

Diabetic Foot Ulcer Prevention Feasibility Study Using PelliTec Pads

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PelliTec blister prevention pads are a circular pad applied to the inside of footwear (not skin) that has a novel friction reducing sandwich construction which moves with the foot reducing pressure and friction. We hypothesise that this will reduce the risk of recurrent foot ulceration. The primary aim of this proof-of-concept study is to determine this can be used safely in patients with healed diabetic foot ulcers in multidisciplinary diabetic foot clinics. The secondary aim is to 1) evaluate the performance and reliability of the pads to confirm they are appropriate for reducing friction and pressure and 2) to assess patient and healthcare professional experience using PelliTec pads in the management of DFU.

Methods:

12-week open-labelled study of 17 patients with healed DFU (complete epithelialisation maintained for 4 weeks) attending 4-weekly podiatry-led study visits. All patients had the PelliTec pads applied to the inside of their footwear over the area of the healed ulcer. All components of usual foot/podiatry care were maintained throughout the study. Feasibility assessments included screening logs of recruitment and retention, follow up rates, adherence/compliance rates. Mechanistic evaluation of PelliTec pads was conducted in a laboratory-based setting to 'simulate' everyday foot loading using research grade insoles (F-scan system). A series of plantar pressure-based parameters (including peak pressure, pressure-time and aggregated pressure) will be calculated and compared with and without the PelliTec pad. Structured telephone interviews will be conducted with patients and podiatrists to explore specific themes relating to the use of PelliTec pads.

Results:

All participants (12 T2DM, 5 T2DF) completed the study. 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.

Conclusions:

This feasibility study has provided early proof-of-concept that PelliTec pad can be used in the setting of a busy multidisciplinary foot clinic to prevent the recurrence of foot ulceration. This will inform a future larger, definitive RCT to determine if this approach can be used to prevent the recurrence of foot ulceration.

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