Feasibility Study To Assess the Use of Blister Prevention Pads for Diabetic Foot Ulcer Prevention.

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Fig 1: PelliTec pads unique self adhesive multi layer construction to reduce pressure and friction

INTRODUCTION

- **Diabetic peripheral neuropathy (DPN) occurs in up to 50% of patients with DM within 10-15 years of onset[1,2].**
- **Foot deformity and callus formation in response to pressure is a key precursor leading to diabetic foot ulceration. [3]**
- **PelliTec (Tectores Ltd.), developed in the UK, is a circular adhesive blister prevention pad shown to be effective at reducing the occurrence of blisters and pressure callus[4], but not in patients with diabetic foot disease.**
- **The pad sticks to the inside of footwear not on the skin and the gel layer moves with the foot to reduce friction.**

AIM: to determine the feasibility of using these pressure relieving pads in the diabetic MDT setting.

METHODS

- **12-week open labelled feasibility study**
- **50 patients were screened, 26 patients were deemed suitable to participate. 22 patients attended visit 1, 5 patients could not be recruited due to re-ulceration (see exclusion criteria below) leaving 17 patients with diabetes (T1 & T2) with evidence of foot deformity and loss of protective foot sensation being recruited from podiatry clinics**
- **INCLUSION CRITERIA: > 18 yrs old, history of plantar foot ulceration, healed at recruitment, doppler ultrasound positive for at least one pedal pulse in each foot**
- **EXCLUSION CRITERIA: active diabetic foot ulcer or charcot neuroarthropathy**
- **INTERVENTION: PelliTec pads were placed on the insole or inner liner of the footwear, at locations corresponding to the site(s) of previous plantar ulceration. Pads were replaced at each study visit or sooner if necessary**
- **FOLLOW UP: Participants were followed up at 4 week intervals for a total of 12 weeks**
- **OUTCOMES: Feasibility measures: time needed to collect/recruit subjects screening logs of recruitment/retention strategies, response rates and PPI/E (<6 wks)**
- **Mechanistic evaluation: repeated measures difference tests conducted in Neuropathy Lab using the research grade F-Scan, to compare plantar foot pressures with and without PelliTec pads during a standardised battery of physical activity tests**
- **Qualitative sub-study: to assess the barriers and facilitators to adoption of medical devices in the management of diabetic foot ulcers. Interviews with patients and healthcare professions. Thematic analysis of interview transcripts will be performed**

RESULTS

- **All participants (12 T2DM, 5 T1DM) completed the study with no drop-outs. Mean age and duration of diabetes were 62.1(10.0) and 16.1(9.9) years respectively.**
- **Most patients had recovered from 'less severe' [SINBAD median (range): 2.0(1.0-4.0)], neuropathic ulcers (n=13, 76%), which were all located in the forefoot.**
- **There was no recurrence of foot ulceration either at the site of the previous ulcer or at a new site over the duration of study follow up.**
- **Mechanistic and qualitative secondary endpoints are being evaluated.**

DISCUSSION

- **This feasibility study has provided early proof-of-concept that PelliTec pads can be used in the setting of a busy multi-disciplinary foot clinic to prevent the recurrence of foot ulceration. Recruitment can be performed successfully from podiatry clinics and patients are willing to participate. Study visits coinciding with existing clinic appointments reduces dropouts and does not impact on clinic flow especially when outcome measures are embedded in clinical activities.**
- **This will inform a future larger, definitive RCT to determine if this approach can be used to prevent the recurrence of foot ulceration.**
- **Analysis of the mechanistic and qualitative sub-studies will guide design and implementation of future trials.**

References:

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