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The effectiveness of felt padding for offloading diabetes-related foot ulcers, at baseline and after one week of wear

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ABSTRACT

Aim: Felt padding is used to offload diabetes-related foot ulceration although limited quality data exists to support its use. This study aimed to quantify pressure offloading from neuropathic plantar foot ulcers in a clinical setting, when felt padding is first applied and after wear.

Methods: This study used a within-subjects, repeated measures design. Data was collected in a high-risk foot service. Peak plantar pressures, contact area and contact time were measured in 15 diabetes subjects with 16 non-complicated plantar neuropathic foot ulcers, with: no felt padding, newly applied felt padding and felt padding after one week of wear. **Results:** Statistically significant decreases in peak pressure of 49% and 32% were measured with newly applied felt padding (188.0 kPa; $p < 0.001$) and worn felt padding (248 kPa; $p = 0.003$) respectively, compared to no padding (367.2 kPa). Worn felt offloaded 32% less pressure than new felt however this did not reach statistical significance ($p = .069$). Corresponding increases in contact area of 18% and 14% occurred with newly applied felt padding (156.9 cm²; $p < .001$) and worn felt padding (150.6 cm²; $p = 0.003$) compared to no padding (132.5 cm²). Contact time was constant across testing conditions.

Conclusions: New felt padding offloaded on average half the pressure applied to sites of plantar neuropathic ulceration, which reduced to one third after wear. Increased contact area under the foot is a possible mechanism contributing to pressure reduction. Further studies are required to evaluate effectiveness of felt padding directly on ulcer healing.

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1. Introduction

Diabetes-related foot ulceration is a serious complication associated with elevated morbidity, mortality and burden of

disease [1,2]. With global diabetes prevalence rates estimated to reach 532 million by 2035 [3], and a 2.5–10% yearly incidence rate of diabetes-related foot ulceration [4], targeted and effective ulcer prevention and management strategies

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are essential. Diabetes-related foot ulceration is caused by multiple factors. A predominating factor in the development of most foot diabetes-related foot ulcers is elevated plantar pressure in the presence of neuropathy. Elevated pressure, a surrogate measure of tissue trauma, is pervasive to initial ulcer formation [5,6], delayed healing [7] and ulcer recurrence [8,6]. Effective offloading of pressure as part of a comprehensive management plan is therefore crucial for timely healing of plantar foot ulcers [7].

Current best available research evidence indicates that total contact casts (TCCs) or non-removable knee-high devices with an appropriate foot-device interface, are the most effective first line option for offloading plantar forefoot neuropathic ulceration [9]. Following these devices is a range of removable devices and other modalities which have mixed evidential support [9]. In practice a wide variety of offloading devices are used clinically [10], as patient, practitioner, intervention and wound-related factors influence final offloading selection considerably [11].

Felt padding has remained an offloading modality of interest as anecdotally: it is easily customised to suit individual foot morphology, structural deformity and ulcer location; can be used where an irremovable device is not suitable or is contraindicated, its removability is obvious to the clinician which may enhance treatment adherence; it can be used in combination with walkers and other devices, and clinically felt padding has been attributed to facilitating good healing outcomes. A recent survey found that felt padding was commonly used for offloading ulceration under the hallux and forefoot, with 94% of clinicians surveyed indicating that they offload with felt padding on average 35% of the time when managing non-complicated neuropathic ulcers [11]. Felt was reported as the most commonly used modality, followed by removable casts/walkers then TCCs/non-removable walkers.

Felt padding is manufactured out of semi-compressed wool felt sheets of 5 mm, 7 mm or 10 mm thickness. Its adhesive backing allows felt to be fixed to the foot, shoe, insole or other ambulatory device. Easy to cut and layer into an arrangement of sizes, shapes and thicknesses, focal offloading of wounds or high pressure sites is gained by shaping apertures or U shapes in the felt around the site of interest (Fig. 1). Despite its reported frequency of use in the management of neuropathic foot ulceration clinically [11], research investigating the effectiveness of felt padding for offloading plantar pressure and ulcer healing within clinical populations is scarce.

In healthy populations felt padding ranging from 3.2 mm to 7 mm thick, and apertured or U'd around the measurement site, has been shown to reduce plantar pressures from 25% to 61% [12–14]. In 28 patients with active plantar neuropathic foot ulcers, Zimny et al. [15] showed initial average reductions in plantar pressure of 63% with the application of a mixed felt (1.5 mm) and foam (6.4 mm) (felted foam) dressing. This compares to up to 87% reduction in plantar pressures achievable with first line offloading options, TCCs and walkers [7]. Two of the few published studies investigating the use of deflective felt padding for plantar wound healing, Birke et al. [16] and Nubé et al. [17] reported favourable healing outcomes with felt padding compared to other offloading techniques,

although higher quality studies are required to verify these findings.

Apart from a lack of research into the effectiveness of felt padding for ulcer offloading and healing on clinical populations, other gaps in the literature are evident. Firstly, current studies report offloading capabilities of felt up to 7 mm thick whereas in wound healing practice it is not unusual for 30 mm of felt to be used. In their case study report, Curran et al. [18] report that pressure reduction was greater with thicker (7 mm) compared to thinner (5 mm) felt, supporting the intuitive concept that higher felt thickness is likely to lead to greater offloading. Clinically the risk of injury and shoe fit issues with thicker felt require consideration, however current offloading data on thinner felt padding options is not reflective of clinical practice in this area. Secondly, felt is a pliable material which fatigues with wear. The magnitude and timing of changes to offloading properties of felt once compressed with wear, have not been reported in the literature.

The aims of this study therefore are to quantify how much pressure is offloaded from sites of active plantar neuropathic foot ulceration when clinician prescribed felt padding is newly applied, and how much this alters after the padding has been worn for a typical clinical period. The specific research questions to be addressed in this study are:

1. What is the percentage reduction in peak plantar pressure over sites of active plantar neuropathic foot ulceration when clinician prescribed felt padding is first applied?
2. How much does the percentage reduction in peak plantar pressure over sites of active plantar neuropathic foot ulceration lower when clinician prescribed felt padding has been worn for 7 days?

2. Material and methods

2.1. Subjects

A within-subject, repeated measures design was used. The study was conducted across the Northern Health Network of Melbourne in conjunction with La Trobe University. Ethics approval was received from two institutional ethics committees (LR58/13, FHEC14/030) and informed consent was obtained from all subjects prior to their participation in the study. Fifteen participants with 16 ulcers were recruited to the study, 14 male and one female. The sample size was pre-specified and based on an 80% probability of detecting a clinically meaningful difference between interventions of 100 kPa in peak plantar pressure (standard deviation of 100 kPa and alpha level of .05). The clinically meaningful difference was based on the author's opinion and has been used in prior offloading research [19].

Subjects were recruited via direct approach from hospital-based and community-based high-risk foot services and were included if they were cognitively aware, over the age of 18 years and had an active plantar neuropathic foot ulcer due to diabetes mellitus which was being offloaded with felt padding as part of their ulcer management plan. Plantar neuropathic foot ulcers were included according to the

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