

Evaluation of the offloading effect of Kerraped® Plantar Ulcer versus post-operative sandal with and without Poron® insole using WalkinSense technology in a diabetic patient with a history of ulceration

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Introduction

Prevalence of diabetes in the UK and worldwide is increasing, due in part to an aging population and a rise in the incidence of obesity. In the UK alone an estimated 2.7m people are known to live with diabetes.¹ Foot problems in diabetes result from complications such as peripheral arterial disease and peripheral neuropathy. Peripheral arterial disease causes damage to large and small blood vessels supplying the lower limbs whilst peripheral neuropathy leads to degeneration of the peripheral nerves with subsequent loss of sensation and autonomic dysfunction. Ulceration of the foot is estimated to affect 12–25% of people with diabetes at some time in their lifetime, with amputation the outcome in 0.5% of cases per year.²

The majority of diabetic foot ulcers occur on the plantar aspect of the foot. As such, one of the key interventions is to mechanically offload pressure from the ulcer and peri-ulcer area. Total contact casting (TCC) is the gold standard in offloading. However, TCC is contraindicated in the presence of infection and/or ischaemia.

This paper reports on the offloading effect of Kerraped® Plantar Ulcer (KPU), a therapeutic offloading shoe system, compared to a standard post-operative sandal using WalkinSense Technology in a diabetic patient with a history of ulceration. KPU has a uniquely designed 18mm thick insole composed of Poron®, Plastazote® and multifoam and has easily removable pegs to allow selective off-loading (Figure 1). A post-operative sandal with Poron® insole (a urethane cushioning material) is first line intervention for plantar ulcerations in the Podiatry Department, particularly as it will accommodate wound dressings and swelling associated with infection, and the cushioning properties of Poron® will redistribute plantar pressures. WalkinSense is a relatively new technology that gives a 3D and real-time view of pressure distribution in the patient's plantar surfaces of the feet as they move.

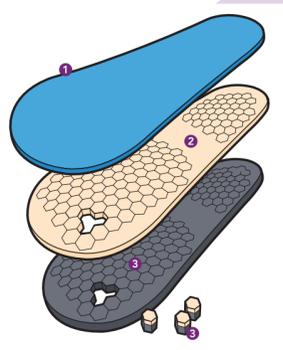


Figure 1. Kerraped® Plantar Ulcer insole cross-section

1. 3mm Poron® Cover
2. Plastazote®
3. EVA Plantar Pegs

Method

Peak plantar pressures and average plantar pressures were measured on a 47 year old male diabetic patient, with diabetic peripheral neuropathy. He was 5'9" and weighed 21 stone and had a history of ulceration beneath the 3rd metatarsal head, which was now healed, and amputation of the left 3rd toe. The patient was required to walk along a corridor for 15m with sensors placed over the likely areas of peak pressure, namely the hallux, the forefoot, the heel and over the healed ulcer site. A total of 16 evaluations were performed, 4 under each of the following conditions:

- a) Post-operative sandal with no insole
- b) Post-operative sandal with 7mm Poron® insole
- c) KPU with PegAssist™ insole in place and intact
- d) KPU with PegAssist™ insole in place and pegs removed at the healed ulcer site

Results

The results for each condition are shown in Table 1. Peak plantar pressure varied by footwear with complete offloading seen with KPU when the pegs were removed at the site of the healed ulcer (Figure 2).

Peak pressures at the healed ulcer site (sensor 4) in the post-operative sandal ranged between 139–237kPa, dropping to between 100–150kPa with the addition of the Poron® insole (Figures 3 and 4). The KPU with an intact insole demonstrated pressures similar to the post-operative sandal with Poron® of between 90–135kPa (Figure 5). However, the KPU with pegs removed under the healed ulcer site removed all pressure at this site resulting in a zero reading and achieved complete offloading (Figure 6).

Table 1. Average results for each footwear (n=4)

	Av pressure kg/cm ² (SD)	Max pressure kg/cm ² (SD)	Speed m/s (SD)	Distance m (SD)	No. steps (SD)
Post-op sandal	0.63 (0.08)	1.79 (0.44)	0.57 (0.13)	15.53 (2.51)	20.75 (1.50)
Post-op sandal with 7mm Poron® insole	0.47 (0.03)	1.40 (0.10)	0.54 (0.07)	13.67 (1.65)	19.25 (0.50)
KPU with intact PegAssist™	0.52 (0.05)	1.37 (0.10)	0.52 (0.06)	14.89 (0.86)	21.00 (1.41)
KPU with PegAssist™ pegs removed at healed ulcer site	0 (0)	0 (0)	0.35 (0.09)	9.79 (6.52)	20.50 (14.55)

Figure 2. Average peak plantar pressure by footwear (n=4)

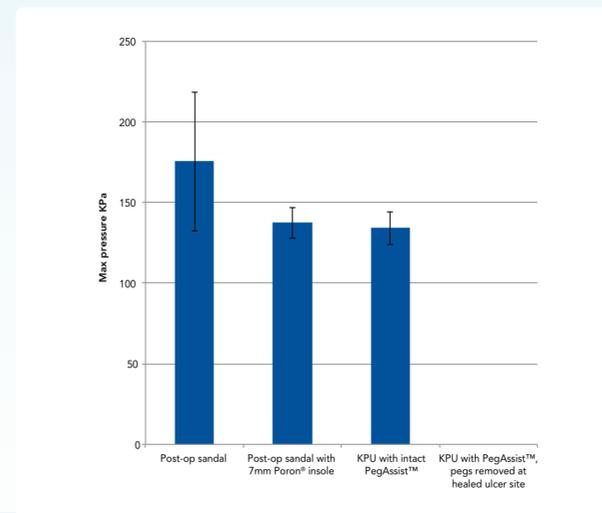


Figure 3. Post-operative sandal with no insole

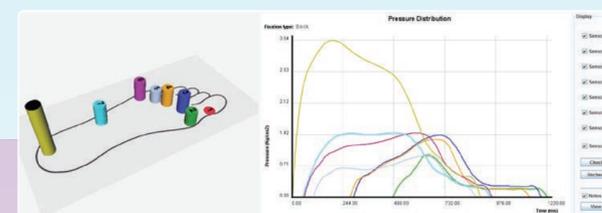


Figure 4. Post-operative sandal with 7mm Poron® insole

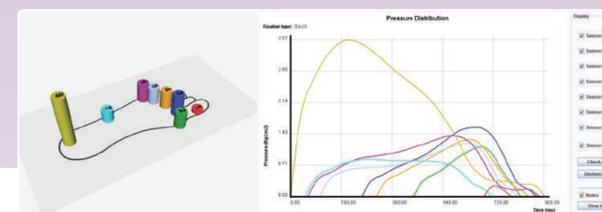


Figure 5. KPU with PegAssist™ insole in place and intact

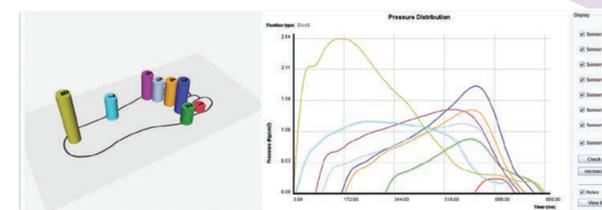
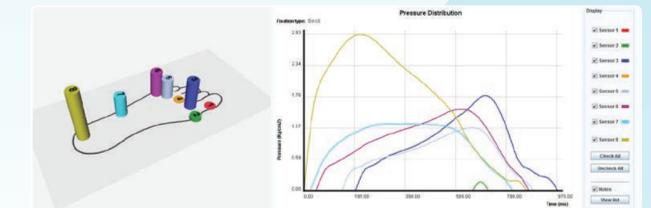


Figure 6. KPU with PegAssist™ insole in place and pegs removed at the healed ulcer site



Discussion

In the absence of in-shoe plantar pressure targets or thresholds available in the literature to guide clinical practice, the work of Owings et al³ which suggests a reduction of peak plantar pressure below 200kPa as desirable to prevent further ulcer damage and recurrence once healed is a helpful parameter. Reduction of peak plantar pressure and in particular re-distribution of pressure from ulceration sites is essential. The results of this case study utilising KPU are encouraging, as complete offloading of the previous ulcer site was achieved for this patient, and indicate that the same may have been achieved in this patient during an active ulceration episode. Further investigation is warranted of a larger group of patients.

Clinical relevance

The choice of modality to offload diabetic foot ulcers should be as the result of a holistic assessment of the patient to include the severity of the ulcer, available resources, mobility and daily activities of the patient. The KPU system is likely to have beneficial effects in the treatment of diabetic foot ulcers.

Acknowledgements

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References

1. NICE Guidelines. Type 2 diabetes: prevention and management of foot problems, 2004
2. Cavanagh PR. et al., *Lancet*. 366:1725-35, 2005
3. Owings TM. et al., *Diabetic Medicine*. 26:1141-1146, 2009