KerraPro™ in Pressure Ulcer Prevention: Determining a Mode of Action

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Introduction

The role of skin microclimate in pressure ulcer formation was identified 40 years ago.[1] This study assessed the effects of skin temperature, pH, and hydration underneath KerraPro compared with a self-adhesive foam dressing *(Mepilex Border, Mölnlycke Health Care)*, and a dermal gel pad *(Aderma, Smith & Nephew)*. The study also assessed the ability of KerraPro in preventing damage to the skin due to mechanical loading and whether repeated mechanical loading affected the pads structural integrity, elastomeric and pressure redistribution abilities.

Method

Skin temperature was measured using 4 fine wire thermocouple probes secured to the inner forearm and connected to a digital thermometer, with 1 probe left uncovered as a control *(Figure 1)*. Readings were taken at 5 minute intervals over 14 hours *(n=3)*.

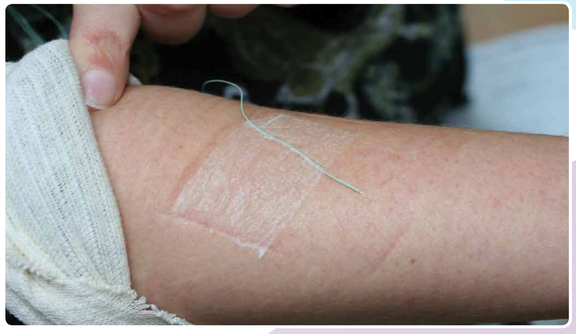

Figure 1 **Thermocouple probe placement**

Skin hydration was measured by using a moisture meter held at constant pressure on the skin surface with values increasing with skin moisture content. Base level measures were taken for hydration of the skin on 4 areas of the inner forearm before the 3 test devices and control area *(no device)* were placed in the same positions. Five hydration readings were then taken across the surface of the dressings after 7 and 14 hours *(n=3)*.
A pH tester was then used to measure base level skin pH on 4 areas of the inner forearm before placing the 3 test devices and control area (no device) in the same positions. Skin pH measurements were taken after 7 and 14 hours *(n=3)*.

Figure 2 **Custom-built loading device used to apply sustained pressures *(Bronneberg et al, 2007)***

Pressure *(15 kilopascals)* was applied to human skin explants *(6mm biopsies of living tissue from its natural site of growth)* using a pressure device for 24 hours *(Figure 2)*. Half the explants had KerraPro applied between the pressure device and the explant biopsies, the other half acted as a control with no KerraPro.
Each biopsy was bisected; half the sample was used to extract RNA for analysis of cytokines, the other half was processed for histology. The wear time of KerraPro was assessed compared with Aderma by repeatedly subjecting 12 millimetre thick pads to a compression force of 375 newtons applied through a rounded striker 30 times per minute for 10,000 cycles.

Results

There was no significant difference in percentage change of temperature in the 3 test devices compared with the control device, which was surprising given the occlusive nature of KerraPro and Aderma compared with Mepilex Border, which is vapour permeable and allows moisture to evaporate through the outer foam layer.
After 7 hours, epidermal rehydration was marginally greater under the Aderma device compared with KerraPro and both were significantly greater compared with Mepilex Border, which has a higher moisture vapour transmission rate. At 14 hours, the epidermal rehydration recorded in KerraPro was 310% above the base line compared with 231% with Aderma and 116% with Mepilex Border *(Figure 3)*.
The reduction in skin pH with Mepilex Border and KerraPro at 7 and 14 hours was similar compared with the control, while Aderma showed a small increase in pH.

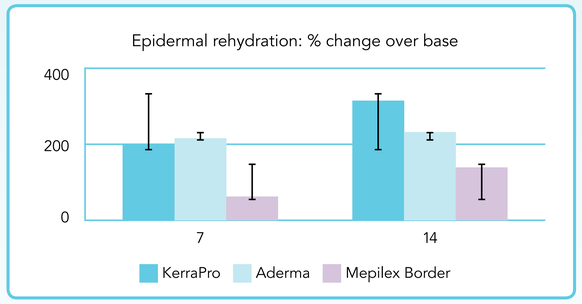

Figure 3 **Percentage change in epidermal rehydration over base line at time points 7 and 14h**

There was a reduction in TNF alpha RNA levels in KerraPro-treated human skin biopsies compared to untreated controls after application of 15 kilopascal of pressure for 24 hours *(data not shown)*. Other cytokines were unchanged between treated and untreated biopsies. This suggests that the pressure relieving qualities of Kerrapro prevents up-regulation of TNF alpha compared with the untreated control upon application of pressure.

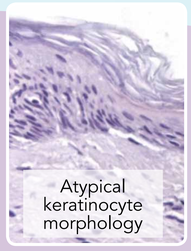

Figure 4 **Histology of untreated control subject to pressure**

Histological analysis showed abnormal keratinocyte morphology in control treated biopsies, indicative of cell death. This defect was almost absent in KerraPro treated biopsies. This suggests that KerraPro is preventing epidermal cell death which could lead to pressure ulcers. Analysis also revealed separation between the epidermis and dermis in control samples which was minimal in KerraPro-treated samples.
KerraPro completed 10,800 cycles in wear time compression tests compared with only 20 cycles for Aderma before it was damaged.

Discussion

Silicone devices used for scar prevention and treatment has been shown to reduce epidermal water loss and increase tissue water content.[2] The data reported here on epidermal rehydration by KerraPro supports this.

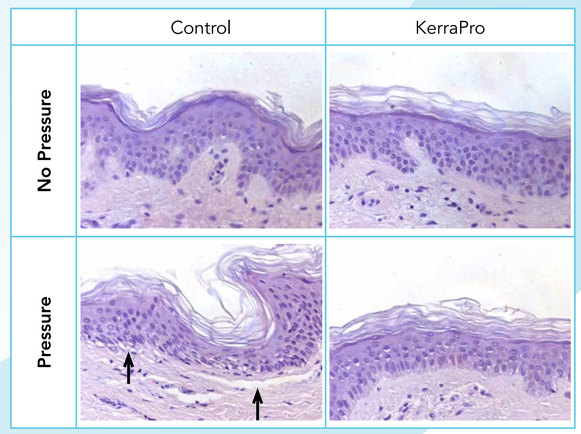

Figure 5 **Histology demonstrating separation between epidermis and dermis in pressure treated skin which is minimal with KerraPro treatment**

Positive clinical effects of KerraPro in restoring injured skin to an uninjured state after 4 weeks of treatment by reducing oedema in the dermis have also been reported[3] and can be partly explained by the experiments reported in this paper.

Conclusion

Kerrapro has a positive effect on epidermal rehydration, physical protection of the skin by pressure redistribution and a possible down regulation of inflammatory cytokines as well as being cost effective in terms of wear time compared with similar devices.

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