Report on a clinical evaluation of the KerraPro Heel silicone heel pad

Heels are at increased risk of injury due to the posterior prominence and lack of padding over the calcaneus. Pressure injuries, once established, are extremely costly, both in terms of the detrimental effect on psychosocial wellbeing and threat to life, as well as financially due to length of hospital stay and resources used to heal the wounds. A new and inexpensive silicone heel pad has been designed to simplify the necessary decisions and to address the problems associated with pressure injuries to the heels. This article will describe an observational evaluation of the product. KerraPro Heel pads were evaluated in two separate cohorts of 17 participants over a 4-week period with the primary aim to evaluate the efficacy of the product in preventing and alleviating pressure injuries on the heels. All participants had been reported as 'at risk' or 'at high risk' of pressure injury to the heels and had a history of developing such lesions. The KerraPro heel pads were compared with the participant's standard protocol. The outcome of the evaluation demonstrated the effectiveness of the KerraPro Heel pads in the prevention and treatment of heel pressure injuries.

prevention; pressure injuries; heel injuries; conformability

Pressure injuries are defined as localised injury to the skin and/or underlying tissue, usually over a bony prominence, as a result of pressure, or pressure in conjunction with shear.[1] Due to the thin layer of subcutaneous tissue between the skin and bone, the heel is the second most common site for pressure injury development after the sacrum and healing times for these particular injuries are long, in many cases over a year[2]. The heel is at increased risk of injury due to its posterior prominence and lack of padding over the calcaneus.[3]

Flushing of the skin, known as hyperaemia, provides sensitive clinical evidence of capillary occlusion and is used in practice to provide individualised care.[4] There is a significant relationship between hyperaemia and pressure injuries;[5] a thorough skin assessment of pressure areas will therefore highlight any redness and provide advanced warnings of pressure injury formation. Non-blanching erythema is an indication of inflammation that is occurring within the tissues beneath the epidermis and possibly below the dermis. The depth of this inflammation is easily identified by High Definition Ultrasound (HDU).

Tissue necrosis is caused by two processes which limit the supply of oxygen and nutrients to the tissues. Sustained pressure in excess of mean capillary pressure firstly occludes the blood supply to the skin. Micro-thrombi then form due to the effects of shear forces.[6] If occlusion of the blood supply is prolonged, it can also injure the lymphatic vessels, and may also squeeze interstitial fluid out from between the cells. As a result, there is little interstitial fluid to act as a buffer between cells, and they may come into contact with each other, resulting in cell rup-

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ture. Furthermore, toxic intracellular products may also build-up, causing necrosis of the surrounding tissue.[6, 7]

Pressure injuries are also extremely costly, both in terms of the detrimental effect on psychosocial wellbeing and threat to life, as well as financially, due to length of hospital stay and resources used to heal the wounds. At the same time, the incidence and prevalence of heel injuries appears to be increasing[8,9], possibly due to the fact that practitioners often have a low understanding of the causative factors, or fail to apply their knowledge to practice.[10] Therefore, it is vital that systems and policies must be put into place in order to prevent these life threatening injuries from occurring. These would address poor practice, as well as support many of the complexities that result in pressure injury. It is important to ensure that policies include the use of equipment to support nurses' decisions in prevention techniques.

A new silicone heel pad has been designed to simplify the necessary decisions and to address the problems associated with pressure injuries to the heels. This article will describe an observational evaluation of the KerraPro Heel Pad.

Heel pressure injuries

Unrelieved pressure increases the risk of pressure injury; pressure over the calcaneum can be 3–5 times greater over the bone than at the surface of the tissues,[11] placing the heel at far higher risk than other parts of the body.

Shear stress describes the resisting forces when one object attempts to slide past another.[12] These shear forces, which have the potential to cause pressure injury, is applied tangentially or in parallel[13]. The combination of unrelieved pressure, shear forces and friction can lead to considerable tissue injury.

The heel is the most common site for deep tissue injury,[14] accounting for 41% of all pressure injuries. A cross-sectional international study of 85,838 patients from all care facilities recorded the prevalence of heel injuries ranging from 23–28.9%.[15]

Heel injuries are potentially associated with sitting out of bed with heels on the floor.[16] Protecting the heels in this position is extremely difficult, as there are very few pressure relieving/reducing products available for this specific situation. Therefore, KerraPro Heel has been designed to protect heels when in bed or when sitting out.

KerraPro Heel.

Silicone (made from silicon dioxide, or silica, found in nature as quartz or common beach sand) is commonly used for pressure injury prevention in the immobile patient.[17] KerraPro Heel is a silicone pad designed to prevent pressure injury and to protect against shear forces. It is shaped to fit over the heel or the elbow and held in place by a tubular bandage. It can be worn with slippers (but not shoes), so any need to mobilise is unrestricted.

The KerraPro Heel is designed to diminish and not just redistribute pressure, hence the importance of the evaluation with regards to investigating this claim. Kerrapro's shape conforms comfortably round the heel and Achilles tendon and is suitable for general use and versatile in its application, either directly to the heel and held in place by stocking, sock or bandage, or by fixing in the participant's footwear. However, it is not designed for use as, nor should be used as a primary dressing on broken skin.

Proof of concept is always required for any medical device, even after the CE mark is awarded and after common use. Therefore, Wound Healing Centres undertook an observational evaluation to demonstrate that the product achieves what it claims to.

Method

KerraPro Heel pads were evaluated in two separate cohorts of 17 participants in 5 care homes over a 4-week period. The aim of the evaluation was to assess the efficacy of the product in preventing and alleviating pressure injuries (EUPAP) on the heels of vulnerable participants and to appraise the product's contribution to the prevention and reversal of pressure injuries in vulnerable adults.

All participants were resident in nursing homes. The average age of the participants was 90 with the oldest participant being 102 years old and the youngest, 68 years old. Two participants died during the 4 weeks and one participant was withdrawn by the nursing home matron following the development of a forefoot wound, which was unrelated to the product.

All participants had been reported as 'at risk' or 'high risk' of pressure injury to the heels and had a history of developing such lesions. Risk specifically related to the participants included severe immobility within the bed and the chair and for some, agitation, which caused people to continually move their feet up and down the bed, creating shear force damage. Six participants had small regions of non-blanching erythema, indicating a category 1 pressure injury on one or both of their heels. One participant had only mild blanching erythema on both heels but was included into the study given her Waterlow score of 26 and subsequent 'high risk' category. The participants were largely unable to express opinions on the product as they had varied degrees of dementia, compromising their ability to express themselves. Two participants were able to express themselves sufficiently. All participants had existing pressure injuries on one or both heels prior to the use of KerraPro Heels.

Potential participants were provided with an information sheet outlining the purpose of the evaluation. Those who agreed to participate were asked to sign a consent form agreeing to this and a consent form for photography. As many participants suffered from dementia, it was not possible to obtain informed consent from each of them. Therefore, the nursing home manager gave consent when deemed to be in the participants' best interest to take part.

Prior to the commencement of the study, a tissue viability specialist examined the heels of each participant. Any participant with identified non-blanching erythema of the heels was considered eligible for the study. Each participant received standard pressure protection for 6 weeks prior to the KerraPro Heel evaluation. This differed for each participant's individual needs. Five participants had been using an alternative polymer-based pressure relieving heel product prior to the evaluation and the outcomes were recorded in order to compare its efficacy with the KerraPro Heel. Each participant was provided with one KerraPro Heel Pad and the control heel was treated according to the participant's previous care protocol. In some participants in cohort 1, this meant the use of an alternative polymer-based pressure relieving heel product (Aderma). Therefore, each participant acted as their own control, maximising the validity of data captured.

Both heels of the participants were photographed, and high definition ultrasound (HDU) was performed to identify the level of inflammation beneath the skin. Where a clinician's physical assessment has a degree of subjectivity, HDU produces a clear value of oedema based on the ultrasound waves returned The heel with the most inflammation identified by HDU was selected for the KerraPro Heel. Scans were also taken of the participant's normal skin adjacent to the affected area to obtain a profile of the uninjured skin. Scans of the injured skin were then compared to the scans of the uninjured skin to provide a measure of how far from normal the tissues were at the start of the study and how they then progressed back towards the normal profile as the study advanced.

The benefit of including ultrasound as an assessment tool is that it provides quantitative information about the condition beneath the skin surface which is not always clinically evident. The scanner used in this project operated at a frequency of 20MHz (Episcan-Longport Inc.). This frequency provides an axial resolution of 65µm.

Results

KerraPro Heel pads were more robust than the alternative product, staying intact for the duration of the study. After 4 weeks, none of the KerraPro Heels displayed signs of breaking or tearing. Conversely, the alternative heel pads lasted for 7–14 days before developing tears or breaking apart. The KerraPro Heels were reported by care staff to be easy to clean with soapy water.

The term 'heel tissue viability' refers to the degree of erythema and oedema present over the heel; an intense, dark, non-blanching erythema with a high degree of oedema indicates pressure injury while a pale pink heel with mild to little oedema indicates a healthy heel. Improvement of heel tissue viability signifies a return to healthy heel tissue from an erythmatous and oedematous heel.

All participants had existing pressure injury or sore red heels with oedema on one or both heels prior to the use of the KerraPro Heel. The KerraPro heel resulted in improvement in the heel tissue viability of all of the participants, both visually and with assessment using HDU. These results clearly show that the KerraPro Heel was able to alleviate pressure injury in the 'at risk' patient and was effective in preventing further tissue injury over the study period.

The secondary aim of establishing the contribution of the heel pad in reducing and alleviating pressure injury to heels was more difficult to quantify. Education on repositioning, both frequency and technique, was improved in both cohorts due to input from the tissue viability specialist, which may have contributed to the improved tissue viability of the heels of all participants. However, both cohorts showed clear and significantly greatly reduction in pressure injury in the heel treated with KerraPro Heel, both in those using alternative heel pads and those participants only using repositioning. This indicates a strong contribution from the KerraPro Heel pads in returning injured heel tissue to healthy condition over the alternative heel pads and repositioning.

Using the scanner's image analysis software, it was possible to measure the amount of oedema

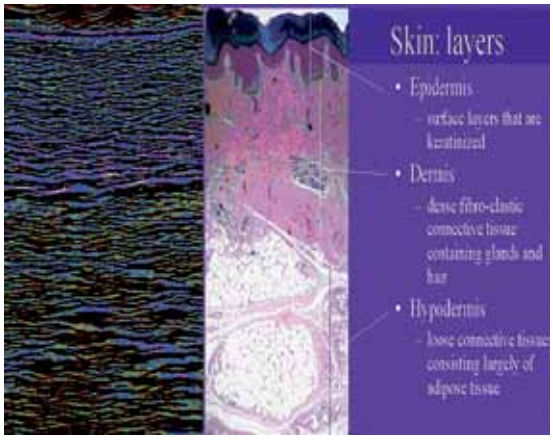

Fig1. Scan of normal skin with adjacent histology section indicating zones

within the dermal tissue. Oedema in the tissue was used as a proxy for determining inflammation in the dermis. Each scan of the tissue was analysed using a form of pixel distribution analysis whereby pixels below certain intensity are classed as Low Echogenic Pixels (LEP). The ratio of LEP's to Total Pixel count (TP) has been shown to reflect changes in dermal water content. Using this technique, it was possible to obtain a quantitative assessment of the level of oedema and hence inflammation present in the injured tissue.

The skin condition was checked daily and participants were reassessed weekly in order to chart the progress of their pressure injury. Photographs were taken at each visit to compare and monitor progression of the pressure injury. All participants were HDU-scanned on day 1 and day 28. Figures 2 and 3 are an example of comparison between normal skin and injured skin.

Each participant was examined with HDU. Figures 4 and 5 are an example of the scans that were undertaken on KerraPro Heel Participants.

In Fig 3, the injured tissue at time 0 had a large number of red pixels in the scan, indicating the presence of oedema. The scan of the same tissue after 4 weeks (Fig 4) showed that there was a dramatic decrease in red pixels and a concurrent increase in blue pixels, indicating an improvement back to the uninjured state.

Comparative results of both cohorts

Cohort 1 LEP:TP ratio

In order to evaluate the effectiveness of the KerraPro Heel across all participants, all HDU scans were assessed and collated to provide an average LEP:TP ratio for the 1st cohort.

It must be noted that LEP:TP levels were very near at time 0 between the treated and control heels at

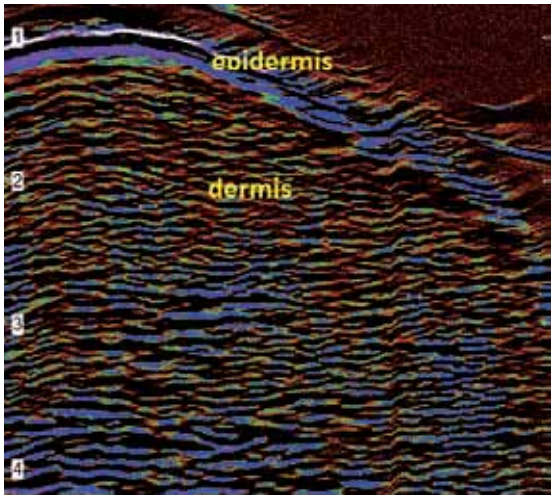

Fig 2. Scan of normal skin

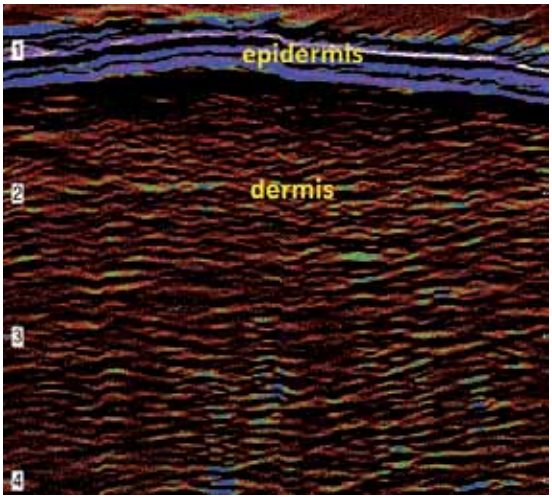

Fig 3. Scan of inflamed skin due to pressure damage

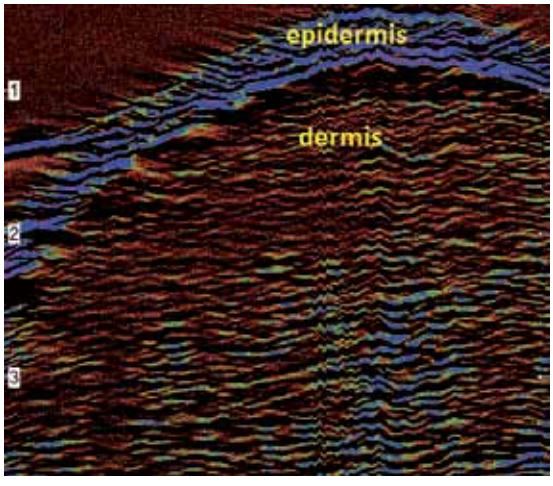

Fig 3. Participant 4: Injured heel at time 0 following use of KerraPro Heel.

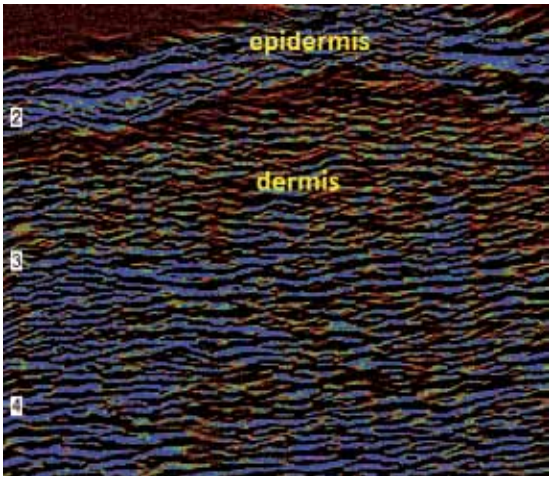

Fig 4. Participant 4: Injured heel on day 28 following use of KerraPro Heel.

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Fig 5. Graph showing Average LEP:TP ratio for Cohort 1

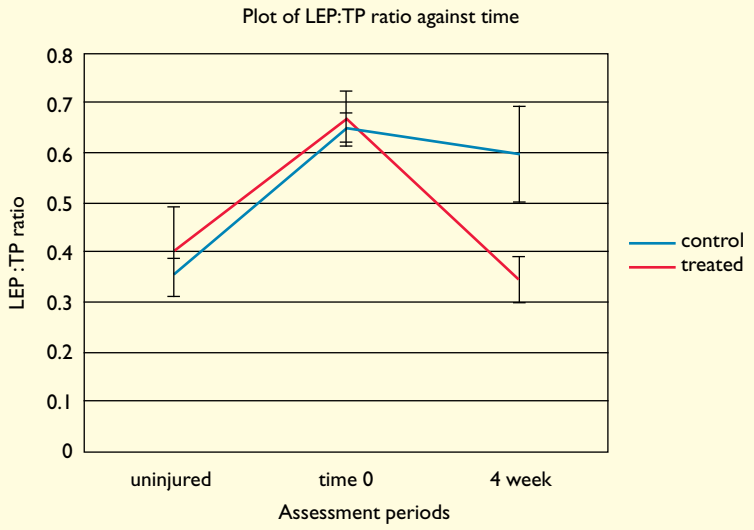
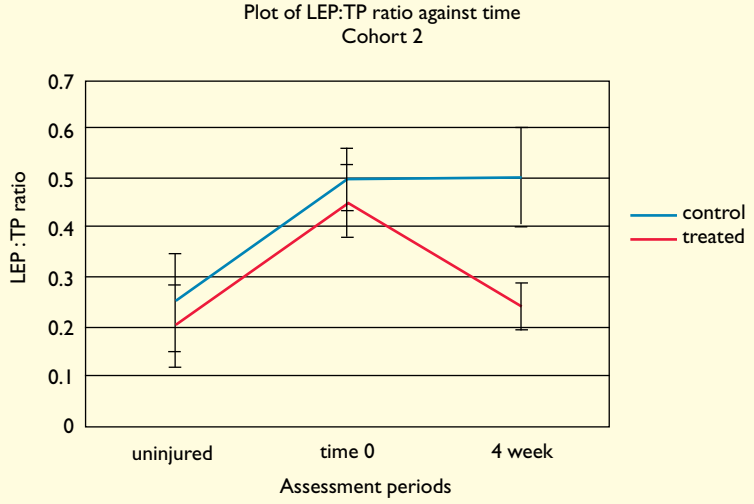


Fig 6. Graph showing Average LEP:TP ratio for cohort 2



time 0. However, it was very clear that the KerraPro Heel aided healing more efficiently than the alternative pads in cohort 1, shown by the progression of the LEP:TP ratio to beyond the uninjured level, whereas the alternative pads only enabled mild progression towards healing. These levels may have been negatively skewed for the alternative pad by the presence of one participant not using an alternative pad as a standard in cohort 2, and another participant using animal wool heel pads, which are believed to have had a detrimental effect on the heel not treated with KerraPro Heel. The alternative pads did aid progression towards healing, though not as pronounced as the KerraPro Heel. All of the alternative pads developed tears or broken portions between day 7-14 of use, which may have reduced the effectiveness of pressure relief and healing. Conversely, the KerraPro Heel showed no signs of damage during the study in either cohort. This has implications on the cost of treatments, however was not analysed in present study.

Cohort 2 LEP:TP Ratio

The overall effectiveness of the KerraPro Heel compared with the participants' standard protocol for all participants in cohort 2 is shown in Fig 6. All HDU scans were assessed and collated to provide an average LEP:TP ratio for the second cohort.

On average, the control heel was slightly more oedematous at time 0 than the heel treated with KerraPro Heel; this may have occurred due to the fact that where there was an existing pressure injury on one foot, it was decided to treat this heel with the KerraPro Heel when the overall LEP:TP may have been higher in the other foot. Conversely, the difference in healing is dramatic. There is on average almost no change in the LEP:TP ratio of the control heel, whereas the ratio in KerraPro Heel-treated heel almost returned to uninjured levels.

Overall LEP:TP Average Ratio

These figures represent the mean data for the 14 participants of both cohorts that were able to have both HDU scans and complete the study.

Analysis of the ultrasound images from the uninjured skin of the participants shows that the mean LEP:TP ratio is approximately 0.33-0.34. As Fig 8 shows, on average, both affected heels tend to be approximately double this ratio at the first assessment visit (time 0 scan), indicating high levels of oedema present. As time progressed, it was clear that the control heels showed very little progression towards healing. Conversely, the heels treated with the KerraPro Heel pads returned to uninjured levels by 4 weeks, as demonstrated in Fig 3–8.

Discussion

The data obtained via the HDU scans, summary mean tables and individual case studies is compelling and would indicate that the KerraPro Heel promotes healing of category 1 pressure injuries to near or equivalent to normal healthy tissue oedema levels within a 4-week period. No participants with a pressure injury at the beginning of the study presented with an injury by the end of week 4, with the majority healing in the second to third week of using the KerraPro Heel. Where there was no alternative device used, injured heel oedema levels remained largely unchanged with simple repositioning or air mattress use. It is speculated that the heels often remain in contact with the bed even with a good repositioning regime and as such, are at an increased risk of pressure injury, as seen

by the lack of healing occurring in untreated heels in cohort 2 who relied on repositioning alone. The alternative pads used predominantly in cohort 1 showed some limited benefit to the oedema levels, though not as pronounced as the use of the KerraPro Heel.

It has been established that the KerraPro Heel device is robust and shows no signs of injury after 4 weeks of use, while an alternative device tended to tear or break apart after 7-14 days of use, potentially reducing its efficacy. In addition, all care staff reported the KerraPro Heel to be easy to use, clean and in only one instance was the KerraPro Heel discarded after being soiled by cover staff who were unaware the device could be washed and reused for the same participant. In contrast, the alternative heel pads tended to tear or break after 1-2 weeks of use and needed to be replaced.

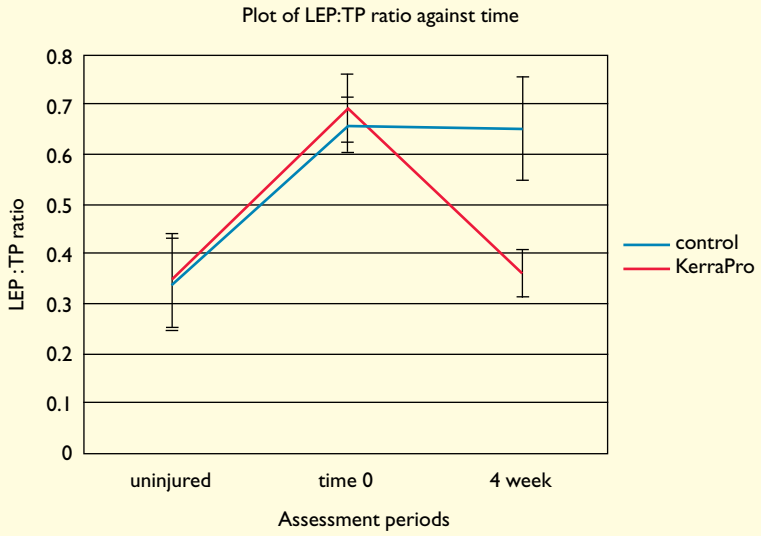
Conclusion

While the evaluation of the KerraPro Heel was only undertaken in a small cohort of 17 participants, there was a strong indication that the KerraPro Heel may contribute to the prevention of and healing of category 1 pressure injuries within a 4-week time period. Despite the small sample size, each participant provided their own control heel, increasing the validity of the results. There is now opportunity for a larger comparative study in order to establish the most efficient heel pad for pressure relief and treatment of pressure injuries of the heel. ■

Fig 7. Numerical data for LEP:TP of the whole study

Assessment Period	Control Heel LEP/TP ratio ±SD	KerraPro® Heel LEP/TP ratio ±SD
Time 0	0.65897 ± 0.05508	0.693168 ± 0.068221
4 Weeks	0.652 ± 0.103	0.361707 ± 0.04796
Uninjured skin	0.3398 ± 0.0921	0.347832 ± 0.094875

Fig 8. Graph showing average LEP



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