both braking forces and propulsive forces during the same stance phase. This fits well into; “repetitive mechanical stress” and an analogy is breaking a metal string into two pieces by simply bending it back and forth
- The shearing action is damaging as demonstrated by the use of a chainsaw. When the engine is off, there is no “shear”, it is impossible to cut a tree branch by applying only “pressure”. When the engine is on, shear applied via the chain severs the branch
- Shear, not pressure, is the main causative factor behind callus formation
- Frictional shear increases temperature of the tissue, similar to rubbing hands together. Previous research clearly indicated that warmer tissue ulcerates much faster
- Shear is significantly higher in diabetics
- Most DFU develop at peak shear locations

Conclusion:
We believe that it is about time we start questioning the status quo in our understanding of the DFU pathology and therapeutic options. The research around foot pressures and the abundance of pressure-reducing footwear and insoles have not moved the needle in amputation rates. It may not be possible to advance the field and prevent DFU if shear continues to be ignored. Therefore, we ask the scientific community to revisit DFU pathology, by taking shear into account.

[O6] PREDICTORS OF THERAPEUTIC FOOTWEAR ADHERENCE AMONG PEOPLE WITH DIABETES

Gustav Jarl[1], Roy Tranberg[2], Ulf Johansson[3], John Alnemo[4], Lars-Olov Lundqvist[3]

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[3]*University Health Care Research Center, Faculty of Medicine and Health, Örebro University, Örebro, Sweden*
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Aim: Low adherence to wearing therapeutic footwear is one of the biggest challenges to prevent diabetic foot ulcerations. The aims were to 1) identify patient groups prone to nonadherence, and 2) to identify modifiable factors associated with adherence, to guide future interventions to improve adherence.

Method: A questionnaire was posted to 1230 people who had been prescribed therapeutic footwear. The dependent variable was 'adherence with wearing therapeutic footwear'. The independent variables were categorized into five domains: One domain (Demographics, health and social support) for identifying nonadherent patient groups and four domains (Health care services, Attitudes to foot ulcers, Strategies for footwear use and Attitudes to footwear) for identifying modifiable factors associated with adherence. Variables that were associated with adherence ($p<0.10$) in the univariate regression analyses were included in forward linear multiple regression analyses (one per domain), using SPSS Statistics, version 25.0.

Results / Discussion: A total of 429 (34.8%) questionnaires were analysed. For the first aim, adherence was significantly lower ($p<0.05$) among people without paid employment, perhaps because adherence often is lower at home. Also, adherence was lower among people without experience of foot ulcers, possibly because foot ulcerations act as a 'wake-up call' to patients. For the second aim, the 'Strategies for footwear use' domain explained more variance (28%) than the other domains (2-11%), suggesting that it is an important modifiable factor. Secondary analyses of the items of this domain suggested substantially different adherence levels related to self-efficacy, consistent footwear choices, and storage of footwear (Table 1).

Conclusion: Clinicians should advise patients to keep their therapeutic footwear visible at home and put their conventional footwear away, and encourage self-efficacy and habitual therapeutic footwear use. Special attention should be paid to patients without experience of foot ulcers and without paid employment.

Table 1. Secondary analyses of items from Strategies for footwear use domain

Variables	**N (%)**	**Adherence as % of waking day time, mean (SD)**	**Comparisons of adherence †**
Confident I would always wear therapeutic footwear if I decided to do so			$F_{(3,405)}$=28.280 (p<.001)
Very uncertain	46 (11.2)	29% (31%)	a
Moderately uncertain	53 (13.0)	33% (29%)	a
Moderately certain	125 (30.6)	45% (28%)	b
Very certain	185 (45.2)	64% (31%)	c
How do you choose between wearing therapeutic and conventional footwear?			$F_{(1,329)}$=56.411 (p<.001)
Decides from time to time	141 (42.6)	32% (28%)	a
Always chooses in the same way	190 (57.4)	57% (30%)	b
Combination of footwear storage variables			$F_{(3,320)}$=19.454 (p<.001)
Conventional footwear visible at home, have put therapeutic footwear away	14 (4.3)	9% (13%)	a
Have put therapeutic and conventional footwear away	10 (3.1)	37% (32%)	b
Therapeutic and conventional footwear visible at home	178 (54.9)	41% (30%)	b
Therapeutic footwear visible at home, have put conventional footwear away	122 (37.7)	61% (30%)	c

SD, standard deviation. † One-way ANOVA. Different letters (a, b and c) denote that adherence was significantly different ($p<0.05$) in the LSD post-hoc test. Similar letters denote that adherence was not significantly different.

[O7] CHARACTERISTICS OF DIABETIC FOOT ULCERS: A COMPARISON OF TWO POPULATIONS WITH 15 YEARS IN BETWEEN

Afram Akturk[1], Jaap van Netten[2], Marloes Vermeer[3], Rombout Kruse[4], Lisette van Gemert-Pijnen[5], Sjef van Baal[6]

[1]*Ziekenhuisgroep Twente (Zgt), University Twente, Almelo, Netherlands*
[2]*Amsterdam Umc, Amsterdam, Netherlands*
[3]*Ziekenhuisgroep Twente, Almelo, Netherlands*
[4]*Ziekenhuisgroep Twente (Zgt), Almelo, Netherlands*
[5]*University Twente, Enschede, Netherlands*
[6]*Ziekenhuisgroep Twente, University of Cardiff, Almelo, Netherlands*

Aim: There have been observations of an increasing complexity of patients with diabetes which led to the suggestion that the population of diabetic foot patients may have changed in the past decades. However this is hardly investigated. The aim is to investigate the differences in baseline characteristics and outcomes (ulcer-free survival days and ulcer healing) in patients with a diabetic foot ulcer treated now or 15 years ago within one centre of expertise
Method: We included all patients with a new diabetic foot ulcer prospectively during 2003-2004 and 2014-2018 in our centre. Primary outcomes were differences in baseline characteristics between both cohorts. Ulcer related outcomes were determined after follow-up period of 12 months.
Results / Discussion: 79 patients were included in 2003-2004 and 293 patients in 2014-2018. PAD (37.9 vs 32.9%), cardiovascular disease (31.1% vs 22.8%) and ESRD (7.8% vs 1.3%) were more often present in 2014-2018 compared to 2003-2004. Furthermore, we found a higher healing rate (75.4% vs 53.2%), median ulcer free survival days in the healed patients (254 days vs 173 days) and median ulcer healing time (106 days vs 278 days)
Conclusion: Our study showed an increase in PAD, ESRD and cardiovascular disease in the current population of patients with diabetic foot ulcers compared to 15 years ago. Furthermore, patients treated in the current cohort had more ulcer-free survival days, healing rate was higher and median ulcer healing time.

[O8] THE ASSOCIATION BETWEEN PLANTAR SKIN MICROCIRCULATION AND THE INDICATORS OF PERIPHERAL ARTERIAL DISEASE IN PATIENTS WITH DIABETES

David Allan[1], Luis Vilcahuaman[2], Hugo Arbanil[3], Roozbeh Naemi[1]

[1]*Staffordshire University, Stoke-on-Trent, United Kingdom*
[2]*Pontificia Universidad Católica del Perú, Lima, Peru*
[3]*Hospital Nacional Dos de Mayo, Lima, Peru*

Aim: The aim of this study was to assess the relationship between plantar skin microcirculation against macrocirculation measures and indices that assess the presence of Peripheral Arterial Disease in people with diabetes.

Method: 32 diabetic patients (Age = 61±(12)years, height = 1.54(±0.1)m, weight = 70.36(±17.4)kg, BMI = 29.66(±6.87)kg/m^2, duration of diabetes = 9(±7)years) of whom consented to participate in this study were recruited. Skin microcirculation measurements were performed at six sites (Hallux, 1st, 3rd, 5th metatarsal heads, midfoot, heel) using a propriety Imaging photoplethysmography (iPPG) prototype device (Cadscan, Chester, United Kingdom).

The participant was positioned supine, with their feet positioned at the edge of an examination couch. The iPPG camera placed 40-45cm away from the foot, dependent on foot size. Three, 30 second, recordings were taken, for both feet. Patients with active ulcers, iPPG was only measured at the contralateral limb.

Macrocirculation was assessed using the Ankle Brachial Index (ABI), measured separately for the dorsalis pedis and posterior tibial artery for both left and right feet and the presence of Peripheral Arterial Disease was classified based on the Fontaine Classification. Demographic data was collected from the patients' medical records.

Results / Discussion: Spearman's Rank test indicated a significant low strength correlation (r=0.267, p=0.046, n=56) between microcirculation at the heel and ABI at the dorsalis pedis. However, no other significant associations were observed between the microcirculation at any other sites, and the ABIs measured at dorsalis pedis and posterior tibial arteries.

Kruskal-Wallis test was then used to investigate if there were any significant differences in microvascular perfusion in patients with different levels of peripheral arterial disease (PAD). Significantly lower values of microcirculation at the 1st ($\eta_H^2 = 0.14$) and 3rd ($\eta_H^2 = 0.11$) metatarsal heads and midfoot ($\eta_H^2 = 0.14$) were observed in in patients with moderate to severe PAD compared to those with mild PAD.

Conclusion: The associations between the measures of macrocirculation and skin microcirculation parameters that were observed in this study indicated that some of these measures are interrelated. However, the relationship indicated a weak association further highlighting that for the assessment of tissue perfusion, both macro and microcirculation need to be considered.

[O9] VERIFICATION OF YEARLY INCIDENCE OF FOOT ULCERS IN PATIENTS WITH DIABETES MELLITUS AT DIABETOLOGIC CENTRE AND RECOMMENDATION OF PREVENTIVE MEASURES (FOOT SCREENING, EDUCATION AND MONITORING) FOR AT -RISK DIABETICS IN CLINICAL PRACTICE

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Aim: In 2014 the Diabetologic Centre launched pilot project on DFU prevention in randomly selected group of diabetic patients without history of foot ulcer. The study aimed to determine yearly incidence of foot ulcers and to suggest a viable system of preventive measures in outpatients care for diabetics at-risk of DFU.
Method: In the period of 7/2014 to 3/2019, 153 diabetics monitored at Diabetologic Center (T2 DM/T1DM/T3cDM = 138/10/5 pts), mean age 66,2 ± 10,9 years , mean duration of diabetes 9,3±6,33 years , mean HbA1c 52,35±12,86 mmol/mol without history of DFU went through preventive screening of feet at Foot clinic, including education on foot care and footwear. Patients were observed for 12 months. Yearly incidence of DFU was determined.
Results / Discussion: Based on clinical findings we divided 153 patients into 4 categories of DFU risk (IWGDF Risk Stratification System): category 0: 78 patients, category 1: 17 patients, category 2: 55 patients, and category 3: 3 patients. After one year, 151 patients were examined and foot ulcer occurred in total of 3 patients (3/151, 1.98%, 1 patient in category 3, 2 patients in category 2).
Conclusion: We confirmed yearly DFU incidence of 2% which correlates with data reported in literature. For prevention of DFU based on our experience, we consider essential to establish a personal contact between at-risk patient and Foot clinic, and provide education by specialist in DFU treatment. Therefore, we recommend to clinically assess the risk of foot ulceration in each diabetic when entering care of diabetologist/GP. Patients of category 1, 2, and 3 without ulceration should be directed for entry feet examination at respective Foot clinic. Patients of category 0 could be further monitored by diabetologist /GP by yearly check-ups focused on the development of neuropathy, foot deformity and peripheral artery disease, thus preventing overload for Foot clinic. In case of risk aggravation they should be sent to Foot clinic. Patients of risk category 1 after entry examination and education at Foot clinic should be further monitored by diabetologist/GP, however in case of acute aggravation in feet they should directly contact Foot clinic where they were registered. Patients of risk category 2 and 3 should be monitored at Foot clinic with a frequency of 3-12 month.

[O10] MULTIVARIABLE CLINICAL PREDICTION MODELS FOR FOOT ULCER RECURRENCE IN HIGH-RISK PEOPLE WITH DIABETES

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Aim: People with diabetes stratified to the highest IWGDF risk group for foot ulceration still vary widely in disease severity. It is important here to differentiate for ulcer risk to provide appropriate and personalized preventative strategies and to adequately allocate limited recourses. The aim of this study was to predict ulcer recurrence in a representative group of high-risk people with diabetes using easy to obtain variables.
Methods: Demographic, disease-related, ulcer-related and organisation-of-care variables from 304 persons with diabetes at high-risk for foot ulceration with 18 months follow-up for ulcer outcomes were used from the DIATEMP foot temperature monitoring trial. Two logistic regression models were created using the R statistical environment: one for recurrent foot ulcers (n=126) and one for recurrent plantar foot ulcers (n=70). Ten-fold cross validation, each including five multiple imputation sets, was used to internally validate the models; model performance was assessed in terms of discrimination and calibration using the area under the receiver operator curve (AUC, range 0-1, 1: perfect discrimination), Brier score (range 1-0, 0: complete concordance between predicted and observed values) and calibration graphs.
Results / Discussion: Predictors for recurrent foot ulceration were: younger age, more severe peripheral sensory neuropathy, shorter time since healing of the previous ulcer, presence of a minor lesion, using a walking aid, and not monitoring foot temperatures. The mean AUC for this model was 0.69 (IQR 0.61–0.74) and mean Brier score was 0.22 (IQR 0.21–0.24). Predictors for recurrent plantar foot ulceration were: younger age, more severe peripheral sensory neuropathy, plantar location of previous ulceration, shorter time since healing of the previous ulcer, presence of a minor lesion, consumption of >1 unit alcohol per week, using a walking aid, and foot care received in a university medical center. The mean AUC for this model was 0.67 (IQR 0.66–0.77) and mean Brier score was 0.16 (IQR 0.13–0.19).
Conclusion: These well-designed and internally validated prediction models are built from a representative group of high-risk IWGDF grade 3 people with diabetes using easy to obtain variables, and predict with good calibration and fair discrimination who is at highest risk of ulcer recurrence. These people should be monitored more carefully and treated more intensively than others.

[O11] MIDFOOT AMPUTATIONS IN DIABETIC PATIENTS: A TERTIARY REFERRAL HOSPITAL EXPERIENCE

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Aim: to evaluate the evolution of midfoot amputations in diabetic patients.
Methods: we made a retrospective observational study with interrogation of surgical database between January 2014 and December 2019 in a tertiary center. We excluded surgical procedures of acute drainage, dermal or skin flap. We analysed baseline clinical characteristics of patients, type and history of diabetes and metabolic control, number of revascularization procedures (endovascular or surgical) and number of patients on haemodialysis. We compared data with major amputations (above and below the knee) in our region.
Results: we found a similar total number of surgical procedures/year during the period (305 ± 14, mean ± SD), but a progressive increase of midfoot amputations (transmetatarsal, Lisfranc and Chopart amputations) in last 2 years (31 ± 21). Other minor surgical procedures /year (sequestrectomy, resections of digital and metatarsal bones, or toe amputation) were stable between years (178 ± 17). Major amputations/year (above and below the knee) were not significantly different during the period (32 ±5). Baseline characteristics of patients were similar during the period: age was 71,6 ±11.8 years, and 79% were male. 99% of patients had type 2 diabetes with a long history of disease (19.6 ± 12 years) and similar metabolic control (HbA1c 7.8 ± 1.5 %). We found a progressive increase in percentage of patients who underwent revascularization (from 31% in 2014 to 50% in 2019) before surgical intervention. 92% of revascularization procedures were endovascular, 8% surgical. Furthermore, we found a significant increase of percentage of patients on haemodialysis (5,6% in 2014 to 10,2 % in 2019). 100% of patients on haemodialysis underwent revascularization. A multivariate analysis showed that revascularization rate and haemodialysis were independently associated with midfoot amputations.
Conclusions: data from this study indicate that epidemiology of surgery of diabetic foot is changing, with a significant increase in midfoot amputations. This rise seems related to an increase of vascular patients who need revascularization procedures and to an increase of patients who are on haemodialysis.

[O12] THE ENORMOUS IMPACT OF COVID-19 IN THE DIABETIC FOOT, END STAGE RENAL FAILURE PATIENTS

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Aim: The aim was to assess what happened to our diabetic foot patients with end stage renal failure attending the hospital for haemodialysis, during the Covid-19 pandemic and lockdown in the UK (23 March to 10 May, 2020).

Method: We studied the short term outcome of 25 diabetic foot, end stage renal failure patients who had an active or previous history of foot pathology and who were under regular follow up by the diabetic foot practitioner whilst attending the outpatient haemodialysis clinic. The number of patients who became positive for Covid-19 were noted and acute foot infections, and deaths were analysed.

Ethnic background was also investigated in the identified Covid-19 positive group of patients.

Results/discussion: Demographically, the follow-up haemodialysis group comprised 16/25 male and 9/25 female patients, the mean age was 62.56 years, 3/25 had type 1 diabetes and 22/25 had type 2 diabetes.

It was striking that 11/25 patients became positive for Covid-19 during the UK lockdown period. Regarding ethnicity, 1/11 were Asian, 5/11 Caribbean, 2/11 African and 3/11 Caucasian.

Of the 11 Covid-19 positive patients, 6 received HDU (High Dependency Unit)/ICU admission. Out of this group, 2 died but 4 went on to recover from Covid-19 pneumonia. Overall, however, out of the 11 patients with Covid-19, unfortunately 5/11 eventually died from Covid-19 pneumonia

1/11 Covid-19 patient also had severe limb and life threatening foot sepsis, requiring hospital admission for emergency surgical debridement and drainage alongside intravenous antibiotic therapy.

1/11 of the Covid-19 positive patients had necrotic apices of their toes secondary to inotrope vasoconstriction from their Intensive care admission with Covid-19 pneumonia.

Regarding the remaining 14/25 patients who did not develop Covid-19, there were 2 deaths one patient was on a palliative care pathway and the other succumbed to non-C0vid-19 sepsis.

1/14 patients presented with acute foot infection needing surgical debridement and 1/14 had an infected leg haematoma which resolved.

Conclusion: Our patents attending our haemodialysis unit were highly susceptible to developing Covid-19 (44% became positive) and there was a high mortality (45% of cases). Such diabetic foot patients on haemodialysis are well known for their susceptibility and poor outcomes to bacterial infections. Our data confirm a similar vulnerability to Covid-19.

[O13] OUTCOMES OF A DIGITAL WOUND IMAGING AND DATA MANAGEMENT SYSTEM FOR THE INTEGRATION OF COMMUNITY AND SECONDARY CARE BASED MULTIDISCIPLINARY DIABETIC FOOT CLINICS.

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Aim: To describe the implementation and outcomes of a digital wound imaging and data management system deployed as an enabler of full integration of community and secondary care based multidisciplinary foot clinics.
Method: Attendances and costs of delivery of services in each setting to describe delivery cost savings. Attendance waiting times at secondary care MDFTs, and patient views by questionnaire.
Results / Discussion: After a successful 9 month pilot full implementation of the project commenced March 2018. In this 22 month period 18% patient appointments were seen in community settings rather than the secondary care MDFT (range 14-24%/month), with accumulated savings of £188,444 due to differential cost of care delivery in community vs secondary care settings. The good outcomes of this MDFT (1.4% major and 2.2% minor amputation rate within 6 months) have been maintained. The integrated wound management system web-linked to a central server enables any deterioration seen by a podiatrist when treating a DFU in a community setting to be rapidly escalated back to the MDFT. Patient feedback is good, with 72% of patients being seen within 30minutes of their appointment time (compared with 3% in 2016), and 71% of patients saying that they had more confidence in the care they were receiving for their DFU.
Conclusion: MDFTs are imperative to achieve the best outcomes for DFUs but are struggling with capacity in most secondary care services. This integrated model of care using proven digital wound imaging and data management system has proved to be effective and safe for the delivery of footcare closer to patients homes, freeing up the MDFT for more complex cases.

[O14] SYSTEMATIC REVIEW OF SURGICAL OUTCOMES USING INTRAMEDULLARY FIXATION FOR MIDFOOT CHARCOT RECONSTRUCTION

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Aim: The purpose of this systematic review was to evaluate the outcomes of intramedullary beaming in patients with Charcot neuroarthropathy and to determine the methodological quality of the studies
Method: We performed a systemic review investigating the outcomes of intramedullary fixation in treating midfoot Charcot neuroarthropathy. This reviewed followed the guidelines in accordance with Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guideline. Four online databases were searched: PubMed, MEDLINE (Clarivate Analytics), CINAHL (Cumulative Index to Nursing and Allied Health) and Web of Science (Clarivate Analytics). To assess the methodological quality of the studies, the Coleman Methodology Score was used. The data was pooled into two outcomes groups for comparison: 1. Studies that reported on the outcomes of Charcot specific implants. 2. Studies that reported on the outcomes using non-Charcot specific implants. A Charcot specific implant was defined as an intramedullary implant specifically designed for arthrodesis of the medial and lateral columns of a foot affected by CN.

Results / Discussion: The search strategy identified 812 potential studies from the four databases and 15 were included in the final review. Compared to our control group, our study group had higher rates of overall hardware complications (32% vs 19%, $p < 0.05$), hardware migration (21% vs 7%, $p < 0.05$), surgical site infection (18% vs 8%, $p < 0.05$), reoperation (33% vs 13 %, $p < 0.05$) and nonunion (25% vs 12%, $p < 0.05$). The study group had significantly lower rates of limb salvage compared to the control group (87% vs 99%, $p < 0.05$) and shorter follow up (16 vs 35 months, $p < 0.05$). Our study and control groups did not differ in the rates of hardware breakage (11% vs 12%, $p = 0.70$), wound healing complications (6% vs 9%, $p = 0.35$), or mortality (2% vs 3%, $p = 0.47$). The median Coleman Methodology Score was 39 (range 30—48), indicating the quality of the studies was low and consistent with methodologic limitations.
Conclusion: The quality of published studies on intramedullary implants for Charcot reconstruction is low. Complications utilizing intramedullary fixation for Charcot reconstruction are high, whether or not Charcot specific implants are used.

[O15] RESULTS OF A MULTICENTRE, PROSPECTIVE, OBSERVATIONAL STUDY ON THE HEALING PROPERTIES OF TLC-NOSF POLY-ABSORBENT DRESSING IN CHRONIC WOUNDS. FOCUS ON THE DIABETIC FOOT POPULATION

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Aim:
The excellent wound healing properties and cost-effectiveness of TLC-NOSF dressings in the local treatment of chronic wounds have already been demonstrated by randomized controlled trials at a high quality level. This work aimed to evaluate the efficacy and safety of new TLC-NOSF dressings with poly-absorbent fibres in an unselected population of patients under real-life conditions. Here we report the results achieved in patients suffering from DFUs.

Method:
A large, prospective, multicentre observational study with two TLC-NOSF poly-absorbent dressings* was conducted in Germany between July 2017 and December 2018. Patients suffering from chronic wounds of various aetiologies (leg ulcers, diabetic foot ulcers, pressure ulcers, etc.) were treated and followed-up for a maximum duration of 12 weeks or four documented visits. Key findings included wound healing rate, clinical assessment of wound healing progression, relative wound area reduction (RWAR), tolerability and acceptance of dressings.

Results/Discussion:
A total of 1,140 patients with chronic wounds were treated with the investigated dressings; among them, 250 patients with diabetic foot ulcers were treated in 76 centres for a mean duration of 56±38 days. By the last visit, 43.6% of wounds had healed and 44.4% had improved, with a median RWAR of 94.0%. Similar results were reported regardless of the wound healing stage (debridement or granulation) at the beginning of the treatment. According to the subgroup analysis by wound duration, the sooner the TLC-NOSF treatment was performed, the higher the wound healing results achieved. The dressings were very well tolerated and accepted by the patients and the health care professionals .

Conclusion:
These results are consistent with those published in articles on randomized controlled trials with TLC-NOSF dressings. They complete the evidence on the good healing properties and safety profile of these dressings, especially in non-selected patients treated in current practice and regardless of the characteristics of wounds and patients.

*UrgoStart Plus Pad and UrgoStart Plus Border, Laboratoires URGO, France

[O16] COST-EFFECTIVENESS ANALYSIS OF A TLC-SUCROSE OCTASULFATE DRESSING IN COMPARISON TO A NEUTRAL DRESSING WITHIN THE TREATMENT OF DIABETIC FOOT ULCERS

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Aim:
Specialisation and multidisciplinary approach for patients with diabetic foot ulcers (DFUs) lead to improved outcomes (e.g. reduction of major amputations and reduction of treatment costs). The application of innovative dressings with TLC-sucrose octasulfate* leads to a significant increase of wound closure rate (WCR) and a reduction of healing time. For the therapy of venous leg ulcers higher cost effectiveness for a TLC-sucrose octasulfate dressing in comparison to a neutral one was already demonstrated. This cost effectiveness analysis (CEA) aims to compare two options of local wound therapy for patients with DFUs, a TLC-sucrose octasulfate dressing* (test) versus (vs.) a neutral dressing (control), in order to demonstrate a higher cost effectiveness based on Explorer RCT also for this indication.
Method:
Clinical results and direct costs for wound dressings, time of care, in patient care in hospitals were analysed from the perspective of German statutory health insurance.
Results/Discussion:
Direct costs for therapy of DFUs were 2,864.21 € with the TLC-sucrose octasulfate dressing* (test) vs.
2,958.69 € with the neutral dressing (control) after 20 weeks. A modelling according to Markov over
100 days showed even higher differences in costs with 5,882.87 € (test) vs. 8,449.39 (control). Sensitivity analysis confirmed the robustness of these results.
Conclusion:
This CEA demonstrates that therapy of DFUs with a TLC-sucrose octasulfate dressing* is reasonable regarding health economics. Both therapy costs as well as cost effectiveness were superior to the local wound therapy of DFUs vs. a neutral dressing.

*TLC-sucrose octasulfate dressing (TLC-NOSF): UrgoStart Contact/UrgoStart Tül

[O17] EFFECTIVENESS OF FAST-TRACK PATHWAY FOR DIABETIC FOOT ULCERATIONS: PRELIMINARY DATA FROM ITALY

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Aim:

International Diabetic Foot Care Group and D-FOOT international developed a fast-track pathway (FTP) for diabetic foot ulcerations (DFUs) to allow a clear identification of DFU's severity, specific management and related timing of referral[1]. After 18 months of implementation across Europe, the effectiveness of FTP in Italy (metropolitan area of Rome) was evaluated.

Method:

The study group was composed of consecutive patients who referred to specialized DF centres because of DFUs. All patients were managed throught a limb salvage protocol based on Guidance[2]. Patients were divided in two groups: early referral (ER) and late referral (LR) patients. According to FTP, ER were considered patients who referred after 2 weeks in the

case of uncomplicated non-healing ulcers (superficial, not infected, not ischemic), whithin 3 days in the case of complicated ulcers (ischemic, deep, mild infection) and whithin 24 hours in the case of severely complicated ulcers (abscess, wet gangrene, fever, sepsis). Healing, healing time, minor and major amputation, survival at 6 months were evaluated.

Results:
One-hundred fifty-six subjects were included. The mean age was 70.4±14.5 years, 89.7% had type 2 diabetes and diabetes duration was 21.±14 years. One hundred nineteen (119) (76.3%) were ER, 37 (23.7) LR. LR patients referred with more cases of larger (>5cm^2) (87.5vs60.4%,p=0.006), deeper (to the bone) (71.9vs54.7%,p=0.01) and severely complicated DFUs (45.9vs21.8%,p=0.003) than ER. The rate of healing, healing time, minor amputation, major amputation and survival for ER and LR were respectively: (98.7vs29.7%,p<0.0001), (9±7vs18±7weeks,p<0.0001), (17.8vs70.3%,p<0.0001), (0vs37.8%,p<0.0001), (94.6vs78.4%,p=0.01). ER was an indipendent predictor of limb salvage [OR95% 5.1(1.9-9.7),p<0.0001] and healing [OR95% 6.5(2.0-13.4),p<0.0001].

Conclusion:
After FTP implementation, lower rate of LR were recorded in comparison to ER. ER predicts favourable outcomes.

[O18] RANDOMIZED CONTROLLED CLINICAL STUDY TO ELUCIDATE EFFECTS ON CELLULAR PROLIFERATION AND DERMAL REPAIR IN COMPLICATED DIABETIC FOOT ULCERS (DFU) DEBRIDED WITH LOW FREQUENCY ULTRASOUND (UAW) COMPARED TO DFU RECEIVING STANDARD WOUND TREATMENT

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Aim: We aimed to elucidate effects on cellular proliferation and dermal repair in complicated diabetic foot ulcers (DFU) debrided with UAW compared to DFU receiving surgical/sharp wound debridement.
Method: An RCT were performed included 51 patients with DFU at specialized diabetic foot unit between November 2017 to December 2019. DFUs stage IB,IIB,IC,IIC, according to the University of Texas Diabetic Wound Classification with duration between 1 and 24 months were included. Patients were randomized and allocated to receive either surgical or UAW debridement for 6 weeks. Soft tissue punch biopsies were taken at patient enrollment, and every second week during 6-week treatment period (0/3/6) for quantitative microbiological analysis and for cellular proliferation analysis by studying CD31-positive vessels, Actin and Masson's trichrome staining. The Wollina wound score (WWS) was used to evaluate wound conditions. Patients were followed-up for 6 months after inclusion.
Results / Discussion: 24 patients were included on Surgical-Group and 27 on UAW-Group. UAW-Group were older (64.1±12.4years vs 58±5.4years, p=0.03), with more diabetes duration (22±12.9 vs 10.3±5.0, p=0.001) and had largest ulcers (7.47±7.56cm^2 vs 4.18±3.32cm^2, p=0.05). After 6 weeks WWS improved in both groups (Surgical-Group 2.5±1.2-day0 to 5.6±0.7-day42 vs UWA-Group 2.15±1.4-day0 vs 5.4±1.5-day42, p=0.93). Bacteria load reduced significantly in UAW-Group comparing Surgical-Group (UAW-Group 4.27±0.37 day 0 to 2.11±0.8 vs Surgical-Group 4.66±1.21 day 0 to 4.39±1.24 day 42; p=0.01). Cellular proliferation improved significantly in UAW-Group comparing Surgical-Group (see table). Similar rate of patients healed was finding in both group after 6 months of follow-up (23 patients [85.1%] in UAW-Group vs 20 patients [83.3%] in Surgical-Group; p=0.856). Time to healing was significantly lower (p=0.04) in UAW-Group (9.7±3.8weeks) than in Surgical-Group (14.8±12.3weeks).

Histology findings	**Surgical-Group Day 0/Day 42**	**UAW-Group Day 0/Day 42**	**Pvalue**

CD31	2.05±1.29/1.77±1.30	1.11±0.42/2.82±0.56	0.001
Actin staining	1.75±1.22/2.00±0.10	0.44±0.57/2.56±0.89	0.001
Masson's trichrome staining	1,10±0.10/1.20±0.26	1.26±0.65/2.81±0.48	0.005

Conclusion: Patients debrided with UAW shows a significant reduction of bacteria load and a significant improve of cellular proliferation after 6 weeks of treatment. WWS improves in both of group of patients after 6 weeks. Time to healing was lower in UAW-Group comparing with Surgical-Group. The rate of patients healed after 6 months are similar. Patients who undergoes UAW debridement have better bioburden control and cellular proliferation, that could explain the lower time to healing.

[P01] EFFECTS OF SUCROSE OCTASULFATE DRESSING ON WOUND HEALING IN A RAT WOUND MODEL

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Aim: Wound dressing is of significant importance to promote cutaneous wound healing process. UrgoStart is a non-occlusive and non-adherent healing matrix dressing (TLC-NOSF), which reduces healing time of chronic wounds (such as venous leg ulcers and diabetic foot ulcers), as reported in randomized controlled trials. The aim of this study was to investigate the effects of this dressing on wound healing in a rat skin defect model, in comparison with a neutral TLC dressing.
Method: Twelve rats were randomized in two groups. A full-thickness skin defect of 12 mm diameter was surgically created on the back of each animal with a biopsy punch. Dressings were immediately applied to the wound and changed 3 times a week till complete closure. For each change performed, wounds were clinically assessed and measured by using image analysis software. After complete healing of the wounds, skin samples were harvested from wound tissue for histological analyses to score the angiogenesis.
Results: Macroscopic observations showed a significant faster elimination of exudates, and faster sprouting and epithelialization of the wound. Consequently, the time to wound closure was reduced by 5 days in the TLC-NOSF group. Microscopic observations indicated a significant greater vascularization of the scar area for the TLC-NOSF group, as well as the size of blood vessels.
Conclusion: Sucrose octasulfate dressing significantly improves the wound healing of surgically created full-thickness skin excision in a rat model, which may be explained by the local vascularization network improvement.

[P02] ADHERENCE TO AT-HOME INFRARED FOOT TEMPERATURE MONITORING IN PEOPLE WITH DIABETES AT HIGH RISK OF ULCERATION

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Aim: At-home monitoring of foot skin temperature is an effective intervention in helping to prevent foot ulcers in high-risk people with diabetes. However, little is known about adherence to this intervention, including associated patient characteristics. The aim was to investigate adherence to at-home monitoring of foot temperature and associated factors in people with diabetes at high ulcer risk.
Method: This study was part of a multicenter randomized controlled trial on effectiveness of at-home foot temperature monitoring on ulcer recurrence prevention (DIATEMP). Participants were people with diabetes with peripheral neuropathy and a history of foot ulceration in the preceding four years. Participants in the intervention arm had to perform daily at-home measurement of foot temperatures and had to note these temperatures in logbooks until a study endpoint (foot ulceration, death, or 18 months follow-up). Adherence was defined as the proportion of days measured divided by the total number of follow-up days (proportion of days covered: PDC). Participants were seen as adherent when PDC>70%. Univariate and multivariate analyses were performed to investigate participant characteristics associated with adherence.
Results and Discussion: In total 151 participants were included. During follow-up, 44 participants developed a foot ulcer and 5 participants died. Of the mean 437 follow-up days, foot temperature was measured a mean 272 days (PDC 64.8%; SD: 38.0). Ninety-three participants (61.6%) were adherent (PDC>70%). Adherence during months 1-3 was significantly higher compared to months 4-18 (78.1% (n=118) vs. 57.2% (n=79); p<0.001). In multivariate analyses, no factors were significantly associated with overall adherence, nor with adherence in months 4-18. In months 1-3, living together (p=0.034, OR=2.406, 95% CI: 1.069 to 5.414) and higher age (p=0.021, OR=1.045, 95% CI: 1.007 to 1.084) were significantly associated with being adherent.
Conclusion: Average adherence to daily foot skin temperature measurements was just above 60%, which is similar to other self-care interventions in people with diabetes. Participants were more adherent in the first three months after starting the intervention, which suggests that adherence requires additional assessment and support after this period. We found limited specific patient or disease-related factors associated with adherence, which hampers defining subgroups that require specific support.

[P03] IS CRYOPRESERVED AMNIOTIC TISSUE BETTER THAN A LYOPRESERVED CONSTRUCT TO TREAT NON-HEALING FOOT ULCERS?

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Aim:

To compare cellular viability and clinical outcomes between a cryopreserved and lyopreserved amniotic tissue (LAT).

Method:

This was an open label prospective cohort study of 40 patients with non-healing foot ulcers. Patients received standard wound care including weekly debridement and offloading. After debridement, patients received weekly application of LAT for 12 weeks. We evaluated the proportion of foot ulcers that healed, the time to heal, healing trajectories, and infection during the course of therapy. We used chi-square to compare dichotomous variables and independent t-tests to compare continuous variables with an alpha of 0.10.

Results:

Cellular viability was equivalent between cryo- and lyopreserved amniotic tissue in live/dead staining analysis. Forty-eight percent of subjects healed in an average of 40.0 (SD 20.1) days. Non-healers were older (63 years vs. 59 years, p=0.011) and had larger ulcers at baseline (7.8cm^2 vs. 1.6 cm^2, p=0.012). Significantly more patients who healed reached a 50% wound area reduction in 4 weeks compared to non-healers (73.7% vs. 47.6%, p=0.093). There was no difference in the slope of the wound healing trajectories of healers and non-healers (0.124 and 0.159, p = 0.85), indicating that the rate of healing was similar in healers and non-healers. The rate of healing was 0.60 mm/ day (SD 0.47) for healers and 0.50 mm/day (SD 0.58) for non-healers (p=0.89).

Conclusions:

LAT is a clinically effective alternative to cryopreserved amniotic membrane.

[P04] DOES SMALL VESSEL DISEASE OCCUR IN THE DIABETIC FOOT?

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Aim: Although peripheral arterial disease is common below the knee in diabetes, the extent of such disease extending to small vessels in the pedal circulation is unknown. The aim was to investigate the extent of small vessel pathology in the diabetic foot and compare it with that in the non-diabetic ischaemic foot.

Method: The study was in two parts. Firstly, digital arteries were assessed from amputated toes from 25 diabetes patients with arterial disease in the calf and foot ulceration/necrosis and 25 non- diabetes patients with leg arterial disease and foot ulceration/necrosis. Medial wall calcification and intimal hyperplasia were assessed semi-quantitatively in digital arteries and scored from 0 to 3 (0- no disease, 1- mild, 2- moderate, 3 –severe). In the second part, tibial /sural nerve specimens from major amputations were assessed for axonal neuropathy and epineurial vasculopathy in 18 patients with diabetic ischaemic limbs and in 14 non-diabetic ischaemic limbs.

Results / Discussion:
In part 1, mean age of diabetes patients was 68±11.6 years, which was significantly less than 75±8.9 in non- diabetes patients (P=0.016). Despite younger age in diabetes patients, calcification in digital arteries was significantly increased, scoring 1.6 ± 1.30 compared with 0.04 ±0.2 in non-diabetes patients (P<0.001.). Similarly intimal hyperplasia was also increased in diabetes at 1.96±0.84 compared with 1.1±0.58 in non-diabetes patients (P<0.001).
In part 2, diabetes patients were aged 66±12.9 years compared with 72±10.2 (P= 0.165) in non-diabetes patients. All diabetes patients had marked axon loss in the sural /peripheral nerves with 10/18 noted as severe. There was intimal thickening of epineurial arteries and hyalinization of arterioles with foci of occlusion. Interestingly, all the non-diabetes patients also had evidence of axonal loss, with 2/14 graded as severe (P<0.05 v diabetes patients), associated with intimal thickening, medial sclerosis of epineurial arteries and arterioles with patchy luminal occlusion.
Conclusion:
The diabetic ischaemic limb is characterized not only by crural vessel disease but also by digital intimal hyperplasia and medial calcification and epineurial arteriosclerosis (with axon loss) indicative of small vessel vasculopathy. Although, the non- diabetic ischaemic foot had

only mild intimal hyperplasia and minimal calcification of digital arteries, it did have similar vasculopathy which raises clues to vasculopathy in diabetic foot such as premature ageing.

[P05] HOW NEWLY FORMED OSTEOCLASTS FROM PATIENTS WITH CHARCOT OSTEOARTHROPATHY DEGRADE DIFFERENT TYPES OF BIOCERAMICS IN VITRO?

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Aim:
In Charcot osteoarthropathy, there is excessive osteoclastic activity and reduced osteoblastic function leading to non-healing fractures and bone fragmentation. We hypothesise that targeted therapy with bioceramics could promote fracture healing in the Charcot foot. However, it is unknown whether novel bone substitutes can withstand the enhanced resorption of Charcot osteoclasts. The aim was to investigate how newly formed osteoclasts generated from peripheral blood monocytes derived from people with active Charcot foot degrade different types of bioceramics and carry out bone resorption.
Method:
Osteoclast precursors isolated from whole blood from seven people with active Charcot foot were cultured in the presence of macrophage-colony stimulating factor and receptor activator of nuclear factor-κβ ligand on β-tri-calcium phosphate (β-TCP), hydroxyapatite (HA) and bovine bone discs. Osteoclast formation and resorption were assessed after 21 days in vitro.
Results / Discussion:
There were numerous newly formed multi-nucleated cells (osteoclasts) on all three substrates. Classical resorption pits were noted on β-TCP and bone discs after calcein staining (immunoflluorecence), toluidine blue staining (brightfield microscopy) and surface profolimetry. Pits were significantly shallower on β-TCP discs (average pit depth 9 μm) compared to resorption pits on bone (average pit depth 17 μm).
Although there were numerous giant osteoclast-type cells on HA discs, these cells exerted only surface disintegration of the biomaterial with intracellular digestion (immunofluorescence) but the erosion profile of these surfaces remained unremarkable.
Conclusion:
We report a difference in osteoclast-mediate degradation of biomaterials: on β-TCP surfaces, there was evidence of extracellular resorption similar to bone resorption whereas HA discs remained unresorbed and cellular activity was limited to endocytosis. These differences in cellular behaviour are important and should be taken into consideration when planning therapies with these novel bone substitutes.
Supported by Diabetes UK project grant

[P06] DIABETIC FOOT COSTS

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Diabetic foot represents a severe complication associated with diabetes mellitus imparting loss in health and economic burden. Previous studies showed a hig variability in cost amount. Aim of this study is to analize costs of healing lesions in diabetic patients and verify factors that influence the economic impact.
Materials and methods: observational retrospective study, we included all diabetic patients with a first access for diabetic foot during 2018 in our diabetic foot clinic. We identified 429 patients and we analyzed the in- and out-hospital costs of these patients. Hospital costs derived from DRG calculation. Out-service costs included: first visit, control visits, dressing, acute phase and definitive ortesis. After calculation of global costs we separate patients with ischemia, need of surgical procedures, patients managed only in out service and impact of infection.
Results: treatment of 429 patients for diabetic foot costs 2063000 Euro, hospital stay impacts for the large part 87% (1800000 Euro). We performed 330 hospitalization in 242 patients (1.36 hospitalization for patient with mean duration of hospital stay of 8±10 days), in-service mean cost was 5456±3300 Euro. Out service costs included: 1 first visit, 3±4 control visits, 47±74 dressing, 1 acute phase ortesis and 1 definitive shoe, with mean cost of 660±900 Euro. Ischaemic patients with need of revascularization presented elevated in-hospital costs respect non-ischaemic (p=0.03) and out hospital too (p≤0.001 respect not ischaemic and patients treated only in out service) (table 1).
Moreover we analize impact of infection: patients hospitalized for infection presented a longer hospital stay 13±11 ws 7±9 day compared to not infected (p<0.001), and higher hospitalization cost 6861±3346 ws 5150±3220 compared to non infected (p<0.001)
Conclusions: our cost analysis underline that hospital treatment impact largely on diabetic foot treatment costs. Clinical conditions like ischemia and infection are responsible of increasing amount, efforts to prevent these conditions, with a optimized and early out-service management, can improve diabetic foot outcomes and save money.

Table 1

	Out service cost	p	Hospital cost	p
Ischaemic (290)	915±836	<0.001	5600±3200	0.03
Not ischemic but hospital treatment	752±548		4400±3857	

Only out service treatment	622±915		--	

[P07] ROLE OF CUSTOM MADE INSOLES IN PREVENTION OF NEUROPATHIC DIABETIC FOOT ULCER RECURRENCE

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Aim: Evaluate the role and effectiveness of custom-made insoles (CMI) in prevention or delaying recurrence of neuropathic diabetic foot ulcers (NDFU)
Method: 49 diabetic patients of matched age, sex, and BMI; 17 (intervention) used CMI inside therapeutic shoes, and 32 (control) used therapeutic shoes only, were recruited after healing of previous NDFU. Patients with peripheral arterial disease, foot deformities, and amputation were excluded. Plantar pressure assessment was done using F-scan in-shoe pressure analysis system (TEKSCAN Ltd). Two kinetic measures were collected; plantar peak pressure (PP) and pressure time integral (PTI) at each area. Patients were followed up until a study end point; recurrent plantar ulcer or study termination at 12 months.
Results / Discussion: Big toe was the commonest site of previous ulceration in control and intervention groups (53.1% and 58.82%) respectively, while metatarsal head areas (1, 2) were the 2nd common site (28.1% and 23.6%) respectively; with no significant difference between both groups. Rate of ulcer recurrence was (34.37% vs 17.64%) within first 12 weeks of study ***(p=0.22)***, and (78.1% vs 52.9%) within the study duration (one year) ***(p=0.07)*** in control & intervention groups respectively. CMI decreased significantly PP among patients with ulcer recurrence during one year study in intervention versus control group ***(p= 0.02),*** with no difference as regard PTI ***(p=0.95).*** On the other side, CMI did not decrease significantly PP ***(p=0.51)*** or PTI ***(p=0.35)*** at same sites of previous ulcers among these patients. CMI increased median ulcer free period; 10 months vs. 6 months in control group with no significant difference ***(p=0.09)***. Ulcer recurrence occurred at same site in 12 patients (37.5%) in control versus 7 (41.17%) in intervention group ***(p=0.8).*** Big toe was the commonest site; 13(52%) versus 4(44.4%) in control & intervention groups respectively. In each group, there was no difference as regard PP or PTI between patients with ulcer recurrence versus those without.
Conclusion: CMI are in need for more evidence to prove its role in prevention of NDFU recurrence. Previously published PP thresholds for ulcer recurrence may need to be reassessed. Other factors than PP and PTI may participate in ulcer recurrence.

[P08] FOREFOOT PLANTAR PRESSURE REDUCTION IN THE "CLASSIC" MODEL OF ROCKER-BOTTOM SHOES. WHO ARE THE NON-RESPONDERS?

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Aim of the study was to assess plantar pressure reduction in the rocker-bottom shoes of a given manufacturer and analyse the possibility to predict shoes efficacy without pedographic assessment.

Method: In-shoe pressure distribution analysis in 20 patients (40 feet) with a high risk of diabetic forefoot ulcers was performed. According to clinical data, the risk regions were determined on the plantar foot surface, where the healed ulcer or pre-ulcerative lesions were located. In-shoe pedography (Pedar, Novel, Germany) was performed in shoes usually worn by the patients, and in orthopaedic shoes "Sursil-Ortho" (Moscow). The maximum peak pressure (MPP) was estimated for the 7 plantar areas (lateral and medial heel, midfoot, lateral and medial MTHs, hallux, smaller toes). Criteria of efficacy were achieving MPP in the risk region <200 kPa or reducing it by at least 25%.

Results / Discussion: The median MPP for the risk region decreased from 209 (138-588) to 151 (5-412) kPa ($p<0,001$). Among the forefoot areas, pressure reduction degree varied from -21% (hallux) to -34% (lateral MTHs). The percentage of feet with MPP >200 kPa in the risk region decreased from 58% to 30% ($p=0,014$), in any area of the forefoot – from 63% to 30% ($p=0,04$). According to the chosen criteria, the tested footwear was effective in 71% of cases. There was no significant difference in gender, age, type of diabetes, previous ulcers or amputations prevalence between patients with sufficient (28 feet) and insufficient (12 feet) effect. The subgroup of "non-responders" had higher baseline MPP in the risk region (304 vs 196 kPa, $p<0,01$), the more frequent appearance of the risk region at hallux (58 vs. 25%, $p=0.043$) and less frequent - at the lateral forefoot (42 vs. 86%, $p=0.005$). Statistical analysis using Spearmen correlation showed that location of the risk area was an independent factor predicting effect of the shoes.

Conclusion: The studied model of rocker-bottom shoes effectively reduced plantar pressure in 71% of feet. The only factors which may predict insufficient response were location of the risk area (higher risk at hallux, lower - at lateral MTHs) and baseline peak pressure.

[P09] BIOMECHANICS OF MIDFOOT CHARCOT NEUROARTHROPATHY IN PEOPLE WITH DIABETES

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Aim: The aim of this study was to describe biomechanical features of midfoot Charcot neuroarthropathy (CN) in people with diabetes.

Method: Participants with diabetes and a diagnosis of midfoot CN confirmed by MRI were consecutively recruited across four clinics in NHS Lanarkshire. Participants underwent 3D motion capture, electromyography (EMG) and plantar pressure analysis. 3D kinematics and kinetics were derived from a five-segment musculoskeletal model with segments for the shank, rearfoot, midfoot, forefoot and hallux. EMG for major muscles in the leg was recorded while plantar pressure was analysed for selected regions of interest.

Results / Discussion: Two females and four males (age range 26-63 years) were recruited with a total of 7 affected feet across different stages of the disease. Intersegment kinematic patterns were highly variable between participants. Midfoot CN could be characterised by reduced movements between the midfoot and forefoot segments across all planes. The majority of participants exhibited no plantarflexion between the midfoot and rearfoot segments. Between the rearfoot and shank segments there was limited plantarflexion. Ankle moments and joint power were markedly reduced. Altered muscle function was notable for all major lower leg muscles tested. During plantar pressure analysis, the largest peak pressures were exhibited in the lateral midfoot. Increased contact areas were observed for the heel and midfoot regions.

Conclusion: Midfoot CN is characterised by important changes in foot biomechanics. These foot biomechanics are highly variable and consistent with individual patterns of foot pathology.

[P10] DIABESITY AND THE FOOT: A TRUCK ON SCOOTER'S WHEELS.

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Aim: To evaluate the distinct contribution of obesity (O) and diabetes (DM) to skin modification in metabolic diseases.

Method: we analysed all patients admitted for bariatric surgery in our Hospital with body mass index (BMI) between 38 and 47 kg/m^2, with (Group 1) or without (Group 2) DM and compared them with non obese diabetic (Group 3) and healthy volunteers (Group 4). We compared: skin hydration score (SHS), skin temperature (ST), ultrasound (US) skin and subcutaneous thickness and anthropometric measures.

Results / Discussion: Between March and September 2018, 120 patients were enrolled. As predictable patients differed in age and BMI. Foot and leg circumferences were significantly higher in O without differences depending on DM ($p<0.01$ in Group 1 and 2 vs 3 and 4). ST was significantly higher in O, irrespectively from DM ($p<0.01$ Group 1 and 2 vs 3 and 4). SHS showed anhydrosis both in diabetics and in severe obesity ($p<0.01$ Group 1 and Group 3 vs Group 2 and Group 4). US revealed in heel and scaphoid region an increase in thickness of skin and subcutaneous tissues (at heel $p<0.01$ Group 1 and 2 vs 3 and 4 and under the scaphoid $p=0.03$ Group 1 and 2 vs 3 and 4) and plantar fascia ($p=0.02$ Group 1 and 2 vs 3 and 4) in all obese.

Conclusion: Severe obesity significantly affect both shape and structure of the foot increasing risk of biomechanical stress while DM modifying skin hydration exerts a synergistic role further increasing the risk of trauma and ulcers.

[P11] EFFECTS OF A 12-WEEK INTERVENTIONAL EXERCISE PROGRAMME ON THE FITNESS, BIOMECHANICS AND SAFETY OF PATIENTS WITH DIABETIC FOOT IN REMISSION: THE BIONEDIAN RANDOMISED CONTROLLED TRIAL

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Aim:To evaluate the effect of an interventional exercise programme on the foot biomechanics, fitness and safety of patients with diabetic foot in remission.

Method: Thirty-eight patients with type 2 diabetes and DF without active lesions (mean age 65±6.9 years, HbA1c 59.2±15.1 mmol/mol, BMI 32±4.7 kg.m^{-2}) were enrolled as part of a randomised controlled study. All subjects were randomised into two groups: an intervention group (I)(n=19) and a control group (C)(n=19).The 12-week exercise intervention focused on ankle and small-joint mobility in the foot, strengthening and stretching of the lower extremity muscles, and improving fitness. We assessed changes (Δ=final minus initial results) in physical activity using the International Physical Activity Questionnaire (IPAQ) in respect of heavy/moderate forms of physical activity, joint mobility by goniometry, muscle strength by dynamometry, and fitness using a senior fit test.

Results: Due to reulceration, we excluded 15.8% of patients from group I (3/19) and 15.8% of patients from group C. Based on the IPAQ, group I was more active in terms of heavy (p=0.03) and moderate physical activity (p=0.06) after intervention compared to group C. Group I improved significantly after the intervention in respect of plantar flexion (left foot: Δ 7±8 vs.-2.2±4.8 degrees, p=0.0004; right foot Δ 5.9±4.6 vs. -1.9±8.1 degrees, p=0.005), dorsal flexion (left foot: Δ 3.7±4.8 vs. 0±4.1 degrees, p=0.03; right foot: Δ 2.5±5.5 vs. 0.3±4.6 degrees, p=0.15) and larger-joint flexibility (p=0.012) compared to controls. Similarly, dynamometric parameters increased significantly in both lower limbs in group I (both legs: Δ 94.8-96.8±87.6 vs. 11.9-24.2±93.6-108 N, p=0.003-0.016) compared to group C. We found a positive trend in fitness in group I compared to group C (p=0.25). We also confirmed positive correlations between heavy physical activity and plantar flexion (r=0.43; p=0.016), selected parameters of flexibility (r=0.47;p=0.007), the senior fit test (r=0.453; p=0.011) and dynamometry (r=0.68;p<0.0001).

Conclusion: Our 12-week interventional exercise programme proved relatively safe, resulting in improved foot mobility, body flexibility, and increased muscle strength in DF patients without active lesions. We recommend introducing such interventional programmes in order to reduce the risks of DF development and reulceration in patients with diabetic foot in remission.

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[P12] DOES THE SKIN HEAT UP BEFORE IT BREAKS DOWN INTO DIABETIC FOOT ULCERATION?

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Aim: Most diabetic foot ulcers are caused by repetitive plantar tissue stress from being ambulatory and suggested to be preceded by a local increase of temperature due to inflammation: "the skin heats up before it breaks down". However, the evidence to support this is meagre at best. We aimed to investigate whether diabetic foot ulcers are preceded by increased local skin temperatures.
Method: 151 participants with diabetes, peripheral sensory neuropathy and a history of ulceration measured temperatures at 6-8 plantar locations on both feet daily, for 18 months or until ulceration. A 'hotspot' was defined as a skin temperature difference >2.2°C for two consecutive days between the same locations on both feet. Participants with a non-traumatic ulcer were classified by having, in the two months prior to ulceration: 1) a true hotspot: a hotspot at or close to the ulcer; 2) a false hotspot: a hotspot at another location; 3) no hotspot. 'Lead time' was the time between the first measurement of a hotspot and ulceration, and we recorded the time between the last measurement of a hotspot and ulceration ('last hotspot').
Results / Discussion: Forty-four participants had a plantar non-traumatic foot ulcer, of which 29 had at least two months of temperature profiles up to ulceration. Eight participants (28%) had a true hotspot (mean (SD) lead time: 37 (14) days, last hotspot: 9 (9) days), seven (24%) a false hotspot (lead time: 29 (17) days, last hotspot: 18 (16) days), and 14 (48%) did not have a hotspot. We found no differences between these groups in demographics, foot and ulcer characteristics. These findings are in contrast with current evidence and the suggested mechanism of skin heating-up from repetitive plantar tissue stress in people with diabetes.
Conclusion: The majority of plantar non-traumatic diabetic foot ulcers in people who are at high risk for developing a foot ulcer do not heat up before they break down. This questions the proposed local temperature increase following repetitive stress during foot ulceration, and implicates that a more careful selection of people with diabetes who might benefit from at-home foot temperature monitoring is necessary.

[P13] BIOMECHANICAL STUDY OF CHARCOT SPECIFIC IMPLANTS FOR INTRAMEDULLARY FIXATION

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Aim: Over the past two decades, an increased number of patients have undergone reconstruction of diabetic Charcot neuroarthropathy (DCN), employing various methods of fixation (internal fixation, external fixation and hybrid techniques). Despite advances in implant technology and our understanding of DCN pathophysiology, complication rates of realignment arthrodesis remain high. This study examined the biomechanical properties (four point bending, cantilever bending and thread pull out resistance) of intramedullary implants designed for midfoot DCN reconstruction. The large implants included A1: 7.4 mm cannulated stainless steel beam, B1: 6.5 mm solid titanium bolt and C1: 7.0 mm cannulated titanium beam. Smaller implants included A2: 5.4 mm cannulated stainless steel beam and C2: 5.0 mm solid titanium bolt.
Method: 4-point bending testing compared flexural properties (static and dynamic) of the body of the implants. Cantilever-bending testing was performed with the maximum bending moment being applied off the main thread of the implant to assess the thread portion. Thread pull out strength was tested by fixing the implants to a Sawbone block on a platform, and the distal portion of the implant in a clamp connected to loading actuator.

Results / Discussion:

(Large Implants) Implant A1 demonstrated higher stiffness, force to failure, and fatigue compared to implants B1 and C1 ($p<0.05$). Pull-out strength of implant A1 was higher than implant B1 ($p<0.05$). Thread fatigue strength of implant A1 was higher than implant C1 ($p<0.05$).
(Small Implants) Implant A2 demonstrated higher stiffness, force to failure, tip fatigue strength and thread pull out strength compared to implant C2 ($p<0.05$), while implant C2 demonstrated higher body fatigue failure than implant A2 ($p<0.05$).
Conclusion: Alteration of beam or bolt parameters (thread shape, thread depth, material, and diameter, solid or cannulated) can influence the biomechanical performance of implants used in Charcot reconstruction. Greater stiffness of an implant resists deformation, providing improved stability. Greater static failure load and fatigue limit improves the implant's ability to withstand higher and repetitive loads before yielding or failing This study should stimulate further clinical research to determine if these biomechanical properties translate into reduced implant failure rates and improved clinical outcomes in patients with DCN.

[P14] IS GENDER ASSOCIATED WITH RISK FACTORS TO DEVELOP FOOT ULCERS?

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Aim

To evaluate if gender is associated with risk factors to develop diabetic foot ulcers.

Method

Risk factors to develop diabetic foot ulcers was examined by using the D-Foot. D-Foot is a software for daily use by Prosthetist & Orthotists and Podorthotists in the Region Västra Götaland, Sweden.

Patients with diabetes (type 1 n=33, type 2 n=64) age 64 ± 13 years, duration with diabetes 17 ± 14 years and BMI 28 ± 5 were included. Based on questions to the patients and assessments, a risk classification was generated from the software. Differences between genders was compared and analyzed with Chi-square test, α-level 0.05.

Results

In table 1 the number of risk factors is presented alongside with the statistics.

Table 1.

Risk factors	***Women n=42***	***Men n=55***	***Value***	***α-level***
Tingling/numbness	19	31	0.945	0.331
Decrease of sweating in the feet	11	19	0.651	0.420
Previous ulcers	8	8	0.417	0.518
Sensory loss (Ipswich Touch test)	16	32	3.448	0.063
Prominent, superficial bony structures	18	19	0.697	0.404
Areas of excessive pressure with callosities	17	30	1.887	0.169
Ulcer #	1	6	2.587	0.108
Insufficient function of the toes/forefoot	12	17	0.062	0.803
Charcot #	1	0	1.323	0.250
Inappropriate shoes	9	25	6.038	0.014*
Hallux valgus/varus	10	12	0.054	0.816
Calcanei valgus/varus	13	15	0.157	0.692

Add/abduction in the forefoot	14	16	0.201	0.654
Callosities	13	26	2.638	0.104
Medial/lateral collapsed heel counter	9	14	0.213	0.644
Excessively worn-out sole	14	19	0.016	0.901
Gait deviation, foot flap/toe drag	2	5	0.667	0.414
Gait deviation, affected from hip/knee	17	16	1.375	0.241
Amputation	0	0	n/a	n/a

Note: differences between genders was analyzed with Chi-square test, degree of freedom = 1.

**alfa-level ≥ 0.05*

 # 2 cells (50,0%) have expected count less than 5.

Conclusion

Men were more likely to wear inappropriate shoes. Improvements in self-care of their feet and use of appropriate shoes may reduce risk of achieving a DFU.

[P15] SHARED PATIENT AND MULTIDISCIPLINARY FOOT TEAM EXPERIENCES IN USING A HANDS-FREE SINGLE CRUTCH AS A NOVEL THERAPY IN THE POST-OPERATIVE REHABILITATION OF DIABETES RELATED FOOT COMPLAINTS.

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Aim: The aim of this study was to report shared patient and health care practitioner experiences in the use of a hands-free single crutch (HFSC) as a novel therapy in the post-operative rehabilitation of diabetes related foot complaints.
Methods: Over an 18-month period, six inpatients chose to self-purchase an HFSC for use in their post-operative rehabilitation. This is a removable device that can be attached to the thigh and acts as an extension to the leg, transmitting weight through a flexed knee whilst allowing use of the upper extremities (Figure A). During inpatient therapy, an assessment of ability to mobilise along a 100 metre walkway was undertaken before discharge.
Figure A: An example of a hands-free single crutch

Results: Within this cohort, 83% were male, 67% had Type 2 Diabetes, age (mean±SD) 55±11 years and HbA1c (mean±SD) 81±26 mmol/mol. Pre-admission, all patients were fully weight-bearing independently except for one who was performing standing transfers only. The reason for admission were three elective reconstructions, two emergency minor lower extremity amputations with surgical washout and one for calcaneal osteomyelitis.
Post-operatively, the affected foot was immobilised in four patients using a total contact cast and two patients using a knee-high, removable cast. The contralateral foot was intact in four patients who wore their own footwear and two patients had a diabetes foot ulcer who wore an offloading shoe when weight-bearing. For the 100 metre walkway test, four patients were independent in using the HFSC, one patient used the HFSC and two elbow crutches, and one patient was unable to use the

HFSC with or without support. No falls were observed during their admissions. Five patients were discharged using the device. On outpatient follow up of these five patients at 12 weeks, two continued to mobilise independently with the device. Of the remaining three patients, two had discontinued use citing fatigue and discomfort and one patient had swapped to an alternative assistive device.

Conclusion: This observational study using the HFSC as a novel therapy in the post-operative rehabilitation of diabetes related foot complaints found mixed results. The success of its use in two patients is promising.

Reference:

iWALKFree. (2018) *iWALK 2.0 Introduction*. Available at: https://iwalk-free.com/product-introduction/ (Accessed 24 April 2020).

[P16] LIMITED ACCESS TO PODIATRY, ANNUAL FOOT CHECK AND INFORMATION ABOUT SELF-CARE FOR PATIENT AT HIGH RISK TO DEVELOP DIABETIC FOOT ULCERS

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Aim

1) To evaluate the risk to develop diabetic foot ulcers (DFU) and to assess the risk factors in a group of patients visiting a department of prosthetics & orthotics and
2) to evaluate if patients, at risk, are offered the recommended interventions e.g. podiatry, annual foot check and information about self-care.

Method

Risk factors were registered (2017-2020) by using a web program, the D-Foot, before patients were provided with assistive devices (insoles/shoes/orthotics).

Results / Discussion

A total of 192 patients with diabetes, 58 (30%) type 1; 132 (69%) type 2; 2(1%) other types were included. Mean age (±SD) were 66±14 years; duration 20±16 years, HbA1c 61±18 mmol/mol and BMI 28±6. Four (2%) were classified in risk group 2 and 162 (84%) and 26 (14%) were in risk group 3 and 4 respectively. Certified prosthetists and orthotists made the examinations and these risk factors were registered. Right foot is presented:
Neuropathy: numbness/tingling sensation were present in 125 (65%); positive Ipswich Touch Test and less sweaty feet were present in 87 (45%) and 58 (30%) of the patients respectively.
Foot deformities: 93 (48%) had pes planus; 23 (12%) had pes cavus; 81 (42%) had hallux valgus; 6 (3%) had hallux varus. Limited range of motion (defined as 0 degree) at hallux joint or at ankle joint were present in one patient respectively. Zero patients had acute Charcot but one patient had manifest Charcot deformity.
Skin pathologies: 54 (28%) had had DFU, 15 (8%) had DFU and 61 (32%) had callosities.
Interventions
Thirty-two patients (16%) experienced that they not had an annual foot check within the last 12 months; 76 patients (40%) reported the lack of podiatry and 62 (32%) had not been informed about self-care of the feet.

Conclusion

The availability of preventative interventions (podiatry, annual foot check and information about self-care) varies in a group of patients with DFU or high risk to develop DFU. There is a need to implement strategies so that patients that have an increased risk to develop DFU are offered the recommended interventions. The goal, for the patient, is to prevent DFU thus improving foot health, quality of life and independence in daily living.

[P17] CORRELATION OF SKIN ADVANCED GLYCATION END PRODUCTS WITH VIBRATION PERCEPTION THRESHOLD IN SUBJECTS WITH TYPE 2 DIABETES MELLITUS

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Aim: To study the association between skin AGEs and vibration perception threshold (VPT) on the foot in subjects with T2DM.
Method: Overall, 40 subjects (20 males, 20 females) were included in the study. Mean age was 63.9±4.5 years and mean T2DM duration 13.6±2.2 years. Skin AGEs were measured with AGE reader mu connect (Diagnoptics) on the dominant arm. Single and triplicate measurements were performed. VPT was measured with a neurothesiometer (Horwell Scientific Laboratory Supplies) on the hallux of both feet.
Results / Discussion: In single measurement, AGEs were significantly correlated ($p<0.05$) with VPT on the right ($r=0.73$) and left ($r=0.62$) hallux. Similarly, triplicate measurement of AGEs showed their significant correlation ($p<0.05$) with VPT on the right ($r=0.72$) and left ($r=0.61$) hallux.
Conclusion: These preliminary results point to a positive correlation between skin AGEs and VPT in T2DM. Further studies are warranted in order to investigate the potential correlations between skin AGEs and other attributes of nerve fibre impairment in T2DM.

[P18] INTER-RATER AGREEMENT OF VIBRATION AND PRESSURE SENSATION IN THE ASSESSMENT OF SENSORIMOTOR DYSFUNCTION IN DIABETES

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Aim: Assessment of large fibre dysfunction is based on tuning fork (TF) for vibration perception and on monofilament (MF) for pressure sensation. Herein we examined the inter-rater variability of the MF and TF alongside with the VibraTip™ (VT), a new measure of vibration perception.

Method: We recruited 100 subjects with diabetes. Patients with active ulcers or peripheral vascular disease were excluded. A consultant diabetologist (CD) initially performed a general physical and foot examination at each foot which included MF, TF and VT. The tests were then performed by a podiatrist (P) and a diabetes specialist nurse (DSN) and the results were compared among the healthcare professionals (HCP); each examiner was blinded to the results of the other examiners. Inter-rater agreement was determined by weighted kappa (k) statistics; k values 0.41-0.60 represent moderate agreement, 0.61-0.8 good and >0.81 very good agreement.

Results / Discussion: Diagnosis of insensation (%) by the CD, P and DSN were as follows: MF insensation 37.5%, 34.5% and 34.0%, respectively; TF insensation, 48.0%, 31.5% and 45.0%, respectively; VT insensation 39.0%, 35.0% and 35.5%, respectively. The inter-rater agreement (k, 95% confidence intervals) between the CD and the P, the P and the DSN as well as the CD and the DSN were as follows: TF 0.62 (0.52-0.73), 0.62 (0.51-0.72), 0.68 (0.57-0.78), respectively; MF 0.67 (0.57-0.78), 0.70 (0.59-0.80), 0.73 (0.63-0.83), respectively; VT 0.72 (0.62-0.82), 0.70 (0.60-0.81), 0.67 (0.56-0.78), respectively. The k statistics suggested good level (>0.60) of agreement of the three neurological modalities between the HCP. Despite the differences observed in the ability of various tests to diagnose reduced sensation, there is good overall agreement in the results of neurological examination by MF, TF and VT between HCP.

Conclusion: Among three different HCP there is good overall agreement in the assessment of large fiber neuropathy by MF, TF and VT. Further research is required to examine the performance of these tests in the diagnosis of neuropathy.

[P19] DIABETIC NEUROPATHIC FOOT - RISK AND PROGNOSIS

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Peripheral neuropathy in persons with diabetes is an underdiagnosed complication which may cause foot deformities. Often the diagnosis is misdiagnosed due to patient dependent and subjective assessment method such as biothesiometri and monofilament. An early detection of diabetic peripheral neuropathy is crucial.

Aim: For this study is to test a new extended assessment form concerning foot deformities and novel point-of-care tools for peripheral neuropathy, compared to the presently used method.

Methods: Persons with type 1 and 2 diabetes and peripheral neuropathy randomly recruited from a new neuropathy screening project at our center. Distal sensimotor peripheral neuropathy (DSPN) was assessed by using both biothesiometri and DPNCheck, sudoscan (sudomotor function) and detection of protective sensation by monofilament and pinprick. Detailed registration of mild deformities without callus; severe deformities abundant callus and/or limited joint mobility.

Results:

Preliminary data of foot deformities and neuropathy in 17 randomly selected persons were evaluated. 12 (71%) persons had deformities, of which four (24%) had mild and eight (47%) severe foot deformities. The mean age of the persons was 69,3 years (±17,0), 53% were males, 82% had T2D, mean Hb1Ac of 55,8 mmol/l (±26,2).
DSPN was present in total of 11 (65%) when assessed by biothesiometri (vibration threshold over 25V), 12 (71%) when assessed by DPNCheck (reduced sural nerve conductance velocity or amplitude). Three (18%) with normal nerve conduction. Ten (59%) had low electrochemical skin conductance when assessed by sudoscan.

Conclusions:

Vibration sensation along with pinprick and monofilament may not be a sensitive single test for diagnosis of peripheral neuropathy or loss of protective sensation. DPNCheck may seem to give an earlier detection of neuropathy in comparison with sudoscan, it can be useful in screening of low risk patients.
Foot deformities are common for persons with diabetes and neuropathy. We assume neuropathy contributes to foot deformities, persons may have reduced protective sensation and increased risk of strain caused by neuropathy. Imperative to prevent and detect neuropathy. A larger study is needed and is ongoing in our center.

[P20] A CALL FOR CARDIOLOGISTS AND DIABETOLOGISTS TO EMBRACE NEUROLOGICAL INVESTIGATION FOR DIABETIC NEUROPATHY IN CARDIOVASCULAR RISK STRATIFICATION

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Aim: In the 2019 ESC Guidelines on diabetes, pre-diabetes and cardiovascular diseases, only retinopathy appears as a target organ damage as a parameter for stratification patients into very high-risk group. The aim of study was to check the strength of association between DN and isolated DR groups with cardiovascular complications.
Method: Chronic kidney disease (CKD) was defined by eGFR $\leq$59 mL/min/1.73 m^2 and proteinuria (PrU) was determined (mg/24h). Neuropathy was diagnosed by neuropathy disability score and sudomotor function using Neuropad®. Presence of coronary artery disease (CAD) and cervico-cerebral ischaemic aterial disease (CCAD) was documented. Lower-extremity artery disease (LEAD) was diagnosed with ankle-brachial index (ABI) and continuous wave Doppler.
Results / Discussion: Of 262 people, 49.6% were male and 71% had T2DM; 130 had DN [90 (69.2%) with retinopathy], 75 had DR without neuropathy, 57 had no evidence of retinopathy, CKD and DN (controls). All (n=48) CKD patients were with DR and/or DN: 15(31.3%) with DR, 10 (20.8%) with DN, 23 (47.9%) with both DN and DR. Patients with DN compared with controls after multivariable logistic regression analysis (MVLR) significant remained model: age (OR 1.16 [95% CI: 1.07-1.25]; p<0.01), duration of diabetes (1.12 [1.05-1.19]; p<0.01), PrU (1.003 [1.00-1.005]; p=0.06), NeuroPad® time 1.11 [1.00-1.22]; p=0.04). Compared with controls, those with DR were more frequently women (62.7% vs. 42.1%; p=0.01) and older (54.8±14.6 vs. 45±12.8 years; p<0.01), had high blood pressure (49.3% vs. 26.3%; p<0.01), T2DM (69.3% vs. 43.9%; p<0.01), had longer duration of diabetes (17.1±7.7 vs. 10.2±7.4y.; p<0.01). After MVLR only duration of diabetes (OR 1.12 [1.05-1.19]; p<0.01) persisted.
DN group was significantly more associated with macrovascular complications (CCAD, CAD, LEAD) [n=56 (43.1%)] vs. DR group n=16 (21.3%) and control group n=9 (15.5%); p<0.01. CAD (n=43) in univariate analysis showed association with DN (OR 2.4 [1.2-4.8]; p=0.01), and in MVLR anaylsis with LEAD (OR 3.4 [1.6-7.1]; p=<0.01).
Conclusion: In the algorithm for cardiovascular risk stratification we would recommend examination of diabetic neuropathy and LEAD as the first line approach. As earlier these complications would be detected the indication for more comprehensive management of diabetic patients would be established.

[P21] HISTORY OF DIABETIS FOOT AMPUTATIONS IS THE MAIN RISK FACTOR OF SEVERE CARDIOVASCULAR AUTONOMIC NEUROPATHY

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Aim: Peripheral nerve dysfunction (PDN) and Cardiac autonomic neuropathy (CAN) are independent predictors of severe cardiovascular events, morbidity and early death among patients with diabetes. We estimated the risk factors of CAN in diabetic patients with PDN and history of diabetic foot amputations.

Method: We examined 76 patients with type 2 diabetes (24 patients without PDN, 26 with PDN and 26 with PDN and previous history of diabetic foot amputation). Anthropometric measurements, biochemical parameters, clinical neurological examination with evaluation according to the Neuropathic Disability Score (NDS) were performed. CAN was determined using several cardiovascular autonomic reflex tests (CARTs) and was defined on three groups: CAN 0 (all CARTs were normal), CAN 1 (possible/early CAN - one abnormal CART was presented), CAN 2 (definite/confirmed CAN –at least two abnormal CARTs were found), CAN 3 (severe/advanced CAN – in the cases of orthostatic hypotension in addition to CARTs abnormalities).

Results / Discussion: CAN 1 was found in 8% patients without PDN, 42 and 21% patients with PDN and history of diabetic foot amputations respectively. CAN 2 was diagnosed in 27% patients with PDN and 58% patients with history of diabetic foot amputations. CAN 3 in 8% and 19% cases respectively. The predictors of confirmed/severe CAN turned out were diabetic foot amputations in anamnesis (OR = 4.9, 95% CI 1.1-7.1; $p<0.05$) and NDS > 10 score (OR=4.1, 95% CI 1.2-7.1; $p<0.05$). The predictors of any stages of CAN were also history of diabetic foot amputations (OR=18.6, 95% CI 3.2-32.7; $p<0.05$), NDS > 5.25 score (OR=6.7, 95% CI 1.2-10.9; $p<0.05$) duration of diabetes > 4 years (OR= 1.6, 95% CI 0.8-2.2; $p<0.05$), HbA1c> 6.8% (OR= 1.5, 95% CI 0.8-2.2; $p<0.05$).

Conclusion: The history of diabetic foot amputations and severe PDN are the main predictors of confirmed/severe CAN in diabetic patients. All these patients should be examined to determine the CAN stages.

[P22] VIBRASCAN: A PLATFORM-BASED TOOL FOR THE ASSESSMENT OF DIABETIC NEUROPATHY

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Aim: To develop an extensive vibration-based tool for the early detection of diabetic neuropathy.

Method: The limitations of existing device named Neurothesiometer was thoroughly studied. Based on that, platform-based operator independent device named VibraScan was developed. It consists of a switch, vibration actuators, user friendly application and light strip to indicate severity level. Subject may sit on a chair, place their feet on the device by holding a switch to indicate vibration threshold. In order to generate required nature of vibration (i.e. amplitude and frequency), actuators were programmed using pulse width modulation technique. The vibration amplitude and frequency were calibrated like Neurothesiometer, however, the method of conducting the test is totally different. In order to compare these devices, twenty healthy volunteers were invited for conducting the experiment. VibraScan and Neurothesiometer were alternately applied to measure vibration perception threshold (VPT). The VPT measurements from devices were noted for each foot. For comparison, Bland and Altman's plot was used to determine the agreement between two methods of measurements [1].

Results: The Bland and Altman plot shows a close agreement between two measurements techniques. For right foot the 95 % of subject VPT lie within ± 0.344 mean difference and for left foot, 95% of subject VPTs lie within ± 0.236 mean difference.

Conclusion: This shows that VibraScan can be used for neuropathy assessment. The method of independently measuring VPT, wirelessly operated, programmable and automatically determining severity level makes the VibraScan an unique and advanced tool for assessing diabetic neuropathy.

Reference:

1. Bland JM, Altman D. Statistical methods for assessing agreement between two methods of clinical measurement. The lancet. 1986 Feb 8;327(8476):307-10.

[P23] ARE THE PROPERTIES OF PLANTAR SOFT TISSUE AND ACHILLES TENDON THICKNESS AND STIFFNESS ALTERED IN PEOPLE WITH DIABETES? A SYSTEMATIC REVIEW

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Aim: To critically evaluate and synthesise evidence for plantar soft tissues and Achilles Tendon thickness and stiffness properties in diabetes.
Methods: Following PRISMA guidelines, six electronic databases were systematically searched for studies published from database inception until February 2020 [Prospero CRD42020166614]. The databases searched include: AMED, CINAHL, MEDLINE, ProQuest Health & Medical Collection, ProQuest Nursing & Allied Health Database, and Web of Science. No date restrictions were imposed, however studies were restricted to those published in English and in peer-review journals. Two reviewers independently screened all titles and abstracts against pre-established criteria. Reference lists of all included studies were also screened. Discrepancies were resolved by consensus or third reviewer adjudication. Following this, all included studies were appraised for methodological quality and risk of bias.

Results / Discussion: 37 non-randomised observational studies were eligible for inclusion, giving a pooled diabetes cohort of 1,442 and 911 controls. Overall findings are summarised in Table 1, however the strength of these findings is marred by the poor quality of evidence and an ineliminable risk of bias; it is difficult for bias to be accurately determined due to insufficient reporting of relevant details. For plantar tissue thickness, 11/21 studies (52%) showed no statistically significant differences between diabetic and control groups. For plantar tissue stiffness, 14/21 studies (67%) showed a statistically significant increase in people with diabetes. For Achilles tendon thickness, 4/8 studies (50%) found a statistically significant increase in people with diabetes. Of the 4 available studies examining Achilles tendon stiffness, results were inconsistent. Marked heterogeneity was observed in the technologies and methods utilised across all studies, precluding the possibility of conducting a meta-analysis.
Conclusion: Although there appears to be a trend towards increased plantar soft tissue stiffness in people with diabetes, evidence for changes these tissues, as well as Achilles tendon thickness and stiffness, in the diabetic foot is inconclusive largely due to poor-quality evidence, methodological flaws and unclear risk of bias within the studies. As the thickness and stiffness of these structures could directly contribute towards diabetic foot ulceration risk, high-quality studies in well-defined populations are necessary to elucidate this ambiguity. Understanding this could be important towards the early identification and thus prevention of those at greatest risk of developing diabetic foot ulcerations.

Table 1: Summary of findings

	PTT	PTS	ATT	ATS
Total papers	21	21	8	4
↑	3 (14.3%)	14 (66.7%)	4 (50%)	1 (25%)
↓	2 (9.5%)	0	0	1 (25%)
Nil dx	11 (52.4%)	2 (9.5%)	2 (25%)	0
Others	5 (23.8%)	5 (23.8%)	2 (25%)	2 (50%)

Abbreviations: PTT = plantar tissue thickness; PTS = plantar tissue stiffness; ATT = Achilles tendon thickness; ATS = Achilles tendon stiffness; ↑ = statistically significant increase for the diabetic cohort; ↓ = statistically significant decrease for the diabetic cohort; Nil dx = No statistically significant differences between the diabetic and control cohorts; Others = findings varied depending on anatomical regions or groups examined.

[P24] THE EMERGENCE OF PERIPHERAL ARTERIAL DISEASE IN PEOPLE WITH DIABETES IN DAR ES SALAAM, TANZANIA: THE NEED FOR URGENT INTERVENTION

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Background / Aim: The incidence of diabetic foot ulcers is increasing over the past three decades. In 1980's and 1990's vast majority foot ulcers (>80%) were neuropathic in origin and not peripheral arterial diseases (PAD). However, over the past decade, there has been a noticeable increase in PAD among persons who attend DM clinics in Africa. We carried out this study to characterize the epidemiology of PAD in this population and identify attributable risk factors.

Method: During Jan 2014 through Dec 2018 (study-period) and following informed consent, patients who attended diabetes outpatient clinics with foot ulcers were evaluated. Detailed epidemiologic and clinical data were recorded in a standardized questionnaire and included demography, educational level of individuals, social habits and patient outcomes. Logistic regression was performed and adjusted odds ratio (AOR) and 95% confidence intervals (CI) were calculated.

Results / Discussion: Of 5,687 subjects enrolled during the study period, 3,621 (65%) were male; median BMI was 26.5 kg/m^2; median age and diabetes duration were 57 and 8 years, respectively. All patients had some degree of PN; and 28% had PAD. Ischemic heart disease was uncommon (0.4%). Independent factors associated with PAD included hypertension (AOR: 1.3, CI: 1.1-1.5); tobacco (AOR: 1.4, CI: 1.2-1.7); major amputation (AOR: 3.2, CI: 1.9-5.9); or death (AOR: 2.2, (1.6-3.0).

Conclusion: We documented a significant increase in the prevalence of PAD in persons with diabetes who attend outpatient clinics. The increase appears to be linked to hypertension and tobacco and likely reflects the situation for persons with diabetes across the African continent. Reasons for this increase include urbanization of African communities, more sedentary lifestyles, lack of exercise, and diet. PAD is now playing a more substantial role in the causation of foot ulcer in Africa than was previously thought.

[P25] FALLS IN PATIENTS WITH AND WITHOUT DIABETES - A CONSEQUENCE OF NEUROPATHY?

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Aim: Falls are a common reason for hospitalization with limited data regarding differences in people with (Group1) and without (Group2) diabetes mellitus (DM). The aim of this study was to examine differences in demographic, clinical, as well as comorbidities, in these two groups who were hospitalized after falls.
Method: In this retrospective study we examined all falls in two teaching hospitals from June 2017 until August 2019. 458 patients (Group1: n=109; age 75.8 ± 9.6; 22 men and 87 women; Group2: n= 349; mean age 76.0 ± 8.9 years; 72 men and 277 women) admitted after falls were included in the study.
Results / Discussion: Falls were more common in women than men (79.5 vs 20.5%), while no gender differences were found between patients the two groups (p=0.569). Neuropathy was more common in Group1 than Group2 (30.3 vs 15.2% p=0.001); but no differences in foot deformities and amputations. Common comorbidities and acute diseases reported during admission (Group1 vs Group2) were: hypertension (82.6 vs 83.1%), visual impairment (65.1 vs 57.0%), chronic kidney disease (57.8 vs 62.8%), heart disease (38.5 vs 45.8), dizziness (37.6 vs 39.8%), fatigue (37.6 vs 38.4%), cognitive impairment (19.3 vs 18.9%,), palpitation (13.8 vs 17.2%), osteoporosis (10.1 vs 14.6%,), head trauma (11.9 vs 12.0%), COPD (9.2 vs 11.7%), hemorrhage (10.1 vs 8.0%), muscle weakness (11.9 vs 10.3%), alcohol consumption (10.1 vs 6.3%) and reduced consciousness (7.3 vs 6.9%); for all P=NS. Low back pain and stroke was more in patients in Group1 vs Group2 (33.9 vs 23.2%, p=0.025; 17.4 vs 10.6, p=0.057). Significantly more patients in Group1 used b-blockers compared to Group2 (50.5 vs 15.2%, p<0.001). The median value (interquartile range) of hospital stay was similar between Group1 [8 (6.25-9.0)] and Group2 [8 (6.0-9.0) days, p=0.938).
Conclusion: In this study, falls were four times more common in women than men. Neuropathy was more frequently found in patients with DM hospitalized for falls. No differences were found in other comorbidities, clinical, demographic and biochemical characteristics between groups. Common comorbidities reported by patients who fell were hypertension, visual impairment, chronic kidney disease, heart diseases and dizziness.

[P26] GENDER DIFFERENCES IN DIABETIC FOOT ULCER SEVERITY AND OUTCOME IN BELGIUM

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Aim: Identify gender differences in comorbidities, ulcer severity and outcome during a 6-month follow-up in patients with diabetic foot ulcers (DFU) treated in Belgian diabetic foot clinics (DFC).

Method: 1,771 unique patients with DFUs of Wagner 2 or higher were registered by 35 Belgian DFCs in 2018 in the context of a national initiative for care quality improvement (IQED-Foot). Patient and ulcer characteristics were recorded at baseline together with outcome during a 6-month follow-up period. The competing risks for healing, major amputation or death as a first event were assessed by Cox proportional hazards regression analysis and adjusted for patient and ulcer characteristics, comorbidities and presentation delay.

Results: The majority of patients were male (n=1,276, 72%). The mean (± SE) age of women was higher (73.0±0.5 vs. 68.4±0.3 years, p<0.0001). Women had more renal insufficiency (47% vs. 41%, p=0.0104) and more often never smoked (76% vs. 37%, p<0.0001), while men had a higher prevalence of history of Charcot (7% vs. 5%, p=0.0446) and revascularization of the lower limbs (35% vs. 30%, p=0.0249). Men had more frequently DFUs on the plantar metatarsals and metatarsal heads compared to women (27% vs. 18% of all DFUs, p<0.0001). Although median [P25-P75] presentation delay was similar (3 [1-8] weeks), ulcers were more severe in men. The prevalence of Wagner 2 ulcers was lower in men (56% vs. 64%, p=0.0007), while the prevalence of Wagner 3 was higher (30% vs. 22%, p=0.0071) compared to women. Men more often had critical ischemia (15% vs. 12%, p=0.0416), larger (<1cm^2: 27% vs. 34%, p=0.0156) and deeper ulcers (probe-to-bone: 34% vs. 27%, p=0.0033), more deep (36% vs. 30%, p=0.0441) and systemic infections (6% vs. 3%, p=0.0100) and more frequently loss of protective sensation (87% vs. 83%, p=0.0103). The probability of healing as a first event was 18% higher among women than men (adjusted HR: 1.18, 95%CI 1.01-1.37, p=0.0349).

Conclusion: Although men are younger, they have more severe DFUs and a worse prognosis of healing compared to women. Among many possible contributing factors, a worse vascular state linked to a higher rate of (previous) smoking in men, stands out.

[P27] PLASMA CONCENTRATIONS OF LIPOPROTEINS AND RISK OF MAJOR LOWER-EXTREMITY ARTERIAL DISEASE IN PATIENTS WITH TYPE 2 DIABETES

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Aim: The profile of lipids has not been investigated in patients with lower-extremity arterial disease (LEAD) as for cardiovascular disease. We aimed to evaluate the relationship between lipoproteins and LEAD in type 2 diabetes population.
Method: Plasma concentrations of total-cholesterol, HDL-cholesterol, LDL-cholesterol, non-HDL-cholesterol, triglycerides, apolipoprotein A-I, apolipoprotein A-II, B100 and (a) were measured at baseline using colorimetric, mass spectrometry or computation method in SURDIAGENE cohort. The primary endpoint, major LEAD, was defined as the occurrence of lower-limb amputation (transmetatarsal, transtibial or transfemoral) or requirement of lower-limb arterial revascularisation procedure (angioplasty or surgery) during follow-up, whichever came first. Cox models were fitted to compute HR (95%CI) for endpoint by growing lipoprotein tertiles (T1, T2, T3).
Results/Discussion: Among 1468 patients (women 42%, means±SD age 65±11 years, duration of diabetes 14±10 years at baseline), major LEAD occurred in 142 participants (9.7%) during 6.8 years of follow-up. The risk of major LEAD was lower in the higher (versus lowest) tertile of HDL-cholesterol (HR T2 *versus* T1, 0.97 95%CI [0.65–1.43]; T3 *versus* T1, 0.56 [0.35–0.89]) or Apolipoprotein A-I (T2 *versus* T1, 1.04 [0.70–1.54]; T3 *versus* T1, 0.58 [0.37–0.93]) after adjusting for key confounders. Each 1 SD increase in HDL-C (0.79 [0.65 – 0.97]) or Apo-A1 (0.83 [0.68 – 0.99]) was significantly associated with reduced risk of major LEAD. No evidence for significant interaction was observed between HDL-C and Apo-A1 in their association with the risk of major LEAD. These associations remained significant after considering: 1/ cardiovascular death as competing risk; 2/ individually amputation and revascularization as secondary endpoints; 3/ only participants free for history of LEAD or macrovascular disease at baseline. The non-HDL-cholesterol upper tertile was also associated with increased risk of major LEAD (T2 *versus* T1, 1.31 [0.75–2.31]; T3 *versus* T1, 1.77 [1.01–3.14]) in participants without baseline history of LEAD. No further association was observed with other lipids.
Conclusion: We reported independent associations between HDL-cholesterol, Apolipoprotein A-I and non-HDL-cholesterol and the risk of major LEAD in patients with type

2 diabetes. Our findings provide a picture of lipoproteins' profile in type 2 diabetes population at high LEAD risk.

[P28] HISTORY OF DIABETIC FOOT ULCER IS ASSOCIATED WITH INCREASED RISK OF RECURRENCE IN LONG-TERM FOLLOW-UP COHORTS FROM GERMANY AND THE CZECH REPUBLIC

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Aim:
The diabetic foot ulcer (DFU) is susceptible to recurrence up to 60% chance in three years. We aim to investigate if a history of previous DFU compared with first ever case is associated with increased risk of ulcer recurrence.

Method:
We analysed two cohorts of patients with new DFUs recruited in single diabetes centres in Germany (GER) and in the Czech Republic (CZ). Initial time point was complete primary healing, healing after minor amputation or unilateral major amputation. Time to first recurrent DFU might be censored by dropout, end of observation or death. The patients were followed up 20 years in DEU and 15 years in CZ.
Recurrence rates per person-year and median time of recurrence (using Kaplan-Meier) were calculated stratified by history of DFU. A multiple Cox regression was fitted to investigate the association of history of DFU with time to recurrence adjusted for baseline confounders.

Results / Discussion:
227 patients from GER and 99 from CZ of mean age 69.1 and 58.8 years were analysed. 88.5% (GER) and 75.8% (CZ) had type 2 diabetes, 53.7% and 83.8% reported a history of DFU before the index lesion. In 69.2% / 69.7% of the GER/CZ patients a DFU recurred.
Median times to recurrence in patients without former DFU were 3.1 (GER) resp. 2.9 (CZ) years and in those with previous DFU 1.9 and 2.8 years. Corresponding recurrence rates were 0.20 (GER) per person-year resp. 0.15 (CZ) without former DFU and 0.36 resp. 0.21 with previous DFU.
In the adjusted Cox model, history of DFU was significantly associated with the duration until recurrence in GER (HR=1.63, 95%CI [1.10, 2.41]). The HR in CZ has similar trend but was not significant (HR=1.50 (95%CI [0.70, 3.22]).

Conclusion:
The risk of a new lesion following a repetitive episode of DFU was higher than after the first ever one, independently of other risk factors in two different cohorts. Likewise the ulcer-free time until recurrence was significantly longer following a first ever DFU in GER cohort. These

findings highlight the urgency in prevention of further DFU in patients with their first ever diabetic foot lesion.

[P29] THE WEAKNESS OF THE STRONG SEX: DIFFERENCES BETWEEN MEN AND WOMEN AFFECTED BY DIABETIC FOOT ULCERS (DFU).

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Aim: To evaluate possible sex-related differences in clinical outcomes among patients affected by DFU.

Method: We retrospectively analyzed the data of the admissions in our Department between 2011 and 2015 for DFU. We collected demographic, clinical and procedural data and short- and long-term (at 32±21 month follow up) outcomes: healing rate (HR), time (HT), major amputation (MA) and death (D) rates, respectively. We focused on differences between genders to figure out if sex could be an independent predictor of outcomes.

Results / Discussion: We evaluated 1237 admissions in 842 patients [Age: 68.6±27.9 yrs; diabetes duration: 16.4±13.4 yrs; BMI: 28.2±6.4 Kg/m^2; HbA1c 7.9±1.9%]: 615 males (73%) and 284 females (27%). Males had a higher prevalence of comorbidities (92.2% vs 76.6%, p<0.001), previous DFUs (71.2% vs 57.4%, p<0.001) and revascularizations (65.8% vs 56.3%, p<0.001). Males showed a higher HR compared to females (85.4% vs 63.2%, p<0.001) but with longer HT (124±27 days vs 87±14 days, p=0.02). MA did not differ between groups (9.2% vs 7.1%, n.s.) while D rate was significantly higher in males (24.5% vs 16.1%, p=0.02). In Cox's regression analysis male sex was a positive predictive factor for HR (HR 1.62, CI 1.44-1.79, p<0.001) and a negative one for HT (HR 1.75, CI 1.50-1.82, p<0.001) and D (HR 1.55, CI 1.40-1.72, p<0.001). The difference in mortality was confirmed by a Kaplan-Meier analysis (log rank test: p=0.03).

Conclusion: DFU represents a marker of morbidity and mortality impacting more severely on clinical outcomes and survival in male patients.

[P30] LONG TERM OUTCOMES OF CHARCOT NEUROARTHROPATHY (CNA)

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Background: CNA affects about 0.5% of the diabetic population. These patients have increased morbidity and mortality. We undertook a study to assess the complications and mortality in patients with CNA attending a specialist diabetic foot clinic.
Methods: Retrospective study of patients diagnosed with CNA between 1996 and 2018. Follow up was until July 2018. Patients were seen fortnightly then every 8-12 weeks in the Foot clinic. Data was obtained from medical records for complications, comorbidities, duration of CNA, and treatment; including offloading, bisphosphonate therapy and amputations.
Results: Of the 84 patients included in the study, 62 were male; 63 had type 2 diabetes. Mean age at diagnosis of Charcot foot and diabetes duration was 55.1±13.2 years and 13.7±10.8 years, respectively. 40 patients had CNA affecting the right foot, 35 in left foot and 5 had bilateral Charcot. Diabetic complications were as follows: 100% peripheral neuropathy, 52% retinopathy and 32% nephropathy. Treatment included casting:35.7% had total contact cast, 31% aircast; 12% had scotch cast boot, RCW 7.1%, Slipper cast 10.7% and 29.7% patients given bespoke footwear. 34.5% patients were given bisphosphonate therapy. 14 patients underwent amputation; 11 of these being minor and 8 major, of which 3 were bilateral amputations. 13 (15.5%) patients included in the study died during follow up. Mean age at diagnosis of patients who are alive vs. died at follow-up: 50.8±15.1 vs. 65.0.4±11.1 years ($p=0.001$). Complications were higher in the patients who died vs survivors: CKD 46% vs 32% ($p=0.05$); PAD 62% vs 14% ($p<0.001$); stroke 15% vs 1% ($p=0.011$); CAD 31% vs 14% ($p=0.020$); foot ulcers 23% vs 17% ($p=0.034$). Mean duration of active CNA in patients who received bisphosphonate therapy was 18.4 months compared to 25.9 months in those who did not (n= 52 patients) ($p=0.022$).
Conclusions: This study has looked at outcomes of CNA patients following diagnosis and has shown a high mortality in this group of patients. In addition most patients have multiple micro and macro vascular complications with higher complication rates in people who died; which would explain this increased mortality. Cardiovascular risk modification is important in this high risk population and randomised control trials are needed to improve the care for these patients but also to reduced morbidity, amputations and mortality.

[P31] EPIDEMIOLOGICAL SURVEY OF ANTIMICROBIAL RESISTANCES IN DIABETIC FOOT ULCERS

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[P32] CLINICAL CHARACTERISTICS, COMORBIDITIES AND OUTCOME IN PATIENTS OF A DIABETIC FOOT CLINIC

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[P33] TOWARDS A BETTER RISK STRATIFICATION MODEL FOR PEOPLE WITH DIABETES AT RISK OF INCIDENT FOOT ULCERATION: A PROGNOSTIC MODELLING ANALYSIS OF PATIENTS ON THE SCI-DIABETES REGISTER.

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Aim: The aim of the study was to assess if adding information on clinical, systemic and social environmental factors to the Scottish Foot Ulcer Risk Score (SFURS) improves risk stratification for diabetic foot ulceration.
Method: We extracted and analysed the anonymised digital health data from 59,582 people with diabetes from the Scottish Care Information – Diabetes Collaboration (SCI-diabetes) register. We extracted data on their earliest SFURS score and supplemented this with information on age, gender, time since diabetes diagnosis, Charlson comorbidity index, Scottish Index of Multiple deprivation, ethnicity and type of diabetes. We recorded incident diabetic foot ulcer event between 2007-2016. Using survival analysis methods, we compared the discriminative performance of the following two predictive models using Harrel's C-statistic: (MODEL-1) existing SFURS score; and (MODEL-2) SFURS plus all the aforementioned prognostic factors.
Results / Discussion: Over a 9.8-year period, incident DFU was observed in 2235 (3.8%) registry patients. Cox regression modelling indicated that a high risk SFURS score was the strongest risk factor of foot ulceration (Adjusted hazard ratio (HR) 8.24 [95%CI 7.27-9.33], *P*= <0.001). Other factors that were independently associated with foot ulceration were increased disease duration (adjusted HR for 16+ years vs 0-5 years: 3.22 [95%CI 2.89-3.70] *P*= <0.001), being male (adjusted HR vs females: 1.40 [95% CI 1.28-1.54], P= <0.001), and increased exposure to social deprivation (adjusted HR for least deprived vs most deprived quintile: 0.83 [95% 0.72-0.96] *P*= 0.012). The Harrel's C statistic was superior for MODEL-2 (C-stat:0.75) versus MODEL-1(C-stat: 0.68), indicating that the broader model was better at differentiating individuals who go onto develop a DFU from those who do not.
Conclusion: Adding basic clinical information with the inclusion of more systemic and social environmental factors to the SFURS, may considerably improve risk stratification for foot ulceration in people with diabetes.

[P34] CLINICAL CHARACTERISTICS, MANAGEMENT AND OUTCOME OF HOSPITALIZED PATIENTS WITH DIABETIC FOOT PROBLEMS IN VASCULAR SURGERY DEPARTMENT

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[P35] COMORBIDITIES AND MICROBIOLOGICAL DATA OF HOSPITALIZED PATIENTS WITH DIABETIC FOOT PROBLEMS IN VASCULAR SURGERY DEPARTMENT

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[P36] DATA-DRIVEN SOLUTIONS CAN SUPPORT DAILY CLINICAL PRACTICE AND RESOURCES, BUT CAN ALSO BE A CHALLENGE

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Focus on diabetes data in the healthcare system is important for both the managers, healthcare professionals and the persons with diabetes. It´s a major problem that we not have reliable data on the diabetic foot syndrome in Denmark. In a busy clinical day, the registration of data could be missed.
Aim: of this study was to look at our daily clinical registration of foot data, for the purpose of time consumption, better organization and to give the persons with diabetic foot syndrome the best treatment at the right time.
Method: Our clinic is a large diabetic center with app. 9,000 persons with type 1 and 2 diabetes, 26% per year is seen in the foot clinic (IWGDF at-risk stratification 3). From 2017 until now podiatrists in our center have systematically coded diabetic foot related data in the electronic patient record (EPIC). We continuously follow quality data extracted from EPIC to improve the clinical work.
Results / Discussion: Foot inspection was done in 7,112 cases (2018) and 7,540 (2019) incl. biothesiometri, footpulses and instructions given by the healthcare provider. In 2018 the foot clinic had 4,724 consultations, and 5,220 (2019). Phone consultations was 932(2018) and 1,011(2019). Delivery of therapeutic footwear (sandals/cast) was 294 (2018) and 304 (2019) incl. insoles. Wound treatment was done in 28% (2018) and 26% (2019) consultations. Treatment of callosities if risk of ulceration 392 (2018) and 1,161 (2019) consultations. Prescription of future footwear was made in 49 cases in 2018 and 81 (2019). Reference to podiatrist in the primary setting was 205 in 2018 and 394 (2019). There is an average of 140 patients with an active foot ulcer, the duration of foot ulcers is described in previous studies, and we will continue to monitor the foot ulcer.
Conclusion: It is our experience that minimizing the number of different codes is extremely important. It requires a lot of training to code properly and systematically. Resources can be better distributed based on our data. A data driven strategy in healthcare could improve the outcome and the health economy, future research is needed and is ongoing in our center.

[P37] IMPACT OF OSTEOMYELITIS ON THE CLINICAL OUTCOME OF AUTOLOGOUS CELL THERAPY IN PATIENTS WITH DIABETIC FOOT DISEASE AND SEVERE ISCHEMIA

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Diabetic Foot Study Group

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Introduction: Patients with diabetic foot ulcers (DFU) associated with chronic limb-threatening ischemia (CLTI) represent a group at high-risk of major amputation or sepsis. Diabetic foot infection (DFI) and osteomyelitis (OM) impairs the healing of DFU and threatens patient's life. Autologous cell therapy (ACT) is the only option for patients with DFU and CLTI not eligible for standard revascularization. The aim of study was to assess the impact of OM on the effect of ACT in patients with CLTI and DFU. Methods: Ninety-one diabetic patients with CLTI and DFU treated by ACT in our foot centre were included into the study and divided in two groups – with OM (n=46) and without OM (non-OM, n=45). The presence of OM at baseline was defined by X-ray and by positive probe to bone test (PTB). Infection parameters: swab of the wound, CRP and leukocytes were assessed at baseline. ACT was performed by bone marrow harvesting and intramuscular injected. The effect of ACT was evaluated by the changes in transcutaneous oxygen pressure ($TcPO_2$), wound healing and incidence of major amputation in 12 months after ACT. Results: Out of 46 OM probands was OM observed on X-ray in 70% patients, the PTB was positive in 47%. Between OM and non-OM were presence of multi-resistant pathogens (37 vs 31 %), levels of CRP (13.3 vs. 16 mg/l), lymphocytes (10.4 vs. 9.2 x 10^9/l), neutrophils (33.1 vs. 32.6) and monocytes (2.19 vs. 2.1), NS. The positive effect of ACT has been proven in both groups by a significant increase in $TcPO_2$ after 12 months (in OM from 20 to 42 and 41mm Hg; in non-OM from 18 to 42 and 41mm Hg. Surprisingly, major amputation rate was significantly lower in patients with OM (17%) compared to non-OM (40%) and significantly more healed OM patients than non-OM (35% vs. 33 %) after 12 months after ACT. Conclusion: Our study showed a significant improvement of ischemia after ACT in patients with critically ischemic foot ulcers regardless the presence of OM. We observed significantly less healed ulcers in patients with OM, but surprisingly lower rate of major amputation than in non-OM.

[P38] OUTPATIENT MANAGEMENT OF THE DIABETIC FOOT ULCER DURING COVID-19 PANDEMIC

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Aim: Diabetic foot ulcer (DFU) is a major cause of morbidity and mortality in the world, with much of the economic and social costs related to hospitalization and to lower extremity amputations, but Covid-19 Pandemic is changing our approaches and our health care organization. A prospective descriptive study was done from 15 March to 14 April 2020 to describe our experience in management of DFUs in our local environment setting during COVID-19 pandemic.
Method: In 4 weeks from start of lockdown 95 patients with DFU have been contacted by phone calls and followed in remote with support of nurse at home or caregiver, while a total of 196 patients with new ulcers or worsening foot ulcers were seen during the study period.
Results / Discussion: Among 196 patients, evaluated in outpatient of diabetic foot clinic, 23 (11,7%) patients were hospitalized for IDSA severe infections , gas gangrene or sepsis and the remaining 173 (88,2%) patients were treated as outpatients. The forefoot involving the toes was commonly affected and neuro-ischemic ulcers were the most common type of DFU accounting for 80% of cases. Among them 15 patients with CLI were treated with PTA. One hundred seven patients (54,5%) were treated surgically . Surgery was performed in a fully equipped operating theatre in an outpatient setting with the intention to debride any nonviable or infected tissue, including soft tissue, joint, and bone. Sterile prepping was performed as for any surgery. Local anesthesia was achieved by digital block with lidocaine when neuropathy was not severe enough to make this unnecessary.In particular we performed seven minor amputation operations (6,5%), twenty-one phlegmon incision and drainage operations (19,6%), sixty-four sequestrectomy operations (59,8%) and 16 sixteen onichectomy operations (14,9%).The remaining 89 patients (45,4%) were treated conservatively with debridement , dressing and antibiotics.
Conclusion: DFU cannot wait, but during COVID-19 pandemic we need to treat as many foot complications as possible in the community and improve approaches with telemedicine, because our goal is to avoid unnecessary diabetic foot ulcer -related hospital admissions to reduce the risk of COVID-19 exposure in the hospital and burden on the healthcare.

[P39] EVALUATION OF AN IPAD BASED TELEMEDICINE SYSTEM FOR SECOND OPINION TO REDUCE ELECTIVE MAJOR AMPUTATIONS IN PATIENTES WITH DFU

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Aim:

A second opinion can help to prevent amputations.
Especially in rural or non-city areas the possibility to get a qualified and contemporary second opinion often seems difficult or impossible. Therefore, a telemedical systems could help.

Method:

In our project we created a telemedical iPad based expert system; the technical solution (CheckPadMED) allows a location- and time-independent qualified evaluation of an elective amputation (on the basis of pictures, laboratory, X-rays, MRI, etc.).
Alongside the development of the technical platform there should be a realistic possibility of a valid and repeatable evaluation by a board of experts to verify the necessity of an amputation.

Results/Discussion:

65 patients were included (54 male). The average age was 69,9 years (39-95y), the mean ulcer duration 763,6 days (86-2218 days).
The CRP was 13,6±10,9 mg/dl, the HbA1c 8,3±2%.
55 patients had an angiopathy (pAOD), 64 a neuropathy; all patients suffered from infection.
Six patients were at Stage_2 of Wagner-Classification, 34 in Stage_3 (52%), 24 (37%) in Stage_4. Charcot-foot was documented in 15 cases.
2/3 of the patients (69,2%) had in addition to the serious infection a pAOD.
Only 12 patients (18,5%) showed no clinical signs of pAOD.
76,9% had pAOD without critical Ischemia, 4,6% had a critical Ischemia.
Regarding the infection 3,1% of the patients were stated with only an inflammation of the subcutaneous tissue. 75,4% (n=49) showed a deep tissue infection and 21,5% (n=14) were stated with a systemic component (SIRS).
A qualified expert opinion within 24h is realistic.

With the requirement of an unitary evaluation from three out of six experts the accordance rate reached 76%.

Conclusion:

Therefore the iPad based evaluation tool is definitely comparable to the already well-established quality management measurements.

Experts were able to give a qualified evaluation on the basis of the requested data as to content and data quality.

This can be included in the establishment of Quality indicators in hospitals (obligatory second opinion before elective major-amputation) as well as the implantation in logistics of overlapping sectors (GP >> special DFU ambulance >> Hospital).

The system is suitable for setting a standard in Quality management in hospitals.

[P40] BARRIERS IN THE MANAGEMENT OF DIABETIC FOOT DISEASE IN ITALY: A SURVEY OF DIABETIC FOOT STUDY GROUP OF THE ITALIAN SOCIETY OF DIABETES (SID) AND ASSOCIATION OF MEDICAL DIABETOLOGISTS (AMD).

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Aim: In this work Italian Diabetic Foot Study Group proposed the designation of a survey that allow to identify the barriers and gaps in the management of diabetic foot disease among Italian diabetic foot centers.
Method: The survey was developed through a preset questionnaire which was submitted to each Italian diabetic center specialized in the field of diabetic foot care. The questionnaire was composed of 12 questions focused on the barriers and gaps in the management of diabetic foot: timing of referral, hospital management including both surgical and vascular aspects and follow-up in the community were evaluated. Each center could answer through a score from 1 to 5 for every item analyzed with the following numerical concordance: 1=never; 2=rarely; 3=sometimes; 4=often; 5=always. The national score was estimated using as numerator the total score for each item and as denominator the number of centers; the regional score was estimated using as numerator the total score for each item and as denominator the number of regional centers.
Results / Discussion: Among 100 centers which answered to the questionnaire, 94/100 were included and 6/100 excluded due to missing and/or wrong data. The items with the highest score were late referral (average score 3.3), urgent surgery (3.2), elective hospital admission (3.1). The item with the lowest score was the foot orthotic prescription (1.9). The regions with the highest average global score were respectively Molise (3.9) and Calabria (3.5) while Umbria reported the lowest average score (1.4). This difference among regions identified in the survey could be related to different health care systems and specific pathway of care which can allow (or not) an early referral to specialized diabetic foot centers.
Conclusion: This survey highlighted that critical situations were more frequent in central and southern areas and more rarely in the northern regions. It is evident the need to train

health-care professional, to develop specific pathway of care for improving early referral, to have operating rooms available for urgent surgery, dedicated beds and vascular operating rooms for revascularization procedures as well as specific pathways in the community for patient's management after hospitalization.

[P41] LESSONS FROM PODIATRIC CARE DURING THE COVID-19 PANDEMIC

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Aim: The COVID-19 pandemic brought significant change in the healthcare organization, led to reduced availability of podiatric care and kept some patients at home without foot care. Aim of the study was to evaluate the structure of the care at tertial foot clinic during COVID-19 pandemic and comparable periods in years 2016-2019.

Method: On March 1, 2020 the first case of COVID was diagnosed in our country and state of emergency has been introduced by the government on March 12, 2020 including restrictions on the free movement of persons. In our study, we compare structure of podiatric care during COVID-19 period (1.3.2020-30.4.2020) with the same period (March and April) in 2017-2019.

Results / Discussion: In COVID-19 period there was a significant reduction of number of visits (554 vs. 1255 in 2017; 1228 in 2018 and 1227 in 2019; all $p<0.001$). In addition, decreased number of preventive care between COVID-19 period and comparable periods was seen (3.6% of treated patients vs. 17.3% in 2017; 21.4% in 2018 and 19.9% in 2019; all $p<0.001$). In contrast, there was a significant increasing of virtual visits using methods of telemedicine (e-prescription of drug, phone consultation, videoconferences and photo consultation) – 23.5% of treated patients vs. 1,9% in 2017; 2% in 2018 and 1.8% in 2019; all $p<0.01$).

Conclusion: Covid-19 pandemic led in our center to the reduction of patients visits, especially in the segment of preventive care. In contrast, there has been a major development of telemedicine enabling virtual visits of patients. In the future, we can use this approach to improve podiatric care in our centre.

[P42] MDFT ADAPTIONS OF CLINICAL PRACTICE TO COPE WITH THE PRESSURES OF COVID-19

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Aim: To explore the effect of the Covid-19 pandemic on patient attendance for diabetic foot management.
Method: A national lockdown for Covid -19 placed restrictions on movement from home and advised many 'at risk' patients to self-isolate in their own home. Treatment of diabetic foot ulcer (DFU) patients was adapted to allow patients to attend a site nearer home or receive a visit at home by a community based foot protection team (FPT).
Usual practice was adapted to allow more patients to access DFU care in a practical and patient acceptable manner. The already commissioned integrated digital imaging and wound management system assisted the FPT to monitor wound progress and communicate with the MDFT. We describe the first 2 months experience of the COVID-19 pandemic, March and April 2020.
Results / Discussion: During this period 85 new referrals and 719 follow-up appointments were seen at the acute Trust MDFT, and 655 in shared care with the FPT in a community setting (45%). By contrast in the same period the previous year 147 new referrals and 1163 follow-up appointments were seen at the acute Trust MDFT, with 208 appointments with an active diabetic foot ulcer were seen by the FPT in joint management with the MDFT (14%). Although the increased proportion of patients able to be seen in a community setting has enabled patients to continue to be monitored safely and treated by the FPT in a joint management strategy with the MDFT the dramatic reduction in new referrals is as yet unexplained and of concern.
Conclusion:
DFU patients can continue to receive appropriate treatment during a national lockdown by adapting usual practice and utilising integrated digital imaging and wound management system even when seen in a community setting. However the reduction in new referrals is of concern and needs to be further explored.

[P43] COVID-19 A TSUNAMI THAT HAS ACCELERATED OUR RACE TOWARDS A NEW MANAGEMENT OF PATIENTS WITH DIABETIC FOOT.

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The Covid-19 emergency put a strain on the organization of the whole Italian National Health System and therefore of the diabetes foot (DF) units. Pistoia health care district has about 292473 inhabitants (2018) while the prevalence of diabetes in this population is 6.9%, (~ 18000 patients). The Hospital of Pistoia became a Covid-19 center from 27th February 2020. On February 29th it was closed the 50% of outpatients' access and on March 10th all outpatients' units were closed. Diabetes Unit and DF Unit allowed only visits for acute metabolic failure, GDM and acute diabetic foot lesions. On April 8th there were 403 hospitalized patients for Covid-19 including 60 in the Intensive Care Unit (ICU). 59 patients died including 17 with diabetes. During the same period the DF Unit carried out scheduled visits, joint telemedicine and teleconsulting: 832 metabolic controls, 640 podiatrist's contact and 180 dressing wound, 790 phone calls for drug dosage adaptation, 590 phone calls for podiatry framework monitoring (risk class) and 93 photo and video for the monitoring of patients with diabetic foot. Furthermore, in the period considered, there were hospitalizations for Gangrene, wounds, abscess or critical limb ischemia revascularizations. While, always in the same period, no diabetic foot patient tested positive for Covid-19; patients with diabetes, microalbuminuria and obliterating arteriopathy of the lower limbs were at high risk of mortality (~ 40%), 35 ulcerations were registered, while only one transmetatarsal amputation was performed. As for the onset of new ulcers, a reduction in the incidence of about 15% was detected. It is not known if this result is linked to home isolation respected by patients, to the reduced number of daily steps as well as to the correct use of the prescribed orthoses. In this sense, we began to monitor the lifestyle of the patients (pedometer application) in addition to the metabolic control, also with regard to the appropriate management of the post-emergency phase 2 and subsequent. The emergency medical situation induced by Covid-19, if on one hand represented a tsunami for our diabetic foot services, on the other hand pushed us towards an evolution of the service that probably over time will improve the management of many patients with diabetic foot.

[P44] DIABETIC FOOT CLINIC DURING THE COVID-19 EPIDEMIC

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Aim:

Due to the outbreak of covid-19 epidemic, out-patient foot clinic had to be organized in a different way. We aimed to explore the influence of such modified approach on the structure and outcome of foot pathology in the patients attending the foot clinic at our University hospital..

Method:

We compared the data from the out-patient foot clinic in the periods from January 1st till April 30th of 2018, 2019 and 2020. After resuming the regular activities, we plan to collect the data from May to August, 2020 and compare them to the data from the years 2018 and 2019.

Results / Discussion:

From March 11th until May 4th 2020, all preventative activities of the foot clinic have been temporarily suspended. The clinic remained open for all foot ulcer patients who had no signs or symptoms of covid-19 disease and have not been in contact with covid-19 patients. We offered telephone and e-mail consultations to all who sought for advice. Emergency vascular procedures and surgery were accessible all the time. Only 2 patients needed urgent surgical intervention and no major amputation was done. The number of patients attending the clinic and the procedures done are shown in the table.

	January 1st – April 30th		
	2018	**2019**	**2020**
Patients (N)	1.842	1.934	1.484
Foot screening	846	1.073	691
Ankle/brachial index	366	434	190
Foot ulcer	1.079	1.028	984
Wound swab	76	90	39
Emergency	251	252	194
Phone / e-mail consultation			43

The number of patient visits and the total number of diagnostic and therapeutic procedures dropped by more than 20% in comparison to the previous 2 years. Still, the accessibility of the foot service remained reasonably good throughout the period of the epidemic. The patients appreciated the possibility of phone consultations. The amputation rate did not increase. There was no covid-19 infection among the clinic staff.

Conclusion:

Covid-19 epidemic is a big challenge for the health care system. In order to prevent major disasters it is crucial to keep basic diagnostic and therapeutic activities widely accessible. We shall only be able to evaluate the efficiency of our approach when we collect the follow-up data.

[P45] CORVID19_TRANSFORMING DELIVERY OF DIABETES FOOT CARE

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COVID-19- Transforming Delivery of Diabetes Foot Care

Background and aims: The outpatient multidisciplinary foot clinic remained open during the COVID-19 pandemic as an emergency service. We report a rapidly evolved model of care to provide people with active diabetes foot disease, expert advice and treatment during the crisis.

Methods: Staff and patient safety were prioritised. National and hospital guidance were followed and clinic specific measures were implemented. Activities carried out during a routine clinical week (3rd-7th February 20) were compared with activities carried out during the lockdown (27th April to 1st May 20).

Results: Staff safety: A daily huddle was organised to ensure that every member feels safe and listened to. Personal protective equipment for every procedure (foot inspection, ulcer debridement, cast change) was agreed upon and regularly updated.

Patient safety: Each patient was given a surgical mask upon arrival, triaged by the podiatrist and isolated immediately if reporting unwell or has either fever, cough or sore throat and also if has been abroad. To encourage presentation, a member of staff phoned patients prior their appointments to provide guidance and support. Access to radiology, vascular lab and the vascular or orthopaedic team were conducted when required either in person or remotely. If a patient was not agreeable to acute foot admission, (s)he was offered daily appointments in the outpatient clinic to monitor their progress. People with non-limb nor life threatening conditions were offered community care with regular guidance from the multidisciplinary team. Face to face consultations were significantly reduced from 42±11 attendances per day pre COVID - 19 to 16±3.4 per day during the pandemic (p=0.001). Patient telephone consultations increased from zero pre COVID -19 to an average of 7 per day during the pandemic (p=0.003). There was a trend of a non-significant daily reduction during COVID- 19 in the number of newly referred patients from 1.8±1.3 to 1±1.2, in the DNA (did not attend) rate from 12.2%±6.2 to 9.9%±13.8 and in emergency attendances from 9.7%±5.8 to 7%±5.1.

Conclusion: The rapidly evolving COVID-19 pandemic revolutionised diabetes foot services by shifting hospital based diabetes foot care to community clinics and to the patient's home. Lessons learnt will inform how to continue organising and improving diabetes foot care as the pandemic evolves.

[P46] THE RENAL SIDE EFFECTS OF LONG COURSES OF TRIMETHOPRIM AND CO-TRIMOXAZOLE USED IN THE TREATMENT OF INFECTED DIABETIC FOOT

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Aim: Treatment of infected diabetic foot requires prolonged courses of antibiotics. There are large variations in antibiotic guidelines complicated by increasing bacterial resistance. We analysed the side-effect profile of co-trimoxazole and trimethoprim in this population.
Method: We retrospectively and prospectively analysed all patients treated with trimethoprim or co-trimoxazole for diabetic foot infection between June 2015 to July 2019 who were under our hospital diabetic foot service. The data gathered includes demographics, the duration of antibiotics and blood results for full blood count (FBC), urea and electrolytes performed at baseline and at regular intervals after starting the treatment.
Results / Discussion: After applying our exclusion criteria, this study included 24 males and 7 females. Mean age is 57.7. Most patients (n=27) were prescribed co-trimoxazole. 3 patients used trimethoprim and 1 patient used both antibiotics concurrently as a drug error. The duration of antibiotic course was 27 days on average (min 3, max 99 days). There were 16 patients who suffered from adverse drug reactions (ADR). Additionally, 5 patients had isolated creatinine rise only (≥25 µmol/L) which are not reported as ADR. 2 patients suffered with diarrhoea which resolved after stopping antibiotics. 14 patients suffered from biochemical ADRs. 9 patients suffered from acute kidney injury (AKI); 4 with and 5 without hyperkalaemia (≥ 5.5 mmol/L). 5 patients were found to have isolated hyperkalaemia without AKI. 3 patients in total were admitted to the hospital for treatment. During the course of this study we observed FBC to remain stable and no patient reported any skin changes.
86% of 14 patients with a biochemical ADR had a baseline creatinine of ≤100 µmol/L. Blood tests which showed AKI and isolated hyperkalaemia were respectively performed on average on days 15 and 22.
Conclusion: In our study population the biochemical ADRs of these antibiotics were more frequently observed than they are reported in general population. Our results suggest both antibiotics should be used with caution in diabetic foot patients. Furthermore, baseline renal function does not appear to help predict ADRs. Future work includes studies with larger sample size with data collected for co-morbidities and concurrent medication use.

[P47] A COMPARISON OF BONE HISTOPATHOLOGY AND MICROBIOLOGY IN THE DIABETIC PATIENT WITH SUSPECTED FOOT OSTEOMYELITIS

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Background and aim: Bone biopsy is currently considered the gold standard for diagnosing osteomyelitis (OM), but both microbiological and histological examinations have their limitations. While culture has the advantage of identifying the causative agent, histology may be more sensitive if the patient is on antibiotic therapy and more specific if specimen contamination is a concern. The aim of the present study was to evaluate bone histopathologic and microbiologic findings in patients with clinically suspected diabetic foot OM and to compare both methods.
Method: A total of 38 consecutive diabetic patients (31M/7F, 7 Type 1/31 Type 2 DM, mean age 68±9 years) undergoing surgery for the treatment of suspected foot OM over a six-month period (Jan-June 2019) were included in the study. The diagnosis of suspected OM was based on a combination of clinical signs, positive probe-to-bone results and standard X-ray findings. Bone samples were collected during an open surgical procedure under aseptic conditions. Osteomyelitis was most often located in the forefoot (92%). Microbiologic and histologic results were evaluated and agreement between both methods calculated. **Results:** Positive microbiologic results of bone samples were obtained in 29 (76%) patients while histopathology confirmed OM in 24 (63%) patients. Agreement between histology and microbiology was observed in only 25 (66%) patients and, using Cohen´s kappa, was evaluated as fair (κ=0.21). In the forefoot as the predominant location, microbiology was negative in 9/35 (23%) patients whose histology was positive in 4 (44%) patients.
Conclusion: When comparing microbiologic and histopathologic assessment of bone samples in patients with suspected OM, the degree of agreement between both methods is low. While microbiologic assessment is usually sufficient to confirm suspected OM (76%), especially when located in the forefoot, histology usually does not significantly affect the therapeutic strategy. Furthermore, microbiologic assessment is less expensive and routinely performed and culture results allow targeted antibiotic treatment. In the case of clinical suspicion of OM and negative cultures, histological examination should be added.
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[P48] SUCCESSFUL TREATMENT OF DIABETIC FOOT OSTEOMYELITIS WITH DALBAVANCIN

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Aim: Dalbavancin is a new antibiotic against multi-drug resistant Gram (+) bacteria. Dalbavancin has an extremely long half-life. Current indication is skin and soft tissue infections (ABSSSI), but researchers have successfully administered it off-label to osteomyelitis (OM) patients.
Method: We present a case of successful treatment of diabetic foot (DF) OM
Results / Discussion: A 53-year-old male presented to our DF clinic, with recently onset diabetes mellitus (diagnosed one month ago), with very bad glycaemic control (HbA1c=12,5%). He had diabetic neuropathy, but no peripheral arteriopathy. Two months before, because of an accident with hot water, he presented left foot ulcer, followed by ABSSSI and 1st toe and 1st metatarsal OM (plain x-ray findings). A multi-drug resistant *Enterococcus faecium* was isolated in cultures and a targeted treatment with tigecycline and daptomycin was administered. The patient also received 1,5 gr dalbavancin upon discharge. 2 weeks later, he continued treatment at home with linezolid and tedizolid. A complete medical record with patient's history, informed consent and relative literature was sent to Greek National Health Care Organization (EOPYY), requesting administering off-label another 1,5 gr dalbavancin. In the meanwhile, he was admitted for i.v. tigecyclin, and continued treatment with linezolid at home. He finally received a second dose of 1,5 g dalbavancin. Patient received totally 14 weeks' targeted therapy, mostly off-hospital. When he completed treatment, foot was in excellent condition and x-ray had improved. One and half year after treatment, his foot was in good shape.

Conclusion: Dalbavancin, due to its extremely long half-life, could potentially be the drug of choice for OM caused by multi-drug resistant Gram (+) cocci, in order to avoid hospitalization, especially on non-complient patients. Further research is necessary.

[P49] MICROBIOLOGICAL DATA AND OUTCOME IN PATIENTS WITH DIABETIC FOOT ULCERS-A RETROSPECTIVE STUDY

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[P50] RESULTS OF A MULTICENTRE OBSERVATIONAL SURVEY ON HEALING PROPERTIES OF A TLC-AG POLY-ABSORBENT DRESSING ON WOUNDS AT RISK OR PRESENTING SIGNS OF LOCAL INFECTION. FOCUS ON DIABETIC FOOT ULCERS

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Aim:

Description of the wounds treated with a TLC-Ag poly-absorbent dressing and evaluation of the short-term clinical outcome of this silver dressing on the wound healing process, under real-life conditions.

Method:

A large, prospective, multicentre, observational study of patients presenting with a wound at risk or with clinical signs of local infection for whom the evaluated dressing has been prescribed. Main outcomes included the reductions of the number of wound infection diagnosed and of clinical signs of local infection, wound healing rate, clinical assessment of wound healing progression, relative wound area reduction (RWAR), local tolerability, handling and acceptance of the dressing.

Results:

A total of 2270 patients with acute and chronic wounds of various aetiologies were treated with the evaluated dressing in 81 investigating physicians in Germany for a mean duration of 22 ± 13 days. In this cohort, 545 patients (mean age 71 years old, 57% male) were presenting with a diabetic foot ulcer ; 9.7% and 61,7% of them with a diagnosed infection or with clinical signs of infection, respectively.

At the end of the treatment duration with the silver dressing, the clinical signs of local infection and the diagnosed wound infections of these DFUs were substantially reduced. In the meantime, a clinical improvement of the wound healing was reported with a wound closure rate in 17.8%, improvement in 69%, stabilization in 9.2% and a worsening in 4% of the cases. A median Relative Wound Area Reduction (RWAR) of 38.8% was achieved in those DFUs. Similar results were reported regardless of the level of exudate and of the proportion of wound beds' sloughy and granulation tissues at baseline. The dressing was very well tolerated and very well accepted by both patients and healthcare professionals.

Conclusion:

These results, documented in a huge cohort of patients treated in current practice, comfort and complete the clinical evidence on the good healing properties and safety profile of the TLC-Ag dressing with poly-absorbent fibres in the management of wounds at risk or with clinical signs of local infection, regardless of the characteristics of wounds and patients.

[P51] EVALUATING THE IMPACT OF HOSPITALIZATION FOR DIABETIC FOOT INFECTION ON HEALTH-RELATED QUALITY OF LIFE

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Aim: To gauge the impact of health-related quality of life (HRQOL) in hospitalized patients with diabetic foot infections (DFI), compared to patients with diabetes who presented for outpatient foot care. Our goal was to evaluate patients using the Patient-Reported Outcome Measurement Information System (PROMIS), which has been developed by the National Institutes of Health for increased accuracy of patient HRQOL assessment compared to the legacy Short Form instruments.
Methods: 224 patients (aged 35 to 85 years) completed the PROMIS and 12-Item Short Form (SF-12) survey tools. Secondary outcomes using the Foot and Ankle Ability Measures (FAAM) survey were obtained, and included in the statistical analysis. The PROMIS survey assesses seven health domains: physical function, fatigue, pain interference, depressive symptoms, anxiety, ability to participate in social roles/activities, and sleep disturbance. Each domain has four questions and there is a pain intensity using a single 0–10 numeric rating item. Physical Health Summary (PHS) and Mental Health Summary (MHS) scores are derived from PROMIS domains using oblique factor rotation coefficients. The study group was comprised of hospitalized patients with DFI (n=120) and the control group was comprised of patients with diabetes who were evaluated for routine outpatient foot care (n=104; diabetic foot screening, onychomycosis, and/or callosities). Using the initial 224 patients, a propensity score-matched sample of hospitalized patients with DFI (n=35) and patients with diabetes who were evaluated for routine outpatient foot care (n=35), was created and used for analysis. The two-independent sample t-test was implemented to test for group differences on each of the PROMIS sub-scale outcomes.
Results / Discussion: Using PROMIS, we found that hospitalized patients with DFI reported significantly worse in HRQOL across subscales of physical function, anxiety, depression, fatigue, social role, pain interference and pain intensity (p-value range: 0.0001 to 0.02) compared to patients with diabetes receiving outpatient foot care. There was no significant difference between the two groups on sleep disturbance (p=0.22).

Conclusion: Patients hospitalized for diabetic foot infection report lower quality of life than patients with diabetes receiving outpatient foot care.

Table: Patient-reported outcomes with SF-12, PROMIS, and FAAM for hospitalized patients with diabetic foot infections (DFI) compared to patients with diabetes who were evaluated for routine outpatient foot care

	Overall N=70		Hospitalized DFI n=35		Outpatient Foot Care n=35			
Outcome Measure	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**	**P-value**	**FDR**
SF-12 Summary Scores[A]								
PCS-12								
Orthogonal	35.85	(10.95)	33.23	(10.20)	38.38	(11.23)	0.0525	0.0563
Oblique	38.47	(11.40)	34.56	(10.81)	42.38	(10.74)	0.0034	0.0057
MCS-12								
Orthogonal	45.91	(12.75)	41.59	(12.40)	50.22	(11.74)	0.0039	0.0059
Oblique	41.56	(13.15)	36.61	(12.78)	46.46	(11.75)	0.0014	0.0030
PROMIS Subscale T-Scores[B]								
Physical Function	38.92	(10.61)	34.42	(8.39)	43.43	(10.78)	0.0002	0.0005
Anxiety	52.36	(11.34)	57.85	(11.09)	47.14	(9.05)	<0.0001	0.0005
Depression	51.01	(10.86)	55.84	(10.53)	46.17	(8.96)	<0.0001	0.0005
Fatigue	52.12	(13.23)	55.65	(12.72)	48.60	(12.95)	0.0247	0.0285
Sleep Disturbance	52.49	(5.28)	53.25	(6.07)	51.72	(4.29)	0.2272	0.2272
Social Role	40.24	(11.35)	36.61	(10.35)	43.86	(11.27)	0.0066	0.0083
Pain Interference	58.77	(11.43)	62.53	(11.37)	55.01	(10.32)	0.0057	0.0078
Pain Intensity	5.75	(3.04)	6.80	(3.01)	4.71	(2.72)	0.0034	0.0057
FAAM								
FAAM (%)	45.11	(27.88)	33.34	(22.20)	56.88	(27.26)	0.0002	0.0005
FAAM Sports (%)	8.23	(10.32)	2.05	(4.27)	14.40	(10.93)	<0.0001	0.0005
Overall Function*	2.60	(1.07)	3.05	(0.93)	2.14	(1.00)	0.0002	0.0005

*As reported by patient on a scale of 1 (normal) to 4 (severely abnormal).

[A]Factor coefficients from Hays et al 2018.

[B]Based on assumption of population average of 50 and SD of 10.

Note. M=Sample Mean; SD=Standard Deviation. P-value (two-tailed) associated with the test of group differences (hospitalized vs. outpatients) on each outcome. FDR=False Discovery Rate.

[P52] TREATMENT OF DIABETIC FOOT OSTEOMYELITIS WITH ANTIBIOTIC-LOADED CALCIUM SULPHATE – HYDROXYAPATITE

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Aim: An antibiotic-loaded bone graft substitute, consisting of calcium sulphate and hydroxyapatite (CaS-HA), was recently introduced for local antibiotic treatment of osteomyelitis. We explored the use of this material for the treatment of diabetic foot osteomyelitis.
Method: We conducted a multicentre retrospective cohort study of patients with diabetes mellitus and foot ulceration with underlying osteomyelitis, who were treated with antibiotic-loaded CaS-HA after unsuccessful standard-of-care treatment.
Results / Discussion: We included 64 patients (50 male; median age 63.5 years) with diabetic foot osteomyelitis of the forefoot (N=41), midfoot (N=14) or hindfoot (N=9). Gentamicin-loaded CaS-HA was used in all procedures. Postoperatively, offloading was continued in all patients for a median duration of 4.5 weeks. Systemic antibiotics were continued in 26 patients (40.6%) for a median duration of 2 weeks. Median postoperative follow-up was 45.5 weeks. We noted wound healing in 54 patients (84.4%). Median duration to wound healing was 8.5 weeks. We noted recurrent ulceration in twelve patients (22.2%), major amputations in seven patients (10.9%) and minor amputations in four patients (6.3%). At final follow-up, 47 patients (73.4%) could mobilise weight-bearing.
Conclusion: Surgical debridement and local antibiotic therapy is an effective last resort treatment for diabetic foot osteomyelitis and could potentially reduce amputations.

[P53] OUTCOMES FOR FOOT INFECTIONS IN PATIENTS WITH AND WITHOUT DIABETES

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Aim:
To evaluate outcomes for foot infections in patients with and without diabetes.

Method:
Retrospective review of 382 charts for patients hospitalized with moderate to severe foot infection (Infectious Diseases Society of America class 3 or 4) at one safety net hospital.

Results/Discussion:

Table 1. Past Medical History and Outcomes

	Diabetes N=294	No Diabetes N=88	p-value
Male	221 (75.2)	65 (73.9)	0.804
Age	53.0, 52.73 (10.85)	52.0, 50.22 (15.13)	0.607
Dialysis	28 (9.5)	0 (0)	0.003
Retinopathy	90 (30.6)	0 (0)	<0.001
Neuropathy	267 (90.8)	47 (53.4)	<0.001
Previous Foot Ulcer	188 (63.9)	32 (36.4)	<0.001
Previous Amputation	104 (35.4)	9 (10.2)	<0.001
Peripheral Arterial Disease (PAD)	206 (70.1)	33 (37.5)	<0.001
Laboratory values			
Glycated Hemoglobin (%)	8.85, 9.15 (2.49)	5.5, 5.39 (0.47)	<0.001
White Blood Cell Count (mm^3) (WBC)	9.58, 10.94 (4.29)	8.75, 10.39 (4.01)	0.037
Ankle Brachial Index	1.14, 1.23 (0.53)	1.19, 1.08 (0.29)	0.443
Outcomes			
Reinfection	141 (48.0)	27 (30.7)	0.004
Index Length of Stay	8.0, 10.91 (9.16)	8.0, 8.82 (5.81)	0.771
Total Days Admitted for Foot	13.0, 18.82 (17.68)	10.0, 13.67 (11.51)	0.010
Number of Surgeries	2.0, 2.31 (2.24)	2.0, 1.74 (1.26)	0.006
Readmission for Foot	139 (47.3)	26 (29.5)	0.003
Readmission, any reason	186 (63.3)	31 (35.2)	<0.001
Time to Heal (days)	115, 151.83 (108.77)	73.0, 108.83 (90.57)	0.038

Dichotomous variables presented as N (%). Continuous variables presented as median, mean (SD).

Patients with diabetes were 4 times more likely to have neuropathy (p=<0.001), 2.4 times more likely to have had a previous foot ulcer (p=<0.001), 3.7 times more likely to have a prior foot amputation (p=<0.001), 2.8 times more likely to have PAD (p=<0.001), 1.8 times more likely to have a reinfection (p=0.004), 1.8 times more likely to be readmitted to the hospital for a foot-related issue (p=0.003), and 2.4 times more likely to be readmitted for any reason (p=<0.001).

Conclusion:
Patients with diabetes had significantly higher rate of retinopathy, neuropathy, and dialysis. They had poorer outcomes with higher risk for reinfection, hospital admission, and number of surgeries.

[P54] TEMOCILLIN: A USEFUL ADDITION TO THE ARMOURY AGAINST DIABETIC FOOT INFECTION?

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Aim: To explore whether Temocillin is a useful antibiotic to treat diabetic infections caused by MDR coliforms.

Diabetic foot ulcers (DFU) are often complicated by infection, sometimes involving bone (osteomyelitis), requiring intravenous (IV) antibiotics. Multi-drug resistant (MDR) bacteria are difficult to treat particularly in osteomyelitis. MDR coliforms often require antibiotics that need to be given multiple times a day as an inpatient or are given carbapenems, our last resort antibiotics. Other options eg Ciprofloxacin and Ceftazidime increase the risk of Clostridium difficile infection (CDI).

Temocillin is an IV penicillin antibiotic administered as a bolus twice a day. It has good activity against MDR coliforms, low risk of CDI and penetrates bone; however, the UK license does not include diabetic foot infection.

Method: We treated patients with IV Temocillin at home who grew multi-resistant coliforms sensitive to it from bone, tissue or deep swab samples. Appropriate additional antimicrobials were prescribed where indicated. Data from 22/05/2017 -12/11/2019 was collected, a period of 30 months.

Results / Discussion: 22 patients treated over 30 months. 14 patients with osteomyelitis, 5 patients soft tissue and 3 calcaneal infection. Patients stopped temocillin due to: new microbiology (2), antibiotics no longer required as improved (3) admission for planned surgery (1).

Conclusion: Temocillin is a useful addition to the armoury for DFU where patients have grown MDR coliforms in soft tissue infections and osteomyelitis alongside gram positive or antifungal cover as appropriate. The results show maximum benefits within the first 8 weeks. Continuation should be reviewed if not improving within this timescale or where deterioration is seen. Benefits of this antibiotic include care closer to home, reduced hospital admissions and improved antibiotic stewardship.

[P55] ANTIMICROBIAL-RELATED ADVERSE EFFECTS DURING TREATMENT OF DIABETIC FOOT INFECTIONS: A PROSPECTIVE COHORT STUDY

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Management of diabetic foot infection (DFI) implies a challenging antimicrobial therapy, facing polymicrobism and, in case of osteomyelitis, the necessity of high-dose, prolonged and intravenous combination therapies (1) of which tolerance is unknown in such highly comorbid patients (2). This study assessed the risk and determinants of antimicrobial-related adverse events (AEs) during treatment of DFI.

All patients with DFI were included in a monocentric prospective cohort (06/2018-07/2019) describing the type and severity of antimicrobial-related AEs according to the Common Terminology Criteria for Adverse Events (CTCAE). Their determinants were assessed by logistic regression and Kaplan-Meier curve analysis.

Sixty-five patients with DFI were enrolled : 16 (24.6%) severe infection with systemic symptoms, 50 (76.9%) osteomyelitis. Thirty-for (52.3%) received surgery. Antimicrobials were prescribed for 6.6 (IQR, 2.5-8.5) weeks. Thirty (46.2%) patients presented at least one AE. Fifty-six AEs were notified. Twelve (21.4%) were severe (CTCAE grade ≥ 3): 5 acute renal injuries, and one anemia, diarrhea, nausea, pneumonia, rhabdomyolysis, and Clostridium difficile-associated colitis leading to death. Clindamycin use represented the only independent determinant for AEs (OR, 3.345;95%CI, 1.103-10.193; p=0.033), with 21/30 (70.0%) of clindamycin-treated patients experiencing toxicity (p=0.004). Chronic liver disease was the only factor that increased the risk of clindamycin-related AEs over time.

Occurring in highly comorbid patients, antimicrobial therapy of DFI is associated with a high rate of severe AEs, especially in clindamycin-treated patients, advocating for a close multidisciplinary monitoring of these difficult-to-treat patients.

(1) Valour et al. Antimicrob Agents Chemother. 2014.

(2) Asten et al. Diabetes Res Clin Pract. 2018.

[P56] COMPARATIVE CLINICAL OUTCOMES OF PATIENTS WITH DIABETIC FOOT INFECTION CAUSED BY METHICILLIN-RESISTANT STAPHYLOCOCCUS AUREUS (MRSA) OR CAUSED BY METHICILLIN-SENSITIVE STAPHYLOCOCCUS AUREUS (MSSA).

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Aim: To analyze the clinical outcomes among patients with diabetic foot infection caused by methicillin-resistant *Staphylococcus aureus* (*MRSA*) comparing with cases caused by methicillin-sensitive *Staphylococcus aureus* (*MSSA*).
Method: We abstracted data of 75 patients with mild or moderate diabetic foot infection according to the IWGDF/IDSA classification system, where *Staphylococcus aureus* was isolated from tissue specimens after admission at our diabetic foot unit. We compared several features between the two groups: MRSA versus MSSA. Healing was defined as complete epithelisation of the ulcer and/or the surgical wound.

Results / Discussion: *Staphylococcus aureus* was the only bacterium isolated in 42 occasions (56%) and in 33 occasions (44%) it was associated with other organisms. MRSA was found in 36 patients (48% of *S. aureus* isolated) and in 22 (29.3% of *S. aureus* isolated) was the only pathogen. MSSA was found in 39 patients (52% of *S. aureus* isolated) and in 20 (26.6% of *S. aureus* isolated) was the only pathogen. Table depicts the demographic and clinical outcomes of the study population.

N=75 Patients	**MRSA Group n=36**	**MSSA Group n=39**	**p-value**
Male/Female, n (%)	31(86.1)/6(13.9)	25(64.1)/14(35.9)	**0.029**
Mean age ±SD	59.9±8.4	60.35±12.7	0.106
Type 1/Type 2 DM n (%)	1 (2.8)/35 (97.2)	8 (20.5)/31(79.5)	**0.018**
DM (Years), Mean±SD	18.1±9.7	17.16±10.1	0.695
Glycated Haemoglobin mmol/mol, Mean ±SD	62±4.8	60±4.5	0.648
Smoker, n (%)	19 (52.8)	14 (35.9)	0.141
Nephropathy, n (%)	12 (33.3)	6 (15.4)	0.069
Neuropathy, n (%)	33 (91.7)	37 (94.9)	0.578
PAD (%)	15 (41.7)	9 (23.1)	0.085
SINBAD Classification Score (Points), Mean ±SD	3.6±0.99	2.8±1.06	**0.001**

Mean wound evolution (weeks) (Q_1;Q_3)	17.8±(3;29.5)	9.1 (1;12)	**0.008**
Mild/Moderate infection, n (%)	20 (55.6)/16(44.4)	28 (71.8)/11(28.2)	0.143
Previous antibiotic treatment, n (%)	11 (30.6)	14 (35.9)	0.624
Mean healing time (weeks) (Q_1;Q_3)	18.2(8;28) n=27	9.9 (3;12) n=38	**0.008**
Surgery n (%)	15 (41.7)	13 (33.3)	0.456
Mean healing time after surgery (weeks) ±(Q1;Q3)	10.5 ±(6.7;16.5) n=10	6.1(3;8.7) n=12	0.068

Conclusion: Patients with MRSA diabetic foot infections were significantly associated higher SINBAD Classification Score, longer mean wound evolution and longer mean healing time. We not observed significant differences in the number of surgical procedures to resolve infection or in the mean healing time after surgical treatment.

[P57] ROLE OF PLAIN RADIOGRAPHS ON THE DEVELOPMENT OF COMPLICATIONS IN PATIENTS WITH DIABETIC FOOT OSTEOMYELITIS DURING 12 MONTHS FOLLOW-UP

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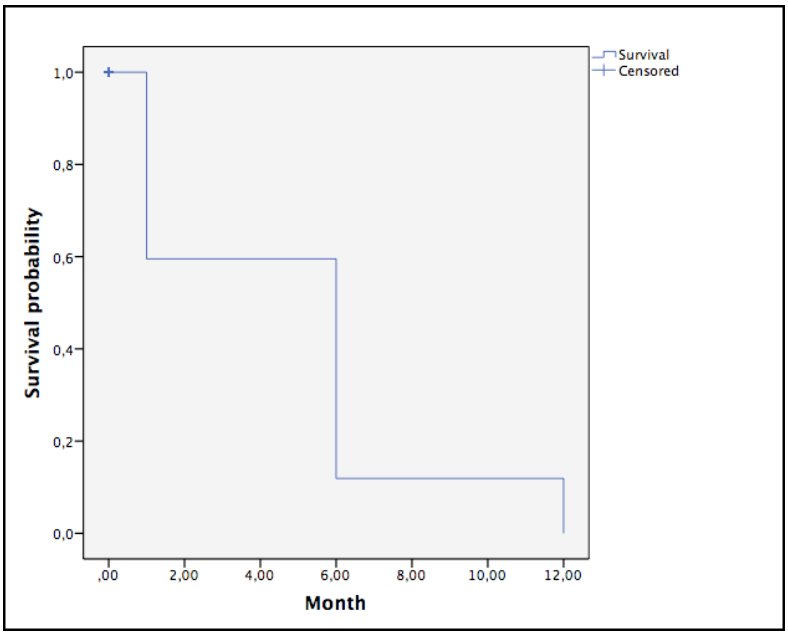
Aim: To analyse the utility of plain radiographs on the development of complications after healing in patients with diabetic foot osteomyelitis (DFO).
Method: A prospective observational study was carried out between November 2014 and November 2018, involving 115 consecutive patients who suffered DFO. All patients were treated by either surgical or medical approach to address bone infection, at a specialized Diabetic Foot Unit. Plain XR of the affected foot were taken (two standard views) in all subjects after healing. We analysed the following XR features for evaluating radiographic images changes: affected bone marrow, active periosteal reaction, sequestrum, cortical disruption and other type of signs. We analysed the association between XR changes and the development of complications after healing in 12 months follow-up.
Results / Discussion: Ninety-five (82.6%) patients were men, with a mean age of 63.0±10.1 years. Ninety-six patients (83.5%) received surgical treatment, and 19 (16.5%) received medical therapy. The mean time until healing from ulcers was 15.8±9.8 weeks. After healing, ten (8.7%) patients had radiological changes as follows: 4 (40.0%) affected bone marrow, 1 (10.0%) active periosteal reaction and 5 (50.0%) others. Eighty-five (73.9%) patients developed a complication during 12 months follow-up, which were distributed as follows: 51 (60.0%) reulcerations, 8 (9.4%) recurrences, 15 (17.6%) new processes of DFO, 5 (5.9%) DFO recurrences and 6 (7.1%) others. The survival time without complications are shown in the figure. Significant differences were observed between the presence of radiological changes after healing and the development of complications for 12 months follow-up 10 (8.7%), p=0.049; OR 1.4 [IC 1.2-1.6].



Conclusion: Plain XR could be useful in selecting patients with DFO who are likely to develop a complication after healing.

[P58] DIABETIC FOOT OSTEOMYELITIS IS CAUSED BY BACTERIAL INVASION THROUGH THE NUTRIENT FORAMEN IN THE EPIPHYSIS

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Aim: This study aimed to discover the route of bacterial invasion into the bone in diabetic foot ulcers.
Method: We examined 16 toe samples from 12 patients (8 men and 4 women; age range, 46-95years) who were diagnosed as having osteomyelitis and suspected to have bacterial clusters on the basis of histopathological examination using hematoxylin and eosin staining. Of the 16 bone samples obtained during surgery, 11 were from 9 patients with diabetes and 5 were from 3 patients without diabetes. Gram staining was performed for all 16 toe samples, ant the presence of Gram stain in the toe was examined. The localization of Gram stain was classified into 4 parts as follows: bone marrow, enthesis (connective tissue between the tendon and the bone), tendon, and soft tissue.
Results / Discussion: All the toes were confirmed to have osteomyelitis by bone culture. Gram stain was detected in 15 toes, and no stain was detected in only one toe. Gram staining was found in the bone marrow (9 toes), enthesis (11 toes), tendon (13 toes), and soft tissue (15 toes). In 9 toes, we confirmed the presence of bacteria along the tendon surface apart from the epiphysis and bacterial invasion into the bone marrow via tendon in epiphysis area. Anatomically, the foramen of the epiphyseal artery is located in this area. No articular cartilage was damaged despite the presence of bacteria on the surface of the cartilage.
Conclusion: Our study indicates that bone infection in the toes may be caused by direct bacterial invasion via tendon through the nutrient foramen in the epiphysis area.

[P59] KELLER ARTHROPLASTY FOR HALLUX LIMITUS AND HALLUX ULCERATIONS

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Aim:

Degenerative changes of the 1st metatarsal-phalangeal (MTP) joint and recalcitrant hallux ulcerations are common conditions encountered by the foot and ankle specialist. We herein present the results of our experience with the Keller arthroplasty to treat such conditions.

Method:

We retrospectively evaluated 54 patients undergoing 57 first MTP arthroplasty procedures, 15 of which were performed as a curative measure for plantar ulcers of the hallux. Thirty-three procedures (58%) were performed on patients with diabetes mellitus. The primary outcome measures were healing and occurrence of postoperative complications.

Results / Discussion:

Forty-five (79%) procedures healed uneventfully while 12 patients (21.0%) experienced complications. No patients underwent a hallux amputation during our 37.6 ± 21.5 month follow up period. While diabetes itself was not associated with complications (27.3% vs 12.5%, p = 0.177), peripheral neuropathy (34.5% vs. 7.14%, p=0.01) and the presence of a hallux ulceration at the time of surgery (67% vs 33%, p=0.000) were both significantly associated with this outcome. Mean shortening of the hallux was 7.3 ±3.5 mm and the mean time to heal ulcerations was 22.2 ± 9.4 days.

Conclusion:

We have shown a high degree of success with minimal postoperative complications when performing the Keller arthroplasty. Most complications can be anticipated in those patients with an open hallux ulcer or neuropathy. Regardless of surgical indication, patients with diabetes were at no greater risk for infectious complications unless they had an ulcer present at the time of operation.

[P60] LONG TERM EFFECTS OF FLEXOR TENOTOMIES

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Aim:

To describe the long-term effects of flexor tenotomies, and demographics of participants with diabetes that participated in a prior study on flexor tenotomies performed by scalpel between Jan 1st, 2006 and Dec 30th, 2009 at Steno Diabetes Center Copenhagen.

Method:

An observational study of participants with diabetes, who participated in a prior study of flexor tenotomy treatment performed at our institution, were invited for a reevaluation of the operated toes and a general foot examination in our clinic. In addition, data from patient electronic health records was obtained.

Results / Discussion:

The original study included 34 participants, of these 21(61.8%) had died, and one (2.9%) was lost to follow up. The remaining 13 patients had a mean follow-up of 146 months (±31.0), 10 were male (76.9%), with a mean age of 67.2 (±24.6) years, six (46.2%) had type 1 diabetes, mean HbA1c of 60.8 mmol/L (±26.8), mean eGFR of 61.7 ml/min (Q1-Q3=42.5-87.8), mean LDL of 1.5 mmol/l (±0.96), five (38.5%) had prior or current Charcot diagnosis, nine (81.8%) had a vibration threshold above 45 V, and nine (81.8%) had missing sensation of monofilament.

At follow-up visit 18 of the initially operated toes (on 13 patients), of which six (33.3%) had reformed hammer, claw or mallet toe deformity, of these four had active flexion, and two had rigid deformities. There were active ulcers on two (11.1%) of the operated toes, and impending ulcers on further six (33.3%) toes. After the initial operation, 12 participants (92.3%) incurred a mean of 14.0 (Q1-Q3=5.0-17.5) ulcers per patient, six (46.2%) incurred one or more amputations, with a total of 10 amputations including five toe amputations, four below knee amputations (crural) and one above knee amputation (femoral).

Conclusion:

This study has shown that people with diabetes, treated with flexor tenotomies are a vulnerable population with a high mortality rate, high risk of amputation, of new ulcers and a risk of hammer, mallet and claw toes reforming over time. These facts highlight the need for close follow-up in the multidisciplinary team, and specifically a need to focus on early detection and prevention of foot complications.

[P61] SYME AMPUTATION: AN ALTERNATIVE TO MAJOR AMPUTATION?

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Aim: Syme amputation represent an alternative to below- or above-knee amputation. Until now this amputation was not considered a viable option for limb salvage. Necessity of intact heel pad and difficulties in prosthesis contribute to a low use of syme amputation. Aim of this study: evaluate if Syme amputation could be an alternative for patients destinated to major amputation for extreme rear foot impairment with loss of heel pad in diabetic patients

Method: retrospective observational study performed with interrogation of surgical database between January 2017 and December 2020, founded 15 diabetic patients with syme amputation. Protesization was obtained with a new 3D print tool, a socket of anatomical form, typically amputation allows linking of the prostethic foot. The suspension of the prosthesis is made vacuumally or by mechanical methods like belt. Outcome evaluated: healig rate, death, time to heal, walking ability.

Results / Discussion:

All patients have type 2 diabetes, mean age was 69±12 years (mean ± SD), 73% were male, long history of diabetes 22 ± 13 years and quite good metabolic control (HbA1c 7.7% ± 1,5) were founded. 6 (40%) patients presented chronic renal damage and 2 (13%) end stage renal failure, ischaemic heart disease was present in 5 (33%) patients. They presented very advanced and complicated wounds, lesions were at tibio-tarsal joint in 20% of patients, 80% presented osteomyelitis of the heel with loss of soft tissues, all Texas grade 3. 12 (80%) patients were ischaemic and underwent revascularization (all angioplasty).

At follow up of 9±10 months: 10 (66%) patients healed, 1 (7%) underwent below the knee amputation, 1 (7%) patient died with lesions, 3 (20%) are still ulcerated. Mean healing time was 66±44 days.

Relapse rate was 14% with a rapid resolution. Walking ability was preserved in 11 (73%) of patients thanks to the innovative brace.

Conclusion: syme amputation could be an alternative to major amputation also in presence of heel and tibio-tarsal infection with soft tissue loss. Our data demonstrate high percentage of limb salvage in patients with high heel impairment too. Extreme surgery in association with new prosthesis tools permit a good preservation of walking ability ensuring better quality of life for patients respect below or above the knee amputation.

[P62] TREATMENT WITH ANTIPLATELET THERAPY BEFORE MAJOR ORTHOPAEDIC CHARCOT RECONSTRUCTIVE SURGERIES IN INDIVIDUALS WITH DIABETES DOES NOT INCREASE THE RISK OF POSTOPERATIVE ANAEMIA AND THE NEED FOR TRANSFUSION.

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Aim: As a concept borrowed from general surgical principles, it is a normal practice to withhold antiplatelet therapy prior to major Charcot foot reconstructive surgery (CFRS). However, there is no robust data to support this view, especially given many such individuals will have coexistent vascular disease benefiting from continued therapy. In our centre, this is approached on a case by case basis. In this analysis, we investigated the effect of continued antiplatelet treatment on post-operative hemoglobin (Hb) and need for transfusion in diabetic foot patients undergoing major CFRS.

Method: A retrospective observational cohort study was conducted in our Multidisciplinary Diabetic Foot Clinic. The data were collected regarding patients that had undergone major CFRS in the period between 2007-2018. The patients were separated into 3 groups: A: Single antiplatelet therapy, B: Dual antiplatelet Therapy (DAPT), C: No antiplatelet therapy. Threshold for post-operative transfusion was a Hb drop below 80 g/L.

Results/Discussion: A total of 48 patients were considered eligible to be included in this study. There were 16 patients (33%) in Group A. The mean Hb drop from baseline was -22.12 g/L and 18.75% of the patients required red blood cell (RBC) transfusion. There were only 3 patients (6%) in Group B. A mean Hb drop of -25.66 g/l was noted post-operatively, and none required RBC transfusion. Finally, there were 29 patients (60%) in Group C. In these individuals, an average -23.93 g/L drop in Hb was observed after surgery. Transfusion was administered to 13.79% of these patients. There was no statistical difference between the groups on post-op Hb drop nor need for transfusion.

Conclusion: We observe that judicious, continued use of antiplatelets agents in diabetic patients undergoing major CFRS may apparently not lead to significant increase in postoperative anaemia requiring RBC transfusion. Our observation needs to be confirmed in a larger, more detailed study and if proven, may have impact on how we approach reconstructive surgical planning in this complex cohort.

[P63] THE USE OF MEDIAL COLUMN BOLTS IN MIDFOOT CHARCOT ARTHROPATHY

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Aim:
Charcot neuroarthropathy (CN) of the foot and ankle is a destructive process. The aim of the treatment is to provide a stable and plantigrade foot for the patient to ambulate using accommodative footwear. Column beaming using intramedullary bolts/screws is a recent technique described to achieve stability and prevent secondary collapse. We performed a review of the current literature up to Jan 2019 to assess the outcome of the use of column beaming in treatment of CN.

Method:
We performed a systematic review of the English literature to assess the efficacy of this technique in surgical correction of CN using the Medial Column Beam. The review followed PRISMA guidelines and incorporated an electronic search of the Medline database using PubMed as search engine as well as Embase, The Cochrane Library, and ProQuest. We included all the studies published until Jan 2018

Results / Discussion:
A total of 234 feet in 226 patients (146 males, 80 females) with an average age of 59 years (range 29-81) were analysed. Diabetes mellitus (DM) was the most cause of CN (184 patients). Average follow-up duration was 36 months (range 3-137 months). Medial column bolt was used in 217 patients. Considerable heterogeneity was noted regarding the radiological outcomes in these studies; however, majority of the authors reported a significant objective improvement in the radiological parameters. The complication rate was identified at 23.9% incidence of wound complications, 21.7% migration/breakage of the implant, 9.7% osteomyelitis and 9.3% non-union.

Conclusion:
Mid-foot reconstruction surgery carries a low rate of post-operative amputation and high rate of ambulation. Column beaming for mid-foot fusion significantly improves the deformity however, it has some particular risks when used alone and therefore surgeons should use these implants with caution within the Multidisciplinary team.

[P64] PLASMA LEVELS AND BONE EXPRESSION OF RANKL, OSTEOPROTEGERIN AND TNFA IN ACUTE CHARCOT FOOT

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Aim:

An exaggerated inflammatory response to a minor trauma is the most current theory regarding the pathophysiology of Charcot neuroarthropathy (CN). Osteolysis mediated through inflammation and activation of the receptor activator of nuclear factor kappa B ligand (RANKL)-osteoprotegerin (OPG) pathway has been proposed to be the primary event for the initiation of CN. The aim of our study was to compare plasma levels as well as the expression of RANKL, OPG and TNFa in bone samples from 3 groups of participants: patients with CN, patients with diabetes (DM) and healthy individuals.

Method:

A total of 59 participants were recruited: 24 patients with CN, 21 with DM and 14 healthy controls. Plasma RANKL levels were measured using ELISA and plasma OPG and TNFa using Luminex assay. Bone samples were collected from 31 participants: 11 patients with CN, 10 with DM and 10 healthy controls. Hematoxylin and eosin staining as well as immunohistochemistry for the expression of RANKL, OPG and TNFa were performed. The distribution and intensity of staining was graded by 2 independent investigators and a total score that ranged from 0-9 was calculated.

Results / Discussion:

Plasma levels of RANKL, OPG and TNFa, as well as the expression of RANKL, OPG and TNFa in bone samples were significantly different among the 3 groups of participants (Table). Multinucleated osteoclasts demonstrating active bone breakdown were observed in bone specimens obtained from patients with CN.

Table. Plasma levels and expression of RANKL, OPG and TNFa

	CN	**DM**	**Control**	**p**	**p**

	group 1	group 2	group 3	1 vs. 2	1 vs. 3
RANKL (pmol/l)	149.5 (114.8-213.1)	81.1 (58.3-140.2)	127.3 (95.2-291.3)	0.013	0.760
OPG (pg/ml)	425.6 (330.1-568.1)	317.7 (216.4-427.8)	198.2 (175.0-233.1)	0.020	<0.001
TNFa (pg/ml)	3.7 (2.7-5.3)	2.7 (2.3-3.3)	1.5 (1.1-1.9)	0.007	<0.001
RANKL score	6.0 (4.0-8.3)	2.0 (2.0-3.5)	1.0 (1.0-1.0)	0.005	<0.001
OPG score	6.0 (6.0-9.0)	4.0 (2.0-4.0)	1.0 (1.0-1.0)	0.010	<0.001
TNFa score	4.0 (3.5-6.8)	2.0 (1.0-2.0)	1.0 (1.0-1.0)	0.009	<0.001

Conclusion:

Increased bone resorption in acute CN is mediated through increased expression of RANKL and TNFa, while increased expression of OPG does not seem to counterbalance the increased RANKL-mediated osteoclastic activity.

[P65] TO WHAT EXTENT DO PATIENTS WITH DIABETIC FOOT COMPLICATIONS RECALL DIABETIC FOOT SELF-MANAGEMENT EDUCATION?

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Aim: Approximately 25% of all patients with diabetes develop a foot ulcer and approximately 80% of all major lower limb amputations are preceded by a foot ulcer. The diabetic foot care education is therefore crucial for the prevention of foot ulcers. This study aimed to compare the instructions that podiatrists communicate to patients, with the instructions remembered by patients immediately after consultations and study the level of agreement.

Method: Participants included four podiatrists and 40 patients with diabetes. Data collection includes podiatrists' notes in the patient record, data from audio-recorded consultations and data from interviews immediately after consultations, as well as background data and the PAID-5 questionnaire. Chi-square tests were conducted to assess agreement.

Results / Discussion: Mean age of patients was 66 years, 65 % with T2 DM, 65 % men, 50% had >12 years of education and 83% were retired. 55% had >2 consultations in the foot clinic during the last two years, and 38% had been to other consultations the same day. In all 28 % of the patients had diabetes distress (≥8 in PAID-5) and 93% were at risk of foot complications (IWGDF 2019 risk stratification 3). In the comparison between the podiatrists' key messages and the patients' recall of these, 40 % (n=16) showed "full agreement", 37% (n=15) showed "almost full agreement", 20 % (n=8) "almost no agreement", and 2% (n=1) "no agreement". There were no significant associations between level of agreement and the various collected patient data (p=0.10 to p=0.65). In the 22% (n=9) cases with no or almost no agreement, almost everyone recalled key messages about footwear, while recall was missing for other essential parts of foot care such as daily observation of the feet.

Conclusion: The hypothesized barriers for effective education in specific foot self-care, did not seem to influence the variation in agreement in this small sample size. Still 22 % of the patients did not recall important key messages. This could be due to the patients' idea of what constitutes foot care. Future studies should further explore characteristics of the consultation and possibilities of enhancing the recall of the education.

[P66] IS THERE ANY RELATIONSHIP BETWEEN MUSCLE STRENGTH AND JOINT MOBILITY IN ADULT PATIENTS WITH DIABETES?

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Aim: It is known how diabetes can negatively affect muscle strength and joint mobility over time, two important risk factors for foot ulcer. The purpose of this pilot study was to verify the presence of a relationship between handgrip strength (HG) and ankle joint mobility (AJM) in adult patients with diabetes.
Method: In 68 patients (M / F: 30:38; type 1/2: 52/16). mean age 45.5±19.1 years. years of diabetes 16.9±13.4. HbA1c 7.9±1.1%. body mass index (BMI) 25.6±6.0 Kg/m^2. the handgrip strength (Jamar-dynamometer). the ankle range of motion (inclinometer) in addition to the posture of the hand (Prayer sign test) were evaluated.
Results / Discussion: For both males and females. there was no significant relationship between JM and HG ankle. Only AJM showed a significant inverse relationship with age ($r = -0.52$: $p < 0.001$) and BMI ($r = -0.45$: $p < 0.001$). Only in females HG was inversely correlated with age ($r=-0.48$: $p < 0.01$). On the contrary. the ankle JM was inversely correlated with age ($p<0.001$) and BMI for both genders ($r=-054$: $p=0.002$; $r=-037$: $p=0.043$ respectively). Males showed lower AJM than females ($p =0.01$) while subjects with T1DM (mean age: 38.2±16.1 years) showed a higher AJM than subjects with T2DM (mean age 65.3±13.2 years; $p<0.001$). No relationship between HG. AJM and the other parameters investigated was detected.
Conclusion: Handgrip strength and AJM despite having been associated with the condition of patients with diabetes did not show a relationship between them. AJM showed a better relationship with patients' age and BMI. These results indicate that further studies in this field are needed.

[P67] CHANGES IN SKIN MICROCIRCULATION FOLLOWING HYPEROXYGENATED FATTY ACIDS EMULSION APPLICATION IN PATIENTS WITH DIABETIC FOOT DISEASE

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Aim: We aimed to analyze the effect of the daily topic application of hyperoxygenated fatty acids emulsion in transcutaneous oxygen pressure in the feet of neuropathic and neuroischemic patients with diabetes.

Method: A longitudinal prospective non comparative clinical trial was performed in a specialized diabetic foot unit between November and December 2019. Fifty patients with diabetes and no active foot ulcer were included. We evaluated the evolution of the $TcPO_2$ (mmHg) values after the application of the tested emulsion (Corpitol® emulsion, Laboratoires Urgo Medical, Chenôve, France) for 3 months. We also analyzed modifications of skin features (skin dryness, skin shedding and skin color). The study was stratified in two different groups for analyses, neuroischemic and neuropathic patients. Neuroischemic patients were classified according to the IWGDF criteria as follows: ankle brachial index (ABI) ≤ 0.9 or ankle systolic pressure ≤ 90 mmHg and toe brachial index (TBI) ≤ 0.7 or toe systolic pressure ≤ 70 mmHg. Transcutaneous oxygen pressure measurement ($TcPO_2$) was performed using TCM400 device (Radiometer, Copenhagen, 2700, Denmark). Wilcoxon test for paired samples was used to explore the differences between study groups with the use of the tested emulsion, and additionally, McNemar test was performed to assess differences in skin during the follow – up period.

Results / Discussion: Neuroischemic patients showed a significant increase in $TcPO_2$ values (35.69 ± 13.88 mmHg) after two months of application of the tested emulsion that remained at month 3 (Day 60: 42.34± 10.98; p= .006. Day 90: 41.62 10.88; p= .011). Skin features, dryness and shedding, showed an improvement from baseline to the end of the study in both groups secondary to the use of tested emulsion (p< .001 and p< .001 respectively). Finally, skin color showed differences from baseline to the last visit in the neuroischemic – group (p= .029).

Conclusion: Tested emulsion showed an increase in the transcutaneous oxygen pressure and an improvement in skin trophism in patients with neuroischemic foot. These findings could support the use of this emulsion in the prevention of diabetic foot problems, especially occurrence and/or recurrence of neuroischaemic DFU.

[P68] EVALUATION OF ADHERENCE TO THE ORAL ANTIBIOTIC TREATMENT IN PATIENTS WITH DIABETIC FOOT INFECTION

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Aim: to evaluate the adherence measure of the oral antibiotic treatment in patients with diabetic foot infection.
Method: observational study of 30 patients with diabetic foot ulcer (DFU) was performed. The inclusion criteria were patients with antibiotic oral treatment for soft tissue infection or osteomyelitis. The patients with soft tissue infection were treated with antibiotic during five days at least and the patients with osteomyelitis during 6 weeks or until the ulcer healing. The adherence were evaluated by the Eight-Item Medication Adherence Scale1 and were divided in low, medium and high adherence. All the antibiotics were prescribed bases on the recommendation of IDSA Guideline. We recollected demographic and sociocultural data about the patients.
Results / Discussion: Seventy seven percent of the patients were men with a mean of age of 64.6±15.4 years. Sixty three percent of the infections were soft tissue and 36.7% were osteomyelitis and the mean time with oral antibiotic was 1.53±1.2 and 5±1.1 weeks respectively. Low level of educational attainment was found in 43% of the patients and 66.7% of the sample were retiree. High adherence to antibiotic treatment was found in 57% of the sample. The patients with high adherence didn't require help to take the medication and had a high level of satisfaction with statistically significant association [p=0.01; OR: 13.7 (1.3-13.6)]. Forty five percent of the patients with osteomyelitis developed adverse events during the treatment and only 26% in the soft tissue group. The patients with osteomyelitis considered the treatment long and had more gastrointestinal events during the antibiotic treatment.
Conclusion: adherence and satisfaction to oral antibiotic treatment was high in patients with diabetic foot infection in general. Patients with osteomyelitis treated by oral antibiotic had more adverse effects than patients with soft tissue infection.

1. Morisky DE, Ang A, Krousel-Wood M, Ward HJ. Predictive validity of a medication adherence measure in an outpatient setting. J Clin Hypertens (Greenwich). 2008 May; 10(5):348-54.

[P69] DOES COOLING OF THE DIABETIC FOOT AS AN ULCER PREVENTION APPROACH REDUCE BLOOD PERFUSION?

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Aim: Diabetic foot ulcers (DFU) cause over 100,000 amputations every year in the US. Current preventive methods provide suboptimal prevention as several reports have indicated that amputation rates have been on the rise. Our group has been challenging the status quo on preventive methods offered to patients. It is known that cooler tissue is resistant to ulceration. In this regard, we previously developed temperature-regulating insoles (TRI) that maintain plantar temperatures at 28℃, which was shown to preserve the tissue. Our aim in this study was to explore whether cooling alters blood perfusion.

Method: Twelve subjects provided their informed consent. Inclusion criteria included being able to walk without assistance and not having active DFU. All subjects wore standard shoes, with TRI only in the right side. Subjects completed 5-minute walking bouts on a treadmill at self-selected speeds. Plantar thermography and tissue Oxygen saturation (StO2) images before and after walking. Average StO2 and temperature values for the forefoot, including hallux but excluding lesser toes, were analyzed and compared.

Results / Discussion: The temperature readings on TRI indicated that temperature regulation was on target in the forefoot (at or below 28℃) and significantly lower (p=0.01) than the control side (26.6±2.6℃ vs 30.9±2.2℃). The average bilateral difference in StO2 was only 3.3% (p=0.08). A set of thermal and hyperspectral images from a representative diabetic subject is shown in Fig 1. Although the sample size was relatively small (n=12), our results indicated that cooling of the diabetic foot may not necessarily cause a reduction in blood perfusion.

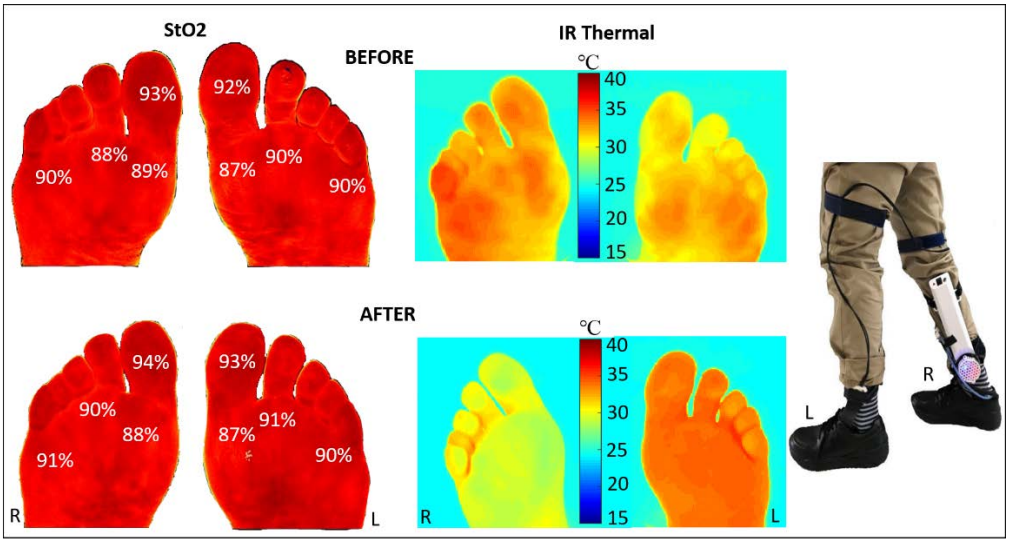

Figure 1. A representative result of a subject with diabetic neuropathy. Hyperspectral (left row) and temperature (middle row) images collected before and after treadmill walking. TRI in-use (right). Bilateral temperature reduction is 1.9˚C, StO2 reduction is 2%. R: Right, with TRI, L: Left, Control shoe.

Conclusion: Temperature regulation of the diabetic foot may revolutionize the preventive care provided to diabetic patients. The benefit of regulating metabolic rates and preserving the tissue against breaking down, while not causing any reduction in blood perfusion is a major step in more effective preventive methods. Our next goal is to conduct a randomized controlled trial in order to reveal the preventive potential of TRI.

[P70] BEWARE OF HIGH RATE OF NON-ADHERENCE WHEN PLANNING ULCER PREVENTION STUDIES IN PEOPLE WITH DIABETIC NEUROPATHY

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Aim: Ulcer prevention studies are often based on the assumption that people with diabetes who are at risk of foot ulcer recurrence should adhere to footwear and daily routine care. We report that more than 70% of foot ulcer recurrences were related to lack of compliance in a cohort of patients with diabetic neuropathy

Method: We conducted a recent multi-centre randomised clinical trial to assess the utility of clinical thermography adjunctive to standard foot care versus standard foot care alone to prevent foot ulcer recurrence in people with diabetic neuropathy and history of foot ulcer. Subjects were followed up monthly until ulceration or for 12 months. When a patient presented to clinic with a new onset of foot ulcer, the podiatrist at each centre asked about the reasons of ulceration. At the end of the study, at a consortium meeting, each case was presented anonymously by the treating podiatrist and the panel decided whether each ulcer can be classified as biological, behavioural or combined (biological+ behavioural).

Results / Discussion: During the study 41 out of 110 patients enrolled in the study developed a foot ulcer. Only 24% of the ulcers were considered biological, whereas 41% were categorised as behavioural and 35% were deemed with combined etiology). Common reasons for foot ulcer recurrence included inappropriate footwear (8 patients), barefoot injury (7 patients), prolonged walking in bespoke footwear (10 patients), callus pressure (8 patients); self-cutting nails prior the foot appointment (3 patients) and external trauma to the foot from heavy object (1 patient). Other reasons included unknown trauma (2), cast rub (1) and pressure from a thick nail (1). Foot ulcers developed more commonly when patients were on holiday or during a long weekend. Only 41% ulcers recurred at the site of previous foot ulcer.

Conclusion: This study shows a high rate of non-adherence to routine care and bespoke footwear which should be accounted for when planning future ulcer prevention studies. It is advisable to use telemedicine to monitor subjects' adherence when comparing the effectiveness of interventions in people with neuropathy.

[P71] 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).

Method: 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.

Conclusion: PAS/FTR is as effective but significantly more efficient than STR for managing DF patients with CLI with indication to endovascular revascularization.

[P72] COMPARISON OF THE IMPACT OF AUTOLOGOUS CELL THERAPY AND CONSERVATIVE TREATMENT ON TISSUE OXYGEN SUPPLY AND COURSE OF THE DIABETIC FOOT IN PATIENTS WITH CHRONIC LIMB-THREATENING ISCHEMIA. A RANDOMIZED CONTROLLED TRIAL

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Aim: Autologous cell-therapy (ACT) is a new treatment method for patients with diabetes and no-option chronic limb-threatening ischemia (NO-CLTI). We aimed to assess the impact of ACT on CLTI in comparison with standard therapy (ST) in a randomized controlled trial.
Method: Forty diabetic patients with NO-CLTI were randomized to receive either cell therapy (n=20) or standard conservative therapy (n=16); 4 patients dropped out of the study. After 3 months, those in ST group were switched to ACT (cell therapy crossover). The effect of ACT on ischemia and wound healing was assessed by changes in transcutaneous oxygen pressure ($TcPO_2$) and the number of healed patients at 3 months. Pain was evaluated by Visual Analogue Scale (VAS) and Wong-Baker Faces pain rating scale (WB). Amputation rates and amputation-free survival (AFS) were assessed at 3 months and then during 12-month follow-up in both groups.
Results / Discussion: $TcPO_2$ increased significantly in the ACT group after 3 months ($p<0.001$) whereas in the control group remained unchanged (NS). After the crossover of ST to ACT, we observed a significant increase in $TcPO_2$ at 3 months after the injection of ACT ($p<0.001$). We also observed significantly more healed patients in the ACT group compared to the ST group ($p=0.01$). Pain was significantly reduced in the ACT group after 3 months compared to baseline in both VAS and WB scores (both $p<0.001$); in the ST group, we observed even worsening of both pain scores without a significant difference. The rates of major amputation and AFS at 3 months were not significantly different between both groups. In Kaplan-Meier estimate, during 12-month follow-up subjects treated initially by ACT showed a trend towards higher AFS compared to those treated by ACT after a 3-months delay (65 vs. 43.8%).
Conclusion: Our randomized controlled study showed that ACT in patients with no-option CLTI and diabetic foot significantly improved limb ischemia and wound healing after 3 months when compared to standard conservative therapy. We also observed a trend to a higher amputation-free survival during 1 year follow-up in patients treated initially by ACT compared to those treated by ACT after a 3-months delay.

[P73] DO PATIENTS HOSPITALISED FOR A DIABETIC FOOT ULCER SUFFER FROM CHRONIC KIDNEY DISEASE AND DOES CHRONIC KIDNEY DISEASE AFFECT THE SEVERITY AND THE OUTCOME OF THE ULCER? A PILOT STUDY.

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Aim:

To evaluate the prevalence of chronic kidney disease (CKD) in people admitted for a diabetic foot ulcer (DFU), and to assess the effect of CKD on DFU severity and outcome at six months.

Method:

This prospective single center cohort study included DFU patients admitted between July 2016 and September 2019. Renal function, expressed as the glomerular filtration rate (GFR), was estimated using the CKD-EPI (CKD-Epidemiology Collaboration) equation within 48 hours of admission and repeated within 48 hours before discharge.

Patients were grouped according to eGFR (group A: > 60 ml/min/1.73m^2; group B: 30-59 ml/min/1.73m^2; and group C: < 30 ml/min/1.73m^2). Ulcer severity was assessed using the SINBAD classification. Outcome was evaluated at 6 months and scored as: healing, minor or major amputation, and death.

Following variables were entered in a logistic regression to determine their independent effect on outcome: age, gender, smoking, BMI, cardiac and peripheral arterial disease, prior DFU, DFU duration, osteomyelitis, HbA1c, and eGFR.

Results:

149 patients were included; 75% were male, with a mean age of 68 years. Neuropathy (79%), cardiac (54%) and vascular (40%) disease, and history of DFU (52%) and amputation (32%) were common.

Patients were grouped according to eGFR (A: 50%; B: 31%; and C: 19%), meaning that 50% of patients had an impaired renal function. Eleven patients (7%) received dialysis, three (2%) had a kidney transplant. There was no difference between eGFR at admission and at discharge.

Statistical analysis (Kruskal-Wallis) showed no significant differences in DFU severity, according to SINBAD, between groups A, B and C.

Outcome at 6 months was: wound healing in 31%; persisting ulcer in 22%; amputation in 33% (minor) and 5% (major); and death (7%). Regression analysis showed lower eGFR to be the only predictor for negative outcome (major amputation or death: OR=3.185; p=0.003).

Conclusion:

CKD was present in 50% of patients. A relation between CKD and ulcer severity could not be documented. However, eGFR was a significant predictor for negative outcome at six months. Although this population seems comparable to the Belgian diabetic foot population, these results must be interpreted with caution given the small sample size.

[P74] EXAMINATION OF FOOT CORRECT SURGERY AND WOUND CURED SURGERY AT THE SAME TIME

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Aim:

Foot deformity is one of the causes of foot ulcers. The ulcers are recurred after the wound cured. It's very difficult to manage the patient education. The report of long term cases that foot correct surgery and wound cured surgery (debridement and reconstruction surgery) were undergone at the same time.

Method:

wo cases who were admitted to Kasukabe Chuo General Hopital with chronic limb threatening ischemia were studied, They were in 70' and 80' males and their comorbidities were diabetic mellitus and chronic kidney disease (G5d). Their activities of daily living were independence.

Firstly they took revascularization (endovascular therapy) and debridement operation. After that, they took reconstruction surgery (skin graft or stump plasty) and prophylactic surgery(distal osteotomy and metatarsal head resection) was performed.

Results / Discussion:

They were in rehabilitation using off-loading device after reconstruction surgery and maintained their independence in activities of daily living ,and the ulcer treatment and foot correction at the same time were no problem.

Making an adapted foot orthosis for the cured foot and attended a hospital. They didn't recurred for two years.

Conclusion:

Many patients with foot ulcers are elderly, and it is not common practice to perform foot corrections that require rest separately from ulcer treatment. In some cases, by performing foot correction at the same time as ulcer treatment, it is thought that the compatibility of the foot orthosis was improved and that prevention of ulcer recurrence was also attained. However, for that purpose, it is important that wound management doctors who can properly determine the extent of infection be performed.

[P75] MALNUTRITION IN A DIABETIC FOOT ULCER POPULATION: PREVALENCE, AND RELATION TO ULCER SEVERITY AND OUTCOME.

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Aim:

Although malnutrition is known to compromise wound healing, little is known on the link between malnutrition and diabetic foot ulcers (DFU). This study assessed the prevalence of malnutrition in admitted DFU patients, and the relation with DFU severity and outcome.

Method:

This prospective single-centre cohort study included people with a DFU admitted between July 1, 2016 and September 30, 2019. The Global Leadership Initiative on Malnutrition (GLIM) criteria were used to determine the presence and severity of malnutrition. Ulcer severity was assessed using the SINBAD classification. Outcome was evaluated after 6 and 12 months, and scored as: healing, minor or major amputation, or death. Logistic regression analysis determined which factors associated with the combined endpoint healing/minor amputation: gender, age, smoking, cardiac history, PAD, BMI, history of DFU/amputation, DFU duration, SINBAD classification, osteomyelitis, eGFR, HbA1c, and malnutrition.

Results / Discussion:

110 persons were included.

Malnutrition was diagnosed in 26 (24%). Patients were divided into 3 groups, according to nutritional status: normal (A: n=84); moderately malnourished (B: n=9); and severely malnourished (C: n=17). Demographics (80% males, mean age 68 years) and diabetes characteristics (84% type 2, mean HbA1c 7.4%, prevalence of neuropathy and nephropathy) were comparable between all groups. History of DFU (55%) or amputation (29%), as well as mean duration (111 days) and localization of the DFU (forefoot: 85%) were also equally distributed. Osteomyelitis was highly prevalent (61%).

Severely malnourished people presented with most severe DFU ($p<0.0001$, A vs C; $p=0.001$, B vs C).

No differences were noted in outcome according to nutritional status at 6 months. At 1 year follow-up, no patients with severe malnutrition (C) had obtained wound healing.

Outcome at 6 months was determined by smoking ($p=0.002$), osteomyelitis ($p=0.029$) and HbA1c ($p=0.029$); at 12 months only smoking significantly contributed to outcome ($p=0.03$).

Conclusion:

One quarter of people admitted for a DFU suffered from malnutrition. Ulcer severity was defined by severe malnutrition. Patients with severe malnutrition did not obtain wound healing at 1 year. These

data highlight the need for further research and eventual implementation of malnutrition screening in guidelines concerning the management of the diabetic foot.

[P76] PILOT EXPERIENCE ON THE USE OF S54P4 BIOACTIVE GLASS IN THE SURGICAL MANAGEMENT OF OSTEOMYELITIS (OM) IN DIABETIC FOOT (DF) PATIENTS.

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Aim: Bioactive Glass S54P4* (BGS54P4) is novel bone substitute with anti-bacterial properties, able to completely bond itself to the host tissues. BGS54P4 has been so far used in the management of OM in orthopedic patients. We aimed to test the product on DF patients with OM.

Method: We evaluated a group of DF patients admitted in our Department between July and December 2018 who underwent to interventions for OM, in whom the use of BGS54P4 could minimize the extent of demolition following the surgical procedures. Patients were treated with BGS54P4 on top of standard treatment directly in operating room. Patients were evaluated weekly for six months or until complete healing. During follow up we measured healing rate (HR) and time of healing (HT), need for further debridement procedures, recurrences, adverse or hypersensitivity reactions to study treatment.
Results / Discussion: 8 DF patients were enrolled (male/female 5/3; age 57±4 yrs; duration of diabetes 9.4±1.8 yrs, HbA1c 7.0±0.7%). We observed a HR of 87.5% and a HT of 34±2 days, with only one patient who needed a second surgical look. Nor recurrences neither adverse events during follow up were observed.

Conclusion: This pilot clinical experience, in a real life clinical setting, allows further prospective trials with BGS54P4 in diabetic foot.

*****Bonalive Biomaterials Ltd, Turku, SF.

[P77] EDUCATIONAL LEVEL AND DFU SEVERITY AND OUTCOME

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Aim:

To assess the effect of educational level on diabetic foot ulcer (DFU) severity and outcome.

Method:

This prospective single center cohort study included DFU patients admitted between July 2016 and September 2019. People were grouped according to educational level (group A: no diploma or primary school diploma, 27%; group B: high school, 48%; group C: university degree, 25%). Ulcer severity was assessed using SINBAD. Outcome was evaluated at 6 months and scored as healing/minor amputation versus major amputation/death. Following variables were entered in a logistic regression to determine their independent effect on outcome: age, smoking, cardiac history, prior DFU, DFU duration, SINBAD, eGFR, educational level, living with a partner, and dependency on social insurance.

Results / Discussion:

104 persons were included.

This predominantly male population (80%) had a mean age of 68 years. Neuropathy (83%), nephropathy (clearance <60 ml/minute; 46%), cardiac (57%) and vascular (39%) disease, and history of DFU (55%) or amputation (28%) were common. Osteomyelitis was highly prevalent (61%).

People with low education were older (A versus C: 72 vs 64 years, p=0.014), and had more renal insufficiency (A versus C: eGFR 55 versus 75 ml/min, p=0.025). People with a high school diploma had more antecedents of lower extremity amputation (B versus A: 34% versus 14%, p=0.05).

Median duration of DFU (28 days) and DFU localization (84% forefoot) were comparable for all groups.

People with lowest education presented with most severe DFU (A versus C, p=0.043). At six months follow up, wound healing rates including minor amputation were comparable between groups (57% vs 60% vs 60%); however, people with lowest education had a higher mortality (18% vs 2% vs 8%, A vs B p=0.051) and combined major amputation/mortality rates (21% vs 2% vs 2%, A vs B p=0.007).

Based on logistic regression, outcome (wound healing including minor amputation) at 6 months was determined by age (p=0.025), prior DFU (p=0.021), dependency on social insurance (p=0.002), and smoking (p<0.001).

Conclusion:

People with lowest level of education presented with more severe DFU. Despite this difference at presentation, educational level did not significantly influence a positive outcome at 6 months.

[P78] COST-EFFECTIVENESS OF TLC-NOSF DRESSING IN THE MANAGEMENT OF DFU IN THE UK, FRANCE AND GERMANY: AN OVERVIEW ANALYSIS

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Aim

Diabetes is one of the most widespread disease and a growing global epidemic with increasing prevalence in the adult population. A common side effect is the diabetic foot ulcer (DFU), associated with a high risk of infection and lower-limb amputation.

TLC-NOSF dressing has proven its significant efficacy from a randomized, double-blind clinical trial, EXPLORER, when compared with neutral dressings in 5 countries (France, Spain, Italy, Germany, and UK).

Authors will report the results of the economic impact of using TLC-NOSF dressing from the perspective of the UK, French, and German healthcare Systems.

Method

The studies involved a Markov-model cost-effectiveness design, involving seven health states. From the study endpoint of 20 weeks, extrapolation to a base-case time horizon of one year was adopted in the UK and French models and 100 weeks in the German one.

Deterministic and probabilistic sensitivity analyses were conducted to assess the robustness of the model parameters.

Results

The NICE Guidance has recently supported the use of TLC-NOSF in the DFU treatment, and reported an average annual cost-saving of £342 per patient in the UK; this treatment is also highly cost-effective in Germany (€3,767 cost savings) and in France (€3,345 cost savings). Depending on the uses of this TLC-NOSF dressing, higher are efficacy and cost savings and better is the quality of life.

Conclusion

UrgoStart compared with neutral dressings is the dominant treatment strategy in the management of DFUs, resulting in significant annual cost savings for all three healthcare systems.

[P79] 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 octasulfate wound dressing (TLC-NOSF dressing) *versus* a neutral dressing (TLC) in addition to the same standard of care, was then assessed in patients with neuro-ischaemic DFU, through a European RCT.

Method: 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=126) 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.

Conclusion: Sucrose octasulfate dressing and good standard of care are significantly more effective than neutral dressing, in the management of neuro-ischaemic DFUs, and specifically when treatment is initiated early in the wound evolution.

[P80] FOOT MISUNDERSTANDINGS: REPORTING THE PAN EUROPEAN ASSESSMENT OF PATIENT PERCEPTION AND ITS POSSIBLE IMPACT ON REFERRAL TIMES.

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Aim:
We investigated the pathway & timelines of being referred to specialist diabetic foot clinics in Europe and the patient's perception.

Method:
Consecutive patients affected by a new diabetic foot problem requiring specialist treatment were sampled for 3 months from 1st June to the 31st August 2016 in 5 European countries from 11 specialist Multi-Disciplinary Foot Teams' clinics (MDFT'clinics). Inclusion criteria included all patients being assessed for ischaemic, neuropathic and infective foot disease. All patients completed a standardize questionnaire.

Results / Discussion:
370-consecutive new-patients were recruited; mean age 66.9±15.9 years; 73.2% were men, with type II Diabetes (87.6%). 64.9% patients noted their own problem, in 12.9% a close family-member, only a third of problems were detected by the healthcare professional 27.9%.

43.3% it took 1-month to seek an initial opinion: 32.4% of patients noted their problem being present for 1-6 months before MDFT review, mean-time between discovery of the new-foot problem seeking professional help was 40.3 days, but onward-referral to MDFT occurred within 7 days for 56.2%; but the mean time was 86.2 days (mode 40.3).

284 had ulceration; 61.9% perceived it to be mild or moderate; clinical assessment showed 52.1% were ischemic-ulcers, 51.5% infected-ulcers, 30.6% ischemic-infected ulcers; 22.2% classified as IIID (University of Texas Classification) at time of review in the MDFT.

Conclusion:
We observed delays in presentation, discord in patient perception of the severity of foot problems. Patients are more likely to under/over-estimate their pathology. We believe there is a need for on-going educational and foot awareness program for both carers and patients.

[P81] MMP-INHIBITING WOUND DRESSINGS IN THE TREATMENT OF CHRONIC WOUNDS: THE CLINICAL EVIDENCE FROM A SYSTEMATIC LITERATURE REVIEW

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Aim: Matrix metalloproteinases (MMPs) substantially contribute to the development of chronicity in wounds, being involved in the impairment of the wound healing process. Thus, MMP-inhibiting dressings may support healing of chronic wounds. A systematic review was performed to determine the currently existing evidence base for the treatment of these chronic wounds with those dressings.
Method: A systematic literature search in databases and clinical trial registers was conducted to identify randomized controlled trials (RCTs) investigating the efficacy of MMP-inhibiting dressings. Studies were analyzed regarding their quality and their clinical evidence level.
Results/Discussion: Of 721 identified hits, 16 relevant clinical studies were assessed. Thirteen studies were performed with collagen- and three with sucrose octasulfate-based wound dressings. Indications included diabetic foot ulcers, venous leg ulcers, pressure ulcers or wounds of mixed origin. Among the endpoints, wound size reduction, complete wound closure rate and healing time were specifically chosen. Considerable differences in the quality and subsequent clinical evidence exist between the selected studies. Substantial evidence for significant improvement in healing was identified only for some of these dressings.

Conclusion: Evidence for the superiority of some MMP-inhibiting wound dressings exists regarding wound closure, wound size reduction, healing time and healing rate. The heterogeneity of the clinical outcomes of MMP-inhibiting dressings supports that other mechanisms are involved, which may explain these different clinical benefits. More research is desirable to substantiate the existing evidence for different types of chronic wounds and to generate evidence for some of the different types of MMP-inhibiting wound dressings.

[P82] SUCROSE OCTASULFATE INTERACTIVE DRESSING VERSUS NEUTRAL DRESSING IN PATIENTS WITH NEURO-ISCHAEMIC DIABETIC FOOT ULCERS: A BUDGET IMPACT ANALYSIS FROM AN INTERNATIONAL, MULTICENTRE, DOUBLE-BLIND, RANDOMISED, CONTROLLED TRIAL (EXPLORER)

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Aim:

Diabetic foot ulcers (DFUs) are challenging wounds associated with long healing times, high risk of infection and lower-limb amputation. An innovative local treatment (sucrose octasulfate dressing) has proven its superiority vs. neutral dressing in the treatment of DFUs in a randomised, double-blind clinical trial (EXPLORER). We aimed to assess the budget impact (BI) of the implementation of this treatment versus neutral dressing for patients with DFUs.

Method:

A decision model was built to assess the BI of the sucrose octasulfate dressing for treatment of DFUs patients in a French context. We used data from EXPLORER to inform model parameters, supplemented by estimates from the literature and French Data Base. We estimated individual average costs for each considered year from year 1 to year 4 from the cost-effectiveness analysis with the adjustment of valorization in a Health Insurance perspective.

Results:

Treatment of DFUs with those dressings generated an average annual saving cost of 3 345€ per patient in FranceTherefore, the sooner the treatment is initiated, the better are the healing rates for the patient with less cost for the health system.

Conclusion:

For 105 207 DFUs patients treated with sucrose octasulfate dressings over 4 years, the BI compared to neutral dressings is estimated negative. The introduction of those dressings would represent an economy of 368 328 776 €.

[P83] TENOTOMY IN PATIENTS WITH THE DIABETIC FOOT SYNDROME AND ITS IMPACT ON CLINICAL PRACTICE

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Aim: Leg defects can be a major complication in diabetes. A metabolic disorder leads to breakdown of the structure and mechanical properties of tendons, with diabetic motor neuropathy causing dysfunction of the interosseous and lumbrical muscles and affecting the biomechanics of the foot. The result is increased pressure on the forefoot and, at the same time, the development of deformities, which are most noticeable in the toes. Hammer toe and claw toe deformity are preconditions for the development of defects on the dorsal aspect of the foot, on the top of the terminal phalange and on the plantar aspect of the foot. Studies have suggested that these defects represent 43-55.5% of all leg defects and are an important prognostic factor for treatment, as they precede 63.9% of high-level amputations. In their clinical study published in 2013, Rasmussen et al. described an easy surgical procedure to correct toe deformities and achieving rapid healing of toe ulcerations. The aim of our retrospective study in diabetic patients treated with percutaneous tenotomy between January 2019 and March 2020 was to assess the risks of the procedure, healing time and the recurrence rate.
Method: A series of 43 consecutive patients (63.8% men; 37.23% women) was retrospectively analyzed.
Results / Discussion: Their mean age was 65.2/63.8 years, total number of treated toes 128, ulcerated toes 38; neuropathy was demonstrated in 71.4% of patients and peripheral vascular disease in 23.4%, diabetes duration was on average 22.4 years, average healing time 3.6 weeks and ulcer recurrence rate 2.6%. Local anesthesia was induced in 48.4% of patients.
Conclusion: Flexor tenotomy is a safe and effective procedure, easy to perform in outpatients. To avoid complications, it is useful to undertake the procedure with broad-spectrum antibiotic prophylaxis.

[P84] A BIOACTIVE BETA-GLUCAN GEL AS A TREATMENT OF 'HARD-TO-HEAL' DIABETIC FOOT WOUNDS: THE EXPERIENCE OF A TERTIARY CENTRE

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AIM: To describe the evolution of hard-to-heal diabetic foot wounds treated with a bioactive beta-glucan (BG) gel.

METHODS: We present a retrospective observational study with hard-to-heal diabetic foot ulcers (defined as lesions that did not decrease 50% in size during a 4-week period with the current best standard therapy) treated with BG gel at least for 4 weeks. Data regarding the characteristics of the wounds were recorded at baseline and after 4, 8 and 12 weeks of treatment. The clinical response was qualified as: healed wound, partial response (reduction ≥50% in size), without response (reduction <50% in size) and worsening of the lesion.

RESULTS/DISCUSSION: A total of 36 patients were treated with BG gel for at least 4 weeks. The individuals included were predominantly male (n=28;77.8%) and the median age was 69 years (P25-P75:64-78.8). Most of the wounds occurred in neuroischemic diabetic feet (n=25;69.4%). Twenty two patients (61.1%) presented prior history of diabetic foot ulcers. At baseline, median wound duration was 20 weeks (P25-P75:8-40) with a mean wound surface area of 0.9cm^2 (P25-P75: 0.3-3.1). At final follow-up evaluation, 15 patients (41.7%) completed at least 12 weeks of treatment, 10 (27,8%) completed 8 weeks and 11 (30.6%) had finished only 4 weeks of therapy. Overall, we have obtained full healing in 11 (30.6%) patients, partial response in 13 (36.1%), no response in 7 (19.4%) and worsening in 5 (13.9%). The median healing time was 8 weeks (P25-P75:4-8). The observed overall healing rate was slightly less than the ones described in literature (30.6 *versus* 38.0 to 56.0%), however these patients were submitted to longer treatment and follow-up periods. Despite this limitation, in our work BG gel seems to have a positive effect in hard-to-heal lesions with a 66.7% positive response rate (includes healed and partial response).

CONCLUSION: Treatment with BG gel seems to improve hard-to-heal diabetic foot ulcers as early as after 4 weeks of therapy, with a significant size reduction in up to 67% of cases.

[P85] EFFECTIVENESS OF A NEW DRIED HUMAN AMNIOTIC MEMBRANE-DERIVED THERAPY IN ADDITION TO STANDARD TREATMENT IN TREATING DIABETIC FOOT ULCERS-A PILOT STUDY.

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Aim: To investigate whether a new dried human amniotic membrane-derived therapy (dAM-DT), plus standard care (SC) vs SC alone improves healing by 12 weeks in participants with diabetic foot ulcers (DFUs). Secondary aims: safety, recruitment, retention, feasibility of blinding patients.
Method: A prospective, patient and observer blind, 2 centre, pilot, randomised controlled trial. Patients randomised 1:1 to dAM-DT plus SC or SC alone . Primary outcome: healing (full epithelisation without drainage for 2 weeks) of index ulcer within 12 weeks. Dummy packaging & foot draping used to blind patients. Digital images, wound area by acetate tracing, and AEs assessed every 2 weeks. Patient questionnaires used to assess feasibility of blinding.
Results / Discussion: 31 patient randomised (15 dAM-DT +SC, 16 SC alone; median ulcer area 0.62 (IQR 0.4-1.1) vs. 0.68 (0.3-1.3) cm^2 respectively) and received ≥ 1 treatments. By 12 weeks 27% (95%CI: 1.3-52%) vs 6.3% (0-19.6%) ulcers were healed (p=0.1.). Only 7 participants identified their treatment allocation (5 dAM-DT, 2 SC alone)
Conclusion: Controlled studies with amniotic membrane therapies have been published but none patient *and* observer blind. Although not powered to show a significant difference in healing by 12 weeks, these encouraging results show that this dAM-DT is safe, and patient blinding is possible in future studies.

[P86] INCREASING TRANSCUTANEOUS OXYGEN PRESSURE (TCPO2) IN PATIENTS WITH NEUROISCHAEMIC DIABETIC FOOT ULCERS TREATED WITH A SUCROSE OCTASULFATE DRESSING

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Aim: To analyze $TcPO_2$ values within the treatment of neuroischaemic diabetic foot ulcers (DFUs) treated with a sucrose octasulfate dressing (TLC-NOSF dressing).
Methods: Eleven patients with neuroischaemic DFUs treated with sucrose octasulfate dressing were included in a prospective pilot study in a specialized diabetic foot unit between July 2019 and March 2020. $TcPO_2$ values were measured using TCM400 device (Radiometer, Copenhagen) on the dorsalis pedis or tibial posterior artery angiosome according with ulcer location. $TcPO_2$ values were assessed at day 0, week 4, week 8 and at wound healing. Additionally, wound healing was evaluated based on improvements in the consistency and quality of granulation tissue using the Wollina score system and wound area reduction (WAR). Changes of dressing were carried out twice per week. Student "T" test for dependent samples were used.
Results / Discussion: Eleven patients were included (8 (72.7%) male) with a mean age of 61.90 $\pm$ 8,87 years old, 10 (90.9%) with Diabetes Type 2 and 1 (9.1%) with Diabetes mellitus type 1. HbA_{1c} mean values were 7.62$\pm$1.15 %. Six (54.5%) ulcers were IC and 5 (45.5%) were IIC according with Texas classification. The median area of the DFUs was 1.30 IQR [1.60-1] cm^2 and the median duration was 8 IQR [48 – 2] weeks. Wollina Score mean was 4.18$\pm$1.72 at baseline. Four DFUs (36.4%) were located in the hallux, 2 (18.2%) under the first metatarsal head (MTH), 1 (9.1%) under the second MTH, 1 (9.1%) under the third MTH, 1 (9.1%) under the fifth MTH, 1(9.1%) in the midfoot and finally, 1 (9.1%) in the heel. $TcPO_2$ values after sucrose octasulfate dressing application, showed a significant increasing between day 0 (33.54$\pm$11.16 mmHg) and wound closure (45.27$\pm$13.62 mmHg), p= .016. The ulcer healing time was 8 IQR [8 – 5] weeks.
Conclusion: Local treatment with a sucrose octasulfate dressing in neuroischaemic DFUs showed an increase in $TcPO_2$ values within the treatment. An improvement of the local angiogenesis has been previously mentioned as part of the mechanism of action of this dressing. The increase of the local microcirculation could support this theory.

[P88] FIVE YEAR RETROSPECTIVE ANALYSIS OF MINOR FOOT SURGERY WITH CALCIUM SULPHATE.

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Aim

Foot ulcers are known to be a complication of diabetes. Patients who have had previous ulcers are generally categorized at being high risk of developing further ulcerations and amputations. There have also been studies showing 5 year survival rate in patients with foot ulcers

The aim of this study is to look at 5 year survival and re-ulceration rates in patients who have undergone minor foot surgery between 2011-2015

Objective

This was to see whether patients who have undergone foot surgery are at greater risk of re-ulcerating or have a reduced 5 year survival rate.

Method: retrospectively analysis was undertaken for all patients who underwent day case surgery for management of their infected foot ulcers. All surgery was carried out by one practitioner and was under local anaesthesia with using highly purified calcium sulphate impregnated with antibiotics (gentamycin and vancomycin) as an adjunct. Data was collected from electronic records and patients were followed up for a period of 5 years looking at survival, re-ulceration, major amputations and the need for further foot surgery amongst this cohort of patients.

Results / Discussion: There were 97 patients during that time : 21 females, 76male, mean age 63±32years, follow-up showed mortality of at 5 years 24%. Of the 97, 8 had amputation at the time of surgery of the 89 remaining 8 (9%) re-ulcerated at the same site and 50% of these had further surgical intervention. 42% re-ulcerated but at a different site of which 50% had further surgery but none of the 97 patients went onto have major amputation.

Conclusion:

There is a good 5 year survival rate of 76% which is a better than expected outcome for patients with foot ulceration. A possible reason for this could be that earlier intervention prevents a decline in their general health and perhaps this is linked to what's happening cardio-vascular wise and prevents further decline in mental and physical health.

[Paul Brand Award Oral] ANALYSIS OF PLANTAR PRESSURE PATTERN AFTER METATARSAL HEAD RESECTION. CAN PLANTAR PRESSURE PREDICT REULCERATION?

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Aim: To evaluate the metatarsal head that supports the highest plantar pressure after the first metatarsal head resection (MHR) procedure and its relationship with reulceration in 1-year follow-up period.

Method: A prospective study was conducted between September 2017 and February 2020 in a specialized diabetic foot unit. Sixty-five patients with diabetes who suffered from the first MHR and with non-active ulcer at the moment of inclusion were enrolled. Peak plantar pressure (PPP) and pressure time integral (PTI) were assessed using, FootScan® software. PPP and PTI were recorded at 5 specific locations in the forefoot: 1st, 2nd, 3rd, 4th and 5th metatarsal head. The highest value of the 4 remaining metatarsal was selected. Foot position was stratified using Foot Posture Index-6 and forefoot deformities were recorded.

Results / Discussion: We found a particular PPP transfer pattern following a MHR (see table). PTI showed the same trend. During the one-year follow-up, we found that patients who underwent a MHR in the 1st and 2nd metatarsal heads suffered from the highest PPP in the 2nd and 1st metatarsal heads and it was related with ulcer occurrence, p=0.006 and p=0.005 respectively. Non statistical differences were found between foot type and pressure transference. Hallux abductus valgus and bony prominence were related with the presence of the highest PTI below 1st metatarsal after 2nd head resection, p=0.026 and p=0.021 respectively. Finally, highest PPP and PTI under the 3rd metatarsal after resection of the 5th were related with the presence of bony prominence too, p=0.031 and p=0.026 respectively.

Metatarsal head resected	**Highest PPP location - (N/cm^2),** median [IQR]	**P-value**
1st N=15(23.1%)	2nd metatarsal-22.53 [31.20-16.70]	**<0.001**
2nd	1st metatarsal-25.93 [31.57 – 14.99]	**0.001**

N =16(24.6%)		
3rd N=10(15.48%)	1st metatarsal-26.42 [29.14-22.57]	**0.001**
4th N=4(6.2%)	2nd metatarsal-27.2 [30.66-24.53]	**0.009**
5th N=20(30.8%)	3rd metatarsal-23.19[25.96-18.95]	**<0.001**

Conclusion: Patients who suffered from the first MHR procedure showed a particular pattern of plantar pressure transfer. PPP measurement is an useful tool that could help clinicians to predict the location with the highest risk of develop a new ulcer in order to stablish preventive therapies.

[Prize Oral 1] THE EFFECTIVENESS OF AT-HOME FOOT TEMPERATURE MONITORING IN REDUCING THE INCIDENCE OF ULCER RECURRENCE IN PEOPLE WITH DIABETES: A MULTICENTRE RANDOMIZED CONTROLLED TRIAL (DIATEMP)

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Aim: In diabetic foot ulceration, repetitive mechanical stress from being ambulatory is suggested to cause local inflammation and skin temperature increase before skin breakdown. This allows for monitoring and early intervention to prevent ulcers. We assessed the effectiveness of at-home monitoring of foot temperatures on incidence of ulcer recurrence in people with diabetes.
Method: In this multicentre outcome-assessor blinded randomized controlled trial we assigned 304 people with diabetes, neuropathy and foot ulcer history (<4 years) or Charcot neuro-osteoarthropathy to usual care plus daily at-home infrared thermometry at 6-8 predefined plantar locations per foot (enhanced therapy) or usual care alone. If ΔT>2.2°C between corresponding regions on both feet on two consecutive days, participants were instructed to reduce ambulatory activity with 50% until temperatures normalized. Primary outcome was foot ulcer recurrence in 18 months on the plantar, interdigital, toe apical or medial/lateral forefoot surfaces (i.e. at or adjacent to the measurement sites). Secondary outcomes were ulcer recurrence while adherent to enhanced therapy and ulcer recurrence at any foot site.
Results/ Discussion: On the basis of intention-to-treat, 44 of 151 (29.1%) participants in the enhanced therapy group and 57 of 153 (37.3%) in the usual care group had a recurrent ulcer at a primary site (RR 0.782 [95%CI: 0.566–1.080], P=0.133). Survival curves of ulcer recurrence were not significantly different between groups (P=0.167). Of the 93 participants adherent to enhanced therapy, 31 had ulcer recurrence (33.3%), which was not significantly different from usual care. Fifty-four participants (35.8%) in the enhanced therapy group and 72 (47.1%) in the usual care group had ulcer recurrence at any foot site (RR 0.760 [95%CI: 0.579–0.997], P=0.046).
Conclusion: At-home foot temperature monitoring in addition to usual care to early identify mechanical stress-related areas at risk does not significantly reduce incidence of ulcer recurrence at or adjacent to the measurement location. Adherence to temperature monitoring does not improve that outcome, which gives uncertainly about repetitive stress-related skin temperature increases in ulcer development. Only when foot ulcers on any location, including those not related to the measurement site, are taken as outcome does this intervention seem beneficial over usual care, suggesting a possible additional preventative effect by increasing patient's awareness for their feet and complications that may arise.

[Prize Oral 2] DEVELOPMENT OF A DIABETIC FOOT NAVIGATOR ROLE ACROSS A LARGE DIABETIC FOOT NETWORK ALLOWS CONTINUED PROVISION HIGH-QUALITY DIABETIC FOOT CARE DURING THE COVID19 PANDEMIC: THE SOUTH EAST LONDON DIABETIC FOOT NETWORK EXPERIENCE.

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Aim: Rapid access to a diabetes multidisciplinary foot (MDfT) clinic is essential for optimal outcomes. With the COVID-19 pandemic straining all services, there was a requirement to maintain provision of high-quality, intensive diabetes foot care across the South East London Diabetes Foot Network covering 7 London borough's and a population of 2 million.
Method: An interim diabetic foot navigator role staffed by two project managers from the Health Innovation Network (HIN) and supported by a network of diabetes foot specialists was rapidly introduced in Mid-March 2020. Working from home, they had a remit to connect across boundaries, thereby linking hospital MDfT's and community teams. A detailed COVID-19 plan was developed explaining how both existing patients and new referrals would be managed. This was followed by the formal commencement of a substantive navigator in mid-April 2020. Key elements of the role included:

- Production of process flow diagrams and guidance explaining propped new model.
- A proforma for telephone triage.
- Implementation of a daily capacity conference call to match appointment needs with capacity across network.
- Implementation of virtual support, operated by specialists, using Pando™ and Microsoft Teams software accessible by all members of the network.

Results / Discussion:
As of 13th May 2020, there have been 47 daily tracker meetings, 22 half hour virtual meetings via Microsoft teams and 45 days of 9-5 support via Pando messaging system. The network has provided virtual review to 7 patients reviewed on Pando™, with a median response time of 5 minutes. Of the patients discussed 14% managed in primary care (community), 57% upgraded to hospital clinic for review and 14% admitted to hospital on the (same day). It is too early to comment on the impact of this new model of care on amputation rates, but data is currently being collected.
Conclusion:
The deployment of a network wide diabetes foot navigator has facilitated the coordination of urgent diabetic foot care while maintaining high-quality pandemic response planning. Furthermore, it has enabled the rapid adoption of modern technology tools to facilitate access to expert diabetes foot care advice. It is our expectation that, in future even after the

pandemic response is downgraded, this role may continue as a supportive non-clinical intervention.

[Prize Oral 3] A PROGNOSTIC MODEL TO PREDICT THE RISK OF DIABETIC FOOT ULCERATION. A PROSPECTIVE COHORT STUDY OF PATIENTS WITH DIABETES IN TANZANIA

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Aim:
The aim of this study was to identify a prognostic model which can predict the risk of future foot ulcer occurrence in patients with diabetes.
Method:
1810(M/F:1012/798) patients, with no active foot ulcer participated in this study. Data from a set of 28 parameters related to the vascular, neurological and biomechanical measures of the foot were collected from the participants at baseline. During follow-up 123 (M/F:68/55) patients ulcerated. Survival analyses was utilised to identify the parameters that predict the risk of future diabetic foot ulcer occurrence.
Results / Discussion:
A number of parameters (HR[95%CI]) including: neuropathy (2.525[1.680-3.795]); history of ulceration(2.796[1.029-7.598]); smoking history(1.686[1.097-2.592]); presence of callus (1.474[0.999-2.174]); nail ingrowth (5.653[2.078-15.379]); foot swelling (3.345[1.799-6.218]); dry skin (1.926[1.273 -2.914]); limited ankle (1.662[1.365 -2.022]) and MTP joint (2.745[1.853-4.067]) ranges of motion; and decreased (3.141[2.102-4.693]), highly decreased(5.263[1.266-21.878]) and absent (9.671[5.179-18.059]) sensation to touch; age (1.026[1.010-1.042]); Vibration Perception Threshold(1.079[1.060-1.099]); duration of Diabetes(1.000[1.000-1.000]); plantar pressure at the 1st MTH(1.003[1.001-1.005]), Temperature Sensation (1.019[1.004-1.035]) and Tolerance(1.523[1.337-1.734]) Thresholds to hot stimuli and blood sugar Level(1.027[1.006-1.048]) were all significantly associated with increased risk of ulceration. On the other hand plantar pressure underneath the fifth toe (0.990[0.983-0.998]) and Temperature Sensation (0.755[0.688-0.829]) and Tolerance (0.668[0.592-0.0754]) Thresholds to cold stimuli showed to be significantly associated with a decreased risk of future ulcer occurrence.
Multivariate Survival analysis based on Cox Proportionate Hazard model indicated that nail ingrowth(4.42[1.38-14.07]); Vibration Perception Threshold (1.07[1.04-1.09]); dry skin status (4.48[1.80-11.14]) and Tolerance Threshold to warm stimuli (1.001[1.000 -1.002]) were significant predictors of foot ulceration risk in the final model. Kaplan-Meier survival analyses indicated that ulcer free survival time was significantly ($P<0.05$) shorter in patient with: dry skin ($\chi2= 11.015$); nail ingrowth ($\chi2= 14.688$); Neuropathy ($\chi2= 21.284$), and foot swelling ($\chi2= 16.428$).
Conclusion:
Nail ingrowth and dry skin were found to be the strongest indicators of vulnerability of patients to diabetic foot ulceration where each increased the risk of the future incident of

DFU by more than 4 times. The assessment of neuropathy in relation to both small and larger fibre impairment can be useful in predicting the risk of diabetic foot ulceration.