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) affects up to 50% of patients with diabetes mellitus (DM) within 10-15 years of onset. Foot deformities and callus formation, often due to pressure, are significant precursors to diabetic foot ulceration. PelliTec, developed in the UK, is an adhesive blister prevention pad that effectively reduces blister occurrence and pressure calluses. However, it has not been effective in patients with diabetic foot disease. The pad adheres to footwear rather than the skin, with a gel layer that moves with the foot to reduce friction. The aim is to assess the feasibility of using these pressure-relieving pads in diabetic multidisciplinary team (MDT) settings.

Methods

This study was a 12-week open-labeled feasibility study involving 50 screened patients, out of which 26 were deemed suitable to participate. Of these, 22 patients attended visit 1, with 5 patients unable to be recruited due to re-ulceration, resulting in a final recruitment of 17 patients with diabetes (Type 1 and Type 2) exhibiting evidence of foot deformity and loss of protective foot sensation, sourced from podiatry clinics.

Inclusion Criteria:

- Participants had to be over 18 years old.
- They must have a history of plantar foot ulceration that had healed at the time of recruitment.
- Doppler ultrasound had to be positive for at least one pedal pulse in each foot.

Exclusion Criteria:

- Patients with active diabetic foot ulcers or Charcot neuroarthropathy were excluded from the study.

Intervention: PelliTec pads were placed on the insole or inner liner of the footwear, targeting locations corresponding to previous plantar ulceration sites. Pads were replaced at each study visit or sooner if necessary.

Follow-up: Participants were followed up at 4-week intervals over a total of 12 weeks.

Outcomes:

1. Feasibility Measures:
   - Time required for subject recruitment.
   - Screening logs of recruitment and retention strategies.
   - Response rates and Patient and Public Involvement and Engagement (PPI/E) metrics, with a target of <6 weeks.
2. Mechanistic Evaluation:
   - Repeated measures difference tests conducted in the Neuropathy Lab using research-grade F-Scan technology to compare plantar foot pressures with and without PelliTec pads during a standardized battery of physical activity tests.
3. Qualitative Sub-study:
   - Assessment of barriers and facilitators to the adoption of medical devices in diabetic foot ulcer management.
   - Interviews conducted with both patients and healthcare professionals.
   - Thematic analysis of interview transcripts will be performed to extract insights.

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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