Clinical Evaluation of the *Intelli-Gel® Cushion in a Nursing Home

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* Intelli-Gel® is protected by US Patents 5749111, 6026527, 6413458, 6797765, 7076822 and other US & international patents pending

Abstract

Aim of the evaluation

To evaluate the Intelli-Gel® cushion in order to examine its effect on contributing to the prevention of pressure ulcer damage.

Materials and Methods

5 residents in a nursing home with existing pressure ulcers participated in a 4 week evaluation (mean age 89, range 78-96; mean Waterlow Score 24, range 19-31). Intervention was exchange of the volunteers' existing pressure relieving cushions with the Intelli-Gel® cushion. Clinical inspection of skin quality and high definition ultrasound measurements were carried out at the beginning of the evaluation, after 14 days and at the end of the 4 weeks period. Data was collected from all volunteers at day 14, however only three completed the evaluation.

Results

Both visual inspection and ultrasound measurements showed healing at day 14 for all cases, with particular significance for those with Grade 2 pressure ulcers. At the end of the trial, there was no evidence of pressure damage for the 3 remaining volunteers. In addition, volunteers and nursing staff reported that the cushion increased comfort, improved sitting posture and tolerance.

Conclusions

Based on this evaluation, the Intelli-Gel® cushion has potential to be beneficial for individuals at very high risk of developing pressure ulcers, and for those individuals who have pressure ulcers up to Grade 2. It was envisaged that improvement in skin quality would be due to the pressure redistribution characteristics of the material but the results indicate that the cushion is also acting as a positional device preventing posterior pelvic tilt and unloading the sacrum.

Keywords: pressure ulcer; seating; cushions; prevention

1 Introduction

The Intelli-Gel® cushion is a new cushion designed to reduce the occurrence of pressure damage in people in long term care. The cushion contains a unique gel component that has an open lattice design measuring 330 mm x 305 mm x 54 mm (Figure 1).

The Intelli-Gel® cushion was bench tested at The Rehabilitation Engineering and Applied Research Lab, Georgia Tech University, using an ISO buttock model (Figure 2). The Intelli-Gel® cushion was evaluated against a standard polyurethane foam cushion, a polyurethane foam cushion with a visco-elastic foam topper, and a commercially available air bladder wheelchair cushion that is inflatable to be customized to the individual. The results indicated that the Intelli-Gel® cushion has the **potential** to reduce high pressures associated with the ischial tuberosities, exhibiting the lowest recorded pressures in this region at loads equal to or below 70 kg.

The purpose of this evaluation is to explore the effectiveness of the Intelli-Gel® cushion in a small cohort in long term care.

2 Materials and Methods

2.1 Volunteers

Volunteers were 5 residents in a nursing home who were considered to be at high risk of developing pressure damage, or who had existing pressure damage (no greater than Grade 2, EPUAP). All volunteers had profiling beds and alternating air mattresses but poor seating provision. None of the participants were able to independently transfer, all requiring hoisting. All of the participants were doubly incontinent. All of the participants had poor nutritional intake, despite taking supplements. Volunteers were visited prior to

commencement of the evaluation in order to collect demographic data (Table 1). Informed consent was provided by either the volunteers or those responsible for their care. The research activity undertaken by the Tissue Viability Consultancy Services Ltd complies with the Declaration of Helsinki, 1964.

2.2 High Definition Ultrasound

High frequency diagnostic ultrasound is a non-invasive method, which allows the clinician to obtain a high-resolution image of the wound bed (Young and Ballard 2001, Chen *et al*., 2001, Mirpuri and Young 2001, Kerr *et al*., 2006, Quintavalle et al., 2006, Young *et al*., 2008, Hampton *et al*., 2008, Hampton *et al*., 2009). The technique allows the clinician to measure oedama in the skin and underlying tissues. The presence of oedema in the tissues is one of the main indicators of the development of a Grade 1 pressure ulcer. Oedema will be present at any site that has incurred some sort of damage and is the body's natural response to this damage. Measurements of oedema are taken at both the pressure sore site and at neighbouring uninjured, normal skin for comparison. The ultrasound measures from the skin surface to a depth of approximately 10 mm.

The scanner used (Figure 3) operates at a range of frequencies from 20MHz to 50 MHz (Episcan - Longport Inc.). This frequency gives an axial resolution of 20 - 65µm.

2.2.1 High Definition Ultrasound Scan Analysis

Each scan is analysed using a form of pixel distribution analysis whereby pixels below a 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 (Gniadecka

1996, Gniadecka and Quistorff 1996). Using this technique it is possible to get a quantitative assessment of the level of oedema present in tissues. Figure 4 shows the scan of one volunteer's normal skin and Figure 5 shows the scan of the pressure ulcer.

In order to show the extent to which each volunteer's skin had returned to normal, the data were inserted into Equation 1, and presented as a percent reduction of oedema towards normal skin. Here, the LEP/TP value for normal skin represents zero and the LEP/TP value for first assessment represents 100%. The percent of improvement within this range is then shown after day 14 and then day 28 for each case.

$$\% \text{ oedema reduction} = 100 \left[- \left(l_t - l_n \right) \right] \left(l_0 - l_n \right) \quad (1)$$

Where,

l_n = LEP/TP normal skin

l_0 = LEP/TP day 0

l_t = LEP/TP treatment (either 14 days or 28 days)

2.3 Protocol

2.3.1 Day 0

All volunteers remained in bed prior to assessment. The skin of each participant was examined for signs of pressure damage. Photographs were taken of any areas in the buttocks / sacral region that exhibited signs of pressure damage. A high definition ultrasound scan was taken of each participant's pressure ulcer and adjacent normal skin. The normal skin was scanned to establish a profile of what the uninjured tissue looks like.

The volunteers existing pressure redistributing cushions were removed from their armchairs and replaced with the Intelli-Gel® cushions. The seat bases that supported the cushions were rigid. Volunteers were then mobilised in accordance with their care plan.

2.3.2 Day 14 and 28

The above methodology was repeated, with the exception that the Intelli-Gel® cushion remained in the armchair throughout the period of the evaluation. Therefore none of the volunteers used their old cushion during the period of the evaluation.

3 Results

3.1 Visual Inspection of Skin Quality

On day 0, the first assessment revealed that all of the volunteers had pressure ulcers up to Grade 2 (Table 2). The skin quality on all of the volunteers showed marked signs of improvement in their sacral and buttocks regions after using the Intelli-Gel® cushion. The improvement was seen on both day 14 and day 28. Of particular note were volunteers 1 and 5. Both of these had Grade 2 pressure damage noted at the initial assessment, but both volunteers' wounds showed significant signs of improvement during the second assessment on day 14, as evident by the photographs in Figures 6-10.

Unfortunately volunteer 1 developed a chest infection the week prior to the final assessment and died the day before this. Volunteer 5 also developed a chest infection in the week prior to the final evaluation and had remained in bed for that week. It was therefore considered inappropriate to reassess her, as the results could not have been related to the cushion.

On day 28 volunteers 2, 3 and 4 were assessed for the final time. None of these volunteers showed any evidence of pressure damage.

3.2 High Definition Ultrasound

Table 2 gives the results from the ultrasound measurements. The results show that for volunteer 1, oedema had reduced by 27% towards that of the normal skin. For volunteer two, this reduction was 40% at day 14, and 100% for day 28. For volunteer 3, this was 64% at day 14 and 67% at day 28. A reduction of 39% at day 14 and 78% at day 28 was measured for volunteer 4, and a 16% reduction at day 14 was measured for volunteer 5.

4 Discussion

The result from this investigation indicate that the Intelli-Gel® cushion can contribute to the healing of pressure sores up to Grade 2, as assessed by visual inspection and measured by high definition ultrasound.

Previous laboratory research had shown excellent pressure redistributing characteristics of the Intelli-Gel® cushion. Furthermore, gel has a high specific heat capacity and the Intelli-Gel® insert has an open structure that would appear to be beneficial in terms of moisture transport. Although these factors are known to contribute to reducing the risk of tissue damage, the effects observed in the present investigation may be more closely linked to posture. It was observed that all of the volunteers' sitting posture was much improved using the Intelli-Gel® cushion. Previously, their posture had tended to be asymmetrical and unstable, with all volunteers tending to adopt a posterior pelvic tilt as they slid downwards in the chair. The pressure damage found in all volunteers was

consistent with sliding, as this tended to be over their sacrum. In the case of volunteer 1 and 5 in particular, the pressure damage over the sacrum was attributed to friction and shear forces. When using the Intelli-Gel® cushion the volunteers' sitting posture was far more symmetrical and stable. They tended to remain upright in the chair, rather than sitting in a posterior pelvic tilt and this could account for the improvement seen on the skin in the sacral area of all volunteers, as weight had been transferred appropriately onto the ischial tuberosities.

It is possible that nursing staff were more motivated to better position the volunteers during the course of the evaluation. Since there was no control group, the influence the investigation had on the care of the volunteers cannot be determined. The evaluation was done in the same nursing home with the same nursing staff.

It is possible that the cushion architecture helped to stabilize the pelvis in an appropriate position. The Intelli-Gel® material is encased in polyurethane foam on all sides except the user interface surface. It is likely that there is more immersion into the Intelli-Gel® than the foam border, resulting in increasing structure and support towards the edges of the cushion that could resist sliding, posterior tilt and obliquity. This in turn could inhibit fidgeting. Not all of the volunteers were able to communicate their levels of comfort/discomfort, but those who could, reported that the Intelli-Gel® cushion provided improved comfort compared to their original pressure reducing cushion. However, the nursing staff also reported that the volunteers appeared to be far more comfortable. Of particular note were volunteers 3 and 4, whose agitation and restlessness when sitting was significantly diminished.

Probably for the reasons above, all of the volunteers were able to sit for longer periods of time in comparison to previously, particularly volunteer 3. On average sitting tolerance was extended by two hours for each volunteer.

5 Conclusion

Based on this evaluation alone, the Intelli-Gel® cushion shows potential in contributing to healing pressure ulcers up to Grade 2, and as an aid to preventing pressure ulcers for those at very high risk. Furthermore, the use of the Intelli-Gel® cushion enabled all of the volunteers to sit more comfortably, with an upright and symmetrical posture, for longer. A larger control study involving a modification to this protocol would be the next logical step towards understanding how these findings can be generalised to the wider population.

6 Conflict of Interest Statement

The research lead of this investigation, Fiona Collins, is a Director of Tissue Viability Consultancy Services Ltd and was commissioned by The Kirton Healthcare Group Ltd to conduct this investigation. The Kirton Healthcare Group Ltd has an ongoing professional relationship with Tissue Viability Consultancy Services Ltd, having worked together to provide training days for Occupational Therapists.

Dr Stephen Young is an associate of Tissue Viability Consultancy Services Ltd and was employed to work on this project.

David Wickett, corresponding author, is an employee of The Kirton Healthcare Group Ltd.

7 Acknowledgements

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This manuscript, including related data, figures and tables has not been previously published and the manuscript is not under consideration elsewhere.

Recommended reviewers for this submission:

Role of the funding source

This research was sponsored by The Kirton Healthcare Group Ltd. Kirton's involvement in this evaluation is via the corresponding author David Wickett, who is an employee of the company. His involvement was in interpretation of the data, in contributing to the writing of the manuscript and in the decision to submit the manuscript for publication.

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9 Legends to Figures

Figure 1 Intelli-Gel® cushion insert (330 mm x 305 mm x 54 mm)

Figure 2 The ISO buttock model used for bench testing at The Rehabilitation Engineering and Applied Research Lab (REAR) at Georgia Tech University

Figure 3 High Frequency Diagnostic Ultrasound Scanner

Figure 4 The ultrasound scan of one volunteer's normal skin

Figure 5 The ultrasound scan of one volunteer's pressure sore. The images shows that the deeper layers of the skin is saturated with oedema

Figure 6 Volunteer 1. Day 0. Marked erythema over sacral and buttock region

Figure 7 Volunteer 1. Day 0. Skin moved to reveal a Grade 2 pressure ulcer

Figure 8 Volunteer 1. Day 14. Significant improvement was seen in the pressure ulcer, which was now superficial and commencing epithelialisation. Erythema of the surrounding skin was no longer present

Figure 9 Volunteer 5. Day 0. Grade 2 pressure ulcer and marked erythema over the sacral area

Figure 10 Volunteer 5. Day 14. Significant improvement was seen in the pressure ulcer, which was now superficial and commencing epithelialisation

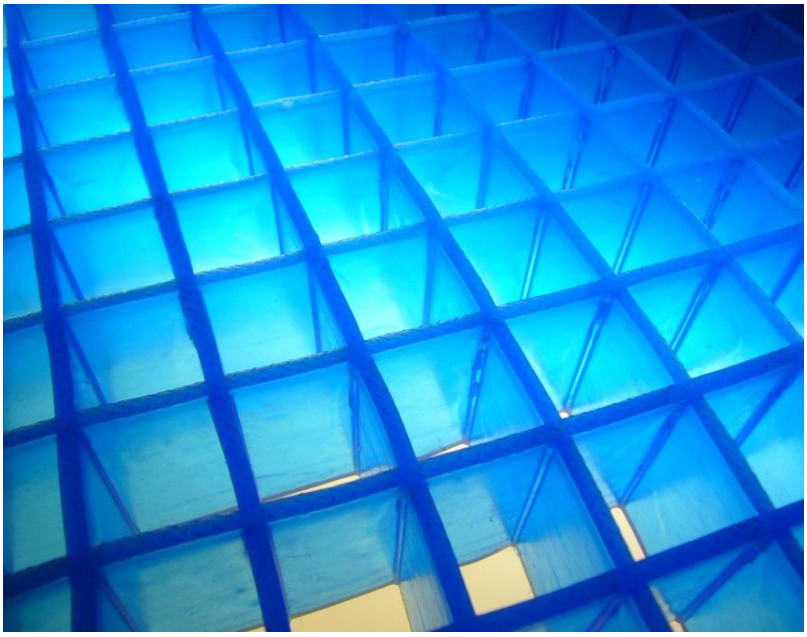

Figure 1. Intelli-Gel® cushion insert (330 mm x 305 mm x 54 mm)

Figure 2. The ISO buttock model used for bench testing at The Rehabilitation Engineering and Applied Research Lab (REAR) at Georgia Tech University

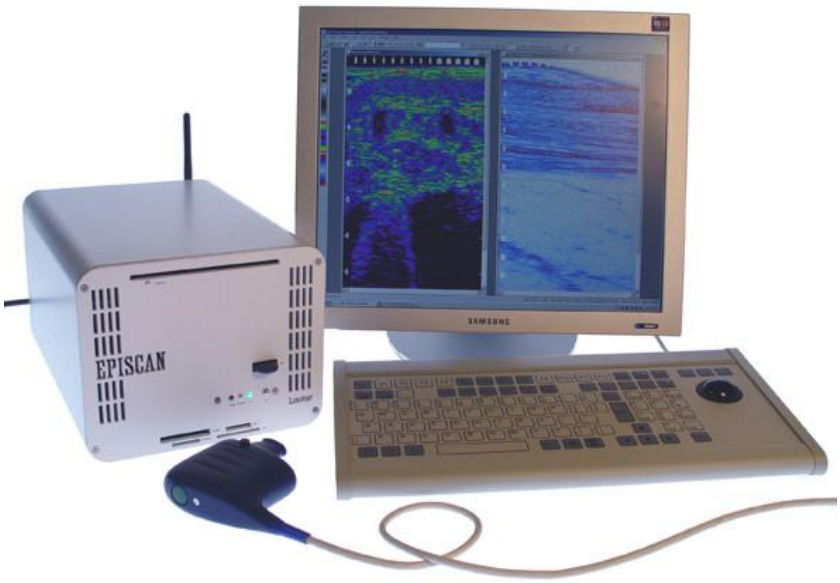

Figure 3. High Frequency Diagnostic Ultrasound Scanner

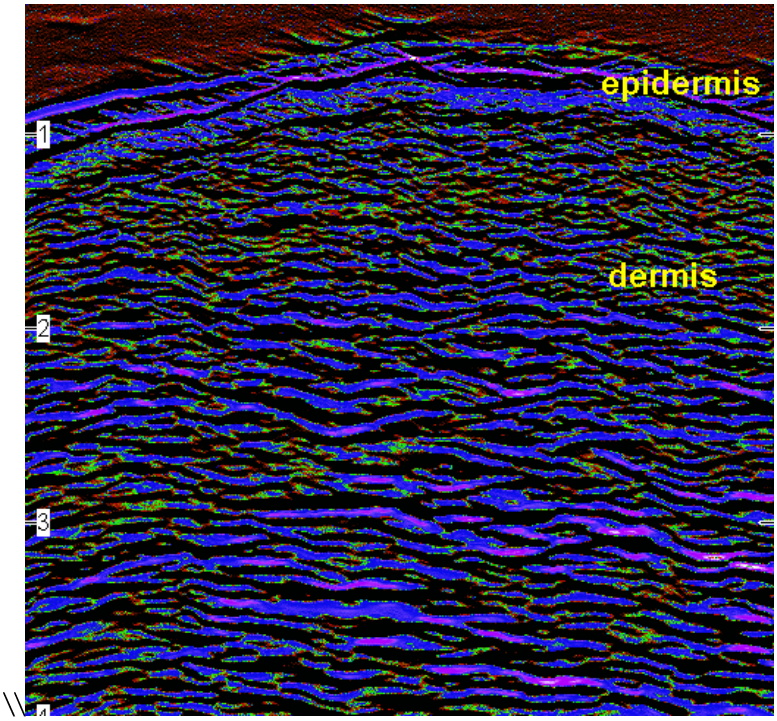

Figure 4. The ultrasound scan of one volunteer's normal skin.

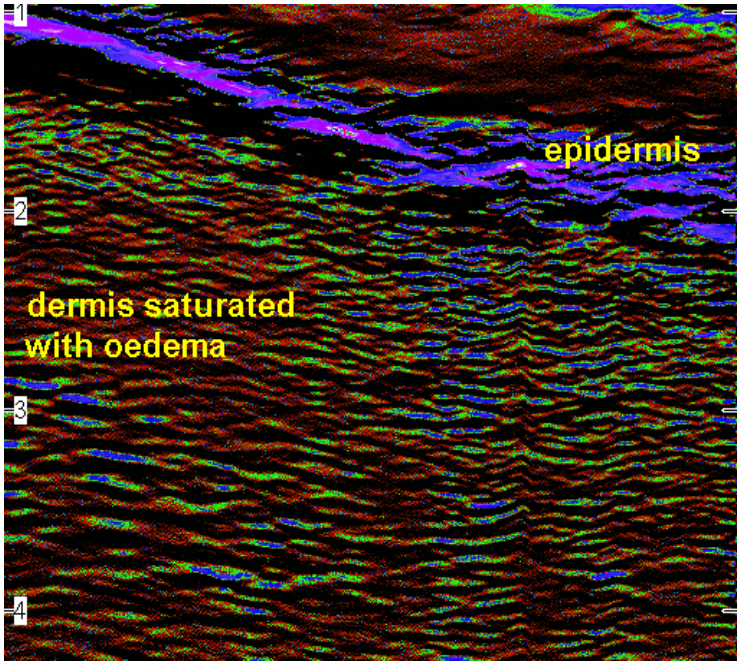

Figure 5. The ultrasound scan of one volunteer's pressure sore. The images shows that the deeper layers of the skin is saturated with oedema

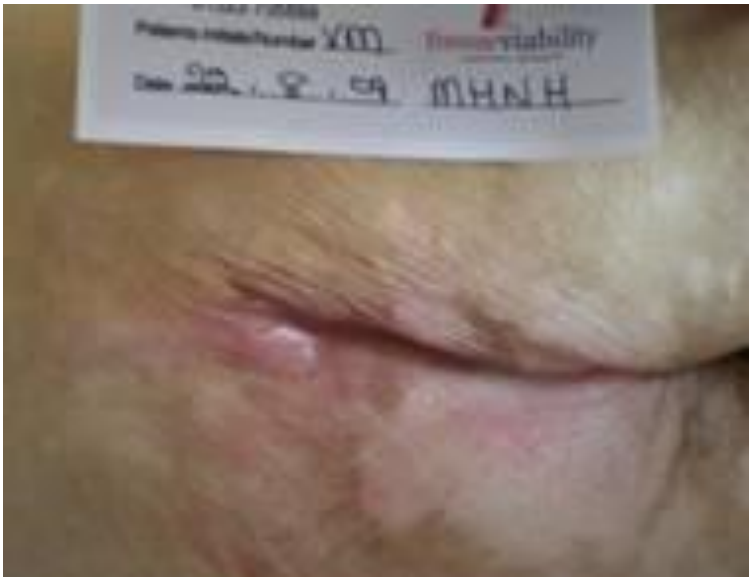

Figure 6. Volunteer 1. Day 0. Marked erythema over sacral and buttock region

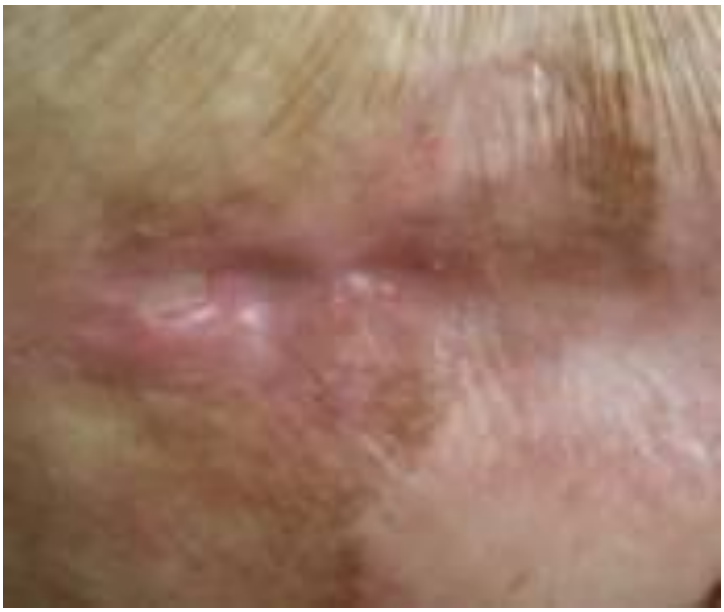

Figure 7. Volunteer 1. Day 0. Skin moved to reveal a Grade 2 pressure ulcer

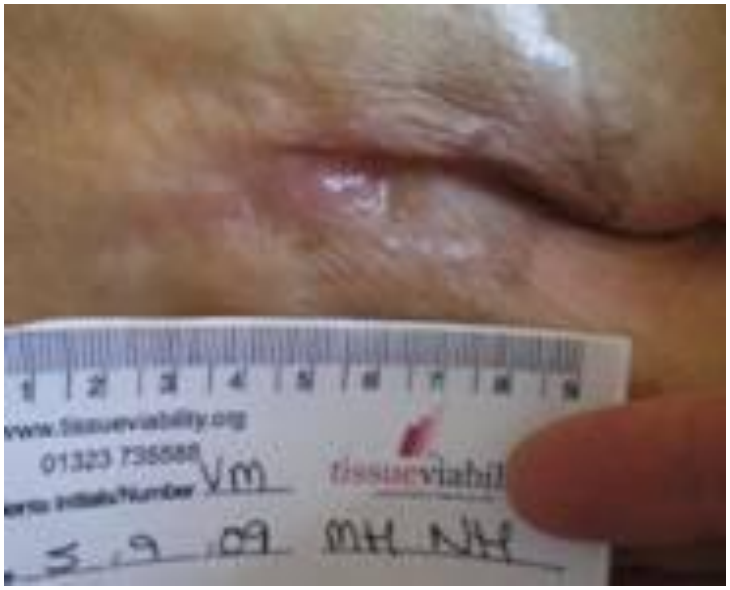

Figure 8. Volunteer 1. Day 14. Significant improvement was seen in the pressure ulcer, which was now superficial and commencing epithelialisation. Erythema of the surrounding skin was no longer present.

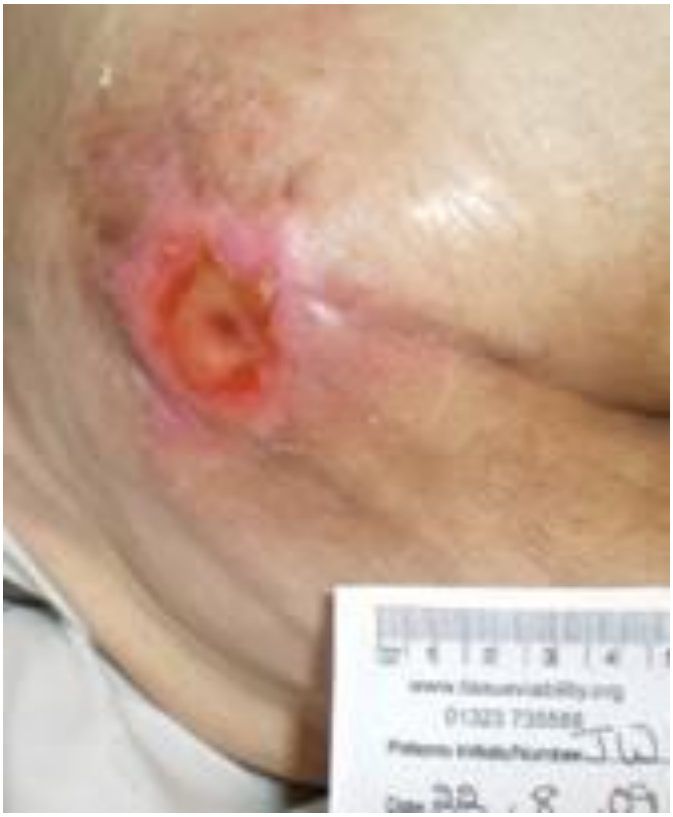

Figure 9. Volunteer 5. Day 0. Grade 2 pressure ulcer and marked erythema over the sacral area

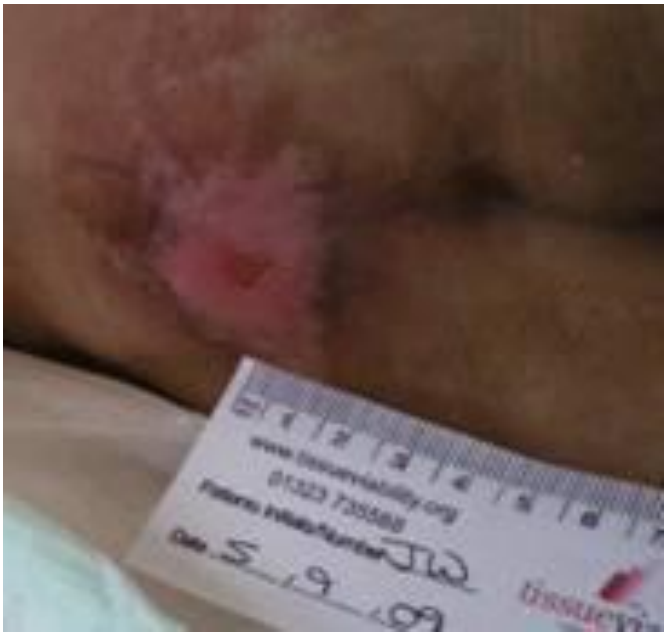

Figure 10. Volunteer 5. Day 14. Significant improvement was seen in the pressure ulcer, which was now superficial and commencing epithelialisation

Table 1. Demographic data at beginning of the evaluation

Volunteer	Age	Sex	Waterlow score	General health	Cushion prior to the evaluation	Number of hours spent sitting
1	96	Female	19	Cardiac failure, general frailty	Propad	05-Jun
2	92	Female	21	Angina: CVA	Castellated foam	Variable, but normally 5-6
3	78	Female	25	Alzheimer's disease: frailty	Propad	07-Aug
4	93	Female	26	CVA; frequent falls; immobility	Medform-visco	Varies greatly between 2-8. Volunteer normally very unsettled
5	85	Female	31	Alzheimer's disease: frailty	Propad	05-Jun

Table 2. Results for the ultrasound measurements

Volunteer	Existing pressure ulcer	LEP:TP Ratios				**% reduction towards normal skin**	
		Normal skin	Day 0	Day 14	Day 28	**Day 14**	**Day 28**
1	Grade 2	0.16	0.46	0.38		**27%**	
2	Grade 1	0.14	0.56	0.39	0.13	**40%**	**102%**
3	Grade 1	0.19	0.52	0.31	0.3	**64%**	**67%**
4	Grade 1	0.19	0.37	0.3	0.23	**39%**	**78%**
5	Grade 2	0.2	0.45	0.41		**16%**	