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Intelli-Gel® Cushion Evidence Pack

Version: March 2011

Contents

Introduction

This document compiles the current evidence in support of the medical claims made by The Kirton Healthcare Group Ltd on the Intelli-Gel® cushion. This is a live document to be updated when new evidence becomes available. There are three types of evidence included:

1. **Post Market Surveillance Statistics**
   A Post Market Surveillance Report describing all customer complaints relating to the Intelli-Gel® Cushion for 2010. The document gives the reported incidence proportions of pressure ulcers during that period (sample of 2,000 users).

2. **Research Reports**
   The Research Reports describe three separate evaluations using different research methods at different stages of the design process of the Intelli-Gel® cushion. The in-house testing evaluated 32 cushion permutations, the independent laboratory bench testing evaluated 4 cushions and the clinical evaluation assessed the final cushion design. A version of the clinical evaluation manuscript has been submitted for peer review publication.

3. **Case Studies**
   One case study describes the success of Intelli-Gel® with a young girl suffering from Lichen Sclerosus. This case study indicates that Intelli-Gel® is reducing the symptoms of Lichen Sclerosus due to both pressure redistribution and skin temperature control. A version of this case study is being considered for peer review publication

Medical Claims

Based on the available evidence, and under the advice of the Tissue Viability Consultancy Services Ltd, The Kirton Healthcare Group Ltd make the following medical claims:

1. **The Intelli-Gel® cushion can aid in preventing pressure ulcers for those at very high risk**
2. **The Intelli-Gel® cushion can aid in the healing of pressure ulcers up to Grade 2 (Pressure Ulcer Advisory Pannel).**

Based on these medical claims, and the supporting evidence, stand alone Intelli-Gel® cushions and chairs manufactured by The Kirton Healthcare Group Ltd incorporating the Intelli-Gel® cushions are registered as Class 1 Medical Devices by the Medicines and Healthcare products Regulatory Authority (MHRA).

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Post Market Surveillance Statistics on the Intelli-Gel® Cushion

Period: 04/01/2010 – 04/01/2011

Quantity Sold: 2,000 into specialist seating, 500 into hospital patient chairs

Sample size: 2,000 individuals at risk of pressure ulcers

This report has been compiled by the R&D Department at The Kirton Healthcare Group Ltd, as part of ongoing post market surveillance of the Intelli-Gel cushion. This is a requirement of the Medical Healthcare Regulatory Authority for Class 1 Medical Devices. The information reported was supplied by the Customer Relations Department at The Kirton Healthcare Group Ltd.

Summary

Of the 2,000 cases there have been only 4 customer complaints that have been associated with the Intelli-Gel® cushion. None of these complaints give evidence of a link between the Intelli-Gel® cushion and the onset of a pressure ulcer. It is reported that one individual was uncomfortable, and that existing pressure ulcers in two individuals did not heal. For one other individual there was a reported reddening in the sacrum area but this was resolved by repositioning the Intelli-Gel® cushion.

Incidence proportions based on the first years sales:
- **In the 2,000 cases during the 12 month period, there have been no reported incidences of pressure ulcers**
- **Of those 2,000 cases, 0.0015% reported that existing pressure ulcers did not heal**
- **0.002% of cases associated the Intelli-Gel® with discomfort**

Interpretation

Although the reported incidence proportions are extremely positive, they need to be interpreted with care. The cause and management of pressure ulcers, whether superficial or deep, is complex and often involves multiple risk factors. The published risk factors are listed below. Due to the nature of the specialist seating range by Kirton Healthcare, all users are considered to have reduced mobility and are therefore at risk of pressure ulcers. It is highly probable that a major proportion of this population sample involved multiple risk factors with varying degrees of risk. Since each case of the population sample will differ in terms of risk level(s) and type(s) it is not possible to statistically generalise the reported incidence proportions.

Intrinsic Risk Factors

- **Reduced mobility or immobility**
- **Sensory impairment**
- **Acute illness**
- **Level of consciousness**
- **Extremes of age**
- **Vascular disease**
- **Severe chronic or terminal illness**
- **Previous history of pressure damage**
- **Malnutrition and dehydration**

Extrinsic Risk Factors (posture and movement)

- **Pressure**
- **Shearing**
- **Friction**

Exacerbating Risk Factors

- **Medication**
- **Moisture to the skin (continence, sweating)**

Inherited Clinical Guideline B: Pressure ulcer risk assessment and prevention. Issue 2001. Review 2005. National Institute for Clinical Excellence

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

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This manuscript is under consideration for peer review publication

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.

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

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.

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

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.

Figure 3. *High Frequency Diagnostic Ultrasound Scanner*

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.

$$\% \text{ oedema reduction} = 100[1-(I_t-I_n)/(I_0-I_n)] \qquad (1)$$

Where,

I_n = LEP/TP normal skin

I_0 = LEP/TP day 0

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

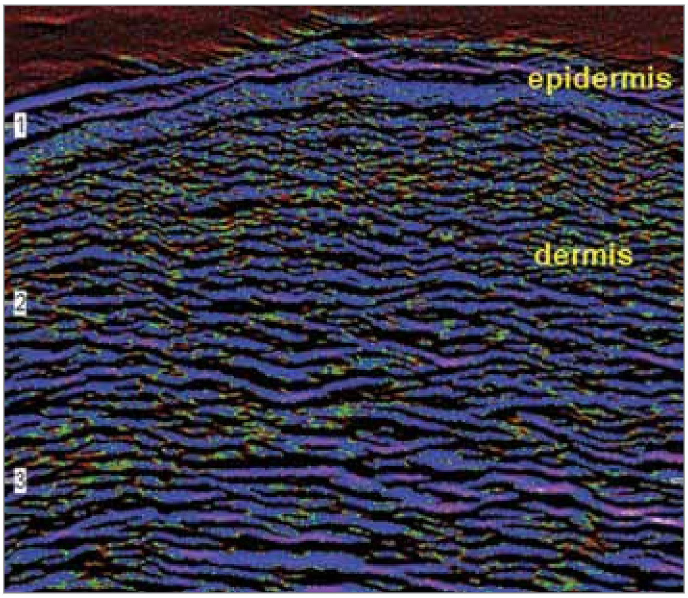

Figure 4. The ultrasound scan of one volunteer's normal skin.

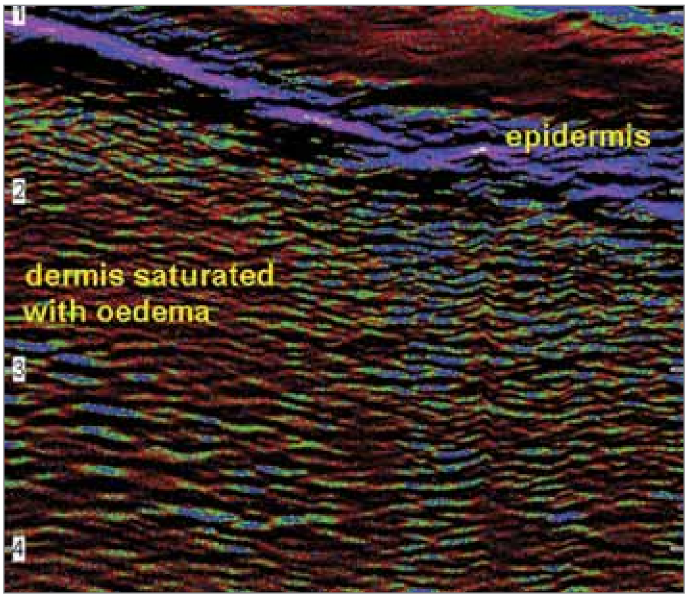

Figure 5. The ultrasound scan of one volunteer's pressure sore. The images shows that the deeper layers of the skin is saturated with oedema

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.

Table 2. Results for the ultrasound measurements

		LEP:TP Ratios				% reduction towards normal skin	
Volunteer	Existing pressure ulcer	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%	

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

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

The authors would like to thank the volunteers and nursing home staff who kindly took part in this evaluation.

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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Laboratory Bench Testing of the Intelli-Gel® Cushion using an Instrumented Buttocks Model

1 Introduction

A new pressure relieving seat cushion for long term care had been developed by The Kirton Healthcare Group Ltd. In-house testing using XSENSOR Pressure Imaging had shown potential for the new Intelli-Gel® cushion to be positioned next to the market leaders for pressure redistribution. Although very positive, there was concern that the results could be biased since the testing was carried out internally at The Kirton Healthcare Group Ltd. Furthermore, a recent study showed that pressure mats exhibit poor repeatability (Pipkin and Sprigle 2008). To verify the in-house findings, the Rehab Engineering and Applied Research Lab (REAR) at the Georgia Institute of Technology were commissioned to undertake independent tests using a more repeatable method involving an instrumented buttocks model.

The data from REAR corroborate the data collected using the XSENSOR system. The new Intelli-Gel® cushion resulted in lower interface pressures under the ischial tuberosity (IT) region than the Air cushion at loads equal to or below 70 kg (11 stones). At these loads, pressures at the IT site were approximately 33% lower than the viscoelastic cushion; and 47% lower than the standard polyurethane cushion. The data from REAR indicated relatively high pressures at the greater trochanter site for the Intelli-Gel® cushion however the buttocks model does not include the thighs where pressures would normally be shared. The Intelli-Gel® cushion was assessed in a follow-up test using the XSENSOR Pressure Imaging System and a human volunteer side leaning. No signs of high pressures at the greater trochanters were observed. Higher pressures towards the outer margins of the buttocks could be beneficial in terms of sitting stability.

2 Materials and Methods

A prototype Intelli-Gel® cushion wrapped in a fire retardant barrier fabric, a viscoelastic foam cushion (with a polyurethane core), a single valve air cushion and a standard polyurethane foam cushion were compared. Pressures were measured at multiple locations along the midline of an instrumented buttock model (Figure 1). The cushions were measured five times a day, over three days, for three loading conditions corresponding to body masses: 56, 70 and 84 kg. The inflation pressure of the air cushion was readjusted for each loading condition. All testing was carried out independently by technicians at REAR.

Figure 1. The REAR instrumented buttocks model showing pressure sensors

3 Results

The mean pressure for each test day, and average of all days are given in Table 1 for the IT sensor with an 84 kg load. Table 2 and 3 present the IT sensor pressures for a 70 and 56 kg load respectively.

Table 1. IT sensor pressure data (mmHg) loaded to 84 kg

Day	Polyurethane cushion	Viscoelastic foam cushion	Intelli-Gel® cushion	Air cushion
1	144.46	86.74	79.6	68.06
2	155.07	100.68	84.22	68.17
3	138.41	87.32	63.12	50.97
AVG	145.98	91.58	75.65	62.4

Table 2. IT sensor pressure data (mmHg) loaded to 70 kg

Day	Polyurethane cushion	Viscoelastic foam cushion	Intelli-Gel® cushion	Air cushion
1	95.03	66.19	47.68	42.39
2	106.31	79.3	51.96	79.3
3	92.97	67.06	44.37	39.39
AVG	98.1	70.85	48.01	53.69

Table 3. IT sensor pressure data (mmHg) loaded to 56 kg

Day	Polyurethane cushion	Viscoelastic foam cushion	Intelli-Gel® cushion	Air cushion
1	61.84	53.53	30.55	46
2	72.83	65.81	44.16	42.27
3	60.75	54.63	36.65	39.43
AVG	65.14	57.99	37.12	42.57

4 Discussion

The data from REAR suggest that for an 84 kg load, the viscoelastic foam cushion reduces IT pressure relative to the standard polyurethane foam by 37%, for a 70 kg load there is a reduction of 28% and for a 56 kg load there is a reduction of 11%. REAR supplied the polyurethane foam cushion which had a 76 mm thickness. The viscoelastic foam was 90 mm thick so the reduction in IT pressure could result in part from the additional thickness. The Intelli-Gel® cushion was also 90 mm thick so comparisons are made to the visco-elastic cushion.

The data indicate that for an 84 kg load, the Intelli-Gel® cushion reduces IT pressure by 17% when compared to the viscoelastic foam cushion. For a 70 kg load the Intelli-Gel® cushion reduces IT pressure by 32% and for a 56 kg load IT pressure is reduced by 36%.

Under an 84 kg load, the Air cushion reduces IT pressure relative to the viscoelastic foam cushion by 32%, under a 70 kg load by 25% and for a 56 kg load 27%.

Taken over all load conditions, these data suggest that when compared to the viscoelastic foam cushion, both the Intelli-Gel® and Air cushion result in similar reductions of IT pressures (27% and 28% respectively). At loads equal to or lower than 70 kg, the Intelli-Gel® appears to be more effective in reducing IT pressures than the Air cushion.

When comparing the pressures at the most distal sensor between the Intelli-Gel® cushion and the viscoelastic foam cushion it can be seen that the Intelli-Gel® cushion results in higher pressures by a factor of approximately 2.5. These sensors could be considered to represent the greater trochanters. Tables 4 and 5 show the pressure data for the IT and greater trochanter sensors for the different load conditions and the difference between these two sites for the Intelli-Gel® cushion and viscoelastic foam cushion respectively. These data show that for the Intelli-Gel® cushion, there is more pressure at the greater trochanter than in the IT area, whereas there is more pressure in the IT area and less at the greater trochanter for the viscoelastic foam cushion. An explanation for why the Intelli-Gel cushion is redistributing pressure to the outer margins of the buttock could be in the claims made by the inventors of the Intelli-Gel material. They claim that Intelli-Gel redistributes pressure due to the 'column buckling' principle. For areas of high pressures (in this case the ITs) the gel columns buckle and pass the loading onto larger surface areas where the pressures are lower (in this case the surfaces surrounding the ITs). In these lower pressure areas, the gel column do not buckle and support the body. Low pressures are associated with the buckled columns because they have low spring-back forces. The ability of the Intelli-Gel cushion to redistribute interface pressure to the outer margins of the buttocks could actually be beneficial when considering sitting stability by 'framing' and securing the buttocks.

Table 4. Pressure data (mmHg) for the IT and greater trochanter sensors at different load conditions for the Intelli-Gel® cushion

Load	IT	Trochanter	Difference
84 kg	75.65	92.2	+16.56
70 kg	48.01	86.09	+38.09
56 kg	37.12	72.91	+35.79

Table 5. Pressure data (mmHg) for the IT and greater trochanter sensors at different load conditions for the viscoelastic foam cushion

Load	IT	Trochanter	Difference
84 kg	91.58	47.51	-44.07
70 kg	70.85	30.4	-40.45
56 kg	57.99	19.98	-38.01

The instrumented buttocks model developed at REAR is capable of producing repeatable results to help to differentiate between cushions. REAR have explained that they switched to this method of testing from using commercially available pressure mapping systems because they found it was not possible to gain repeatable results in equal conditions with pressure mapping systems. Caution is needed however when interpreting the data from the buttocks model. The model represents the pelvis of the body only (Figure 1). The thighs are not represented in this model. The results of this laboratory study have shown redistributing characteristics of the Intelli-Gel® cushion, probably due to column buckling at the high pressure regions of the ITs. Since the thighs are not represented in the buttock model the only area where pressure can redistribute to is the outer margins of the buttocks and the greater trochanter sensors. With the human body, these pressures would be shared across the thighs so in reality they could be lower.

Follow up measurements were made to test this hypothesis. Interface Pressure Imaging data were collected from one 58 year old ectomorph male (BMI 19.4) in normal sitting, side leaning to the left and side leaning to the right. These data were collected at The Kirton Healthcare Group Ltd and the intention was to deliberately load the greater trochanters. Figures 2 – 4 show the resulting pressure maps which show no signs of high pressures at areas that could be associated with the greater trochanters.

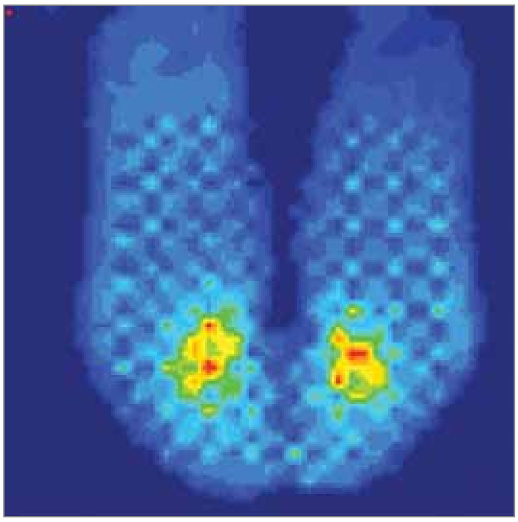

Figure 4. Normal sitting on the Intelli-Gel® cushion

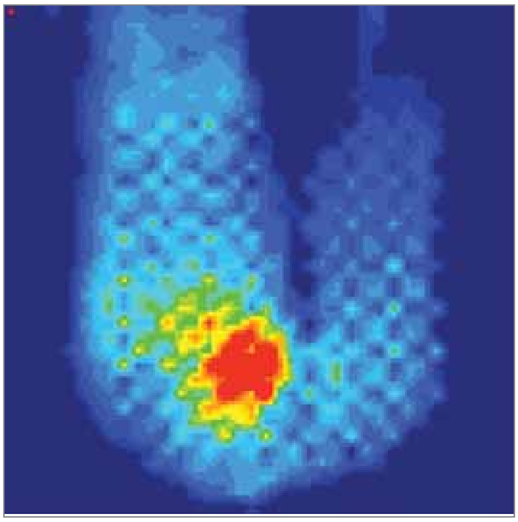

Figure 5. Side leaning to the left on the Intelli-Gel® cushion

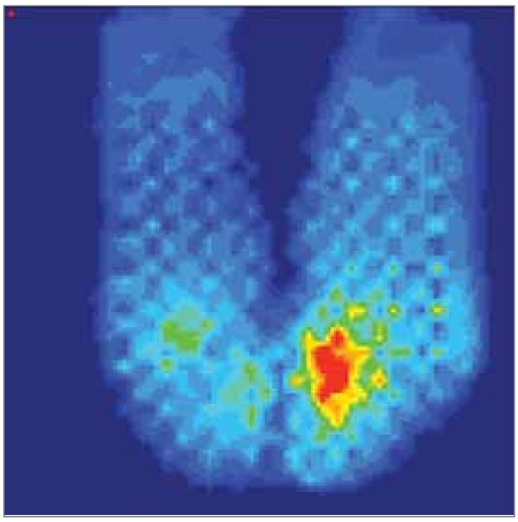

Figure 5. Side leaning to the right on the Intelli-Gel® cushion

5 Conclusion

The data from REAR verify the results from the in-house tests and indicate that the Intelli-Gel® cushion reduces IT pressure to a similar magnitude to air cushions, and could therefore be positioned alongside the market leaders for pressure relief. The data show that the Intelli-Gel® cushion redistributes pressure to the distal margins of the buttocks which could be advantageous in terms of cushion stability. Subsequent in-house interface pressure imaging showed no evidence of any risk of tissue damage around the greater trochanters.

It is recommended that a clinical study using volunteers representative of the intended end users be carried out to validate the effectiveness of the cushion and to determine what medical claims are appropriate.

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Research and Development of Patient Support Surfaces using XSENSOR Pressure Imaging

1 Introduction

The R&D team at The Kirton Healthcare Group Ltd carried out research to source current and future materials for seat cushions that could help to reduce the risk of pressure ulcers. The first part of this report evaluates those materials in varying combinations and with different types of base supports using the XSENSOR Pressure Imaging System and one test subject. The findings indicate a trend where all material combinations that involve the Intelli-Gel® material result in the lowest Peak Pressure Index values.

The second part of this report describes the process of developing a cushion that incorporates Intelli-Gel® for seating in long term care. Two adults (one mesomorph and one ectomorph) and two children participated over the course of the cushion development and the XSENSOR Pressure Imaging System was used for collecting data. The final cushion specification is benchmarked against a viscoelastic pressure relieving foam cushion and a single valve air cushion that is customised to the individual's weight.

The results indicate that the final cushion specification has superior pressure redistributing qualities when compared to the viscoelastic foam cushion, and exhibits similar pressure characteristics to the air cushion. It is recommended that the final specification be tested in an independent laboratory to verify these results.

2 Materials and Methods

2.1 Research into current and future materials

The criteria for the selection of materials included cost, the ability to provide a therapeutic effect over a relatively large surface area (as opposed to a specific site such as directly under the ischial tuberosities), a performance unaffected by seat tilt (fluid bags for example were rejected because they pool when tilted) and no need for set-up or adjustment for multiple users. In addition to redistributing pressure, the ability of the materials to reduce shear, maintain a dry interface and to preserve skin temperatures were important functional parameters. A list of the materials collected is given in Table 1, with accompanying images in Figures 1-10. The materials were tested in various combinations, and are described as having a core material and one or more toppers. Variations in the cushion support were investigated with a rigid flat base, a rigid contoured base and a contoured elastomeric mesh base (Figures 11). Table 1 gives scores for the likely benefit of each material in terms of vapour permeability and specific heat capacity. Specific heat capacity relates to the amount of energy required to heat a material, i.e. materials with a low specific heat capacity heat up easily. An air cushion that can be customised to the individual is also included for benchmarking data as this was considered a market leader for pressure redistribution (Figure 12). All cushions were evaluated on a multi-adjustable test-rig (Figure 14).

Table 1. Selection of materials, with scores for vapour permeability and specific heat capacity

		Material/technology	Thickness (mm)	Figure	Vapour Permeable	High Specific Heat Capacity
Phase 1 research	Topper	Flat gel	15-18	1	✗	✓✓✓
		Castellated gel	20	2	✗	✓✓✓
		Soft spacer fabric	15	3	✓	✗
		Firm spacer fabric	10	4	✓✓	✗
		Red Intelli-Gel®	30	5	✓	✓✓✓
		Blue Intelli-Gel®	25	6	✓	✓✓✓
		Yellow viscoelastic foam	25		✓	✗
		Blue viscoelastic foam	25		✓	✗
	Core	Core spacer fabric	40	7	✓✓✓	✗
		400 density polyurethane foam	40		✓	✗
		650 density polyurethane foam	40		✓	✗
	Other complete cushions	Water-cell cushion (manufactured in 2003)	90	8	✓	✗
		Water-cell cushion (new foam)	90		✓	✗
		100% blue viscoelastic foam	90		✓	✗
		100% yellow viscoelastic foam	90		✓	✗
		Commercial viscoelastic cushion	80		✓	✗
	Base	Rigid flat				
		Rigid contoured		10		
		Flexible contoured (elastomeric mesh)		11		
Phase 2 research	Topper	Red Intelli-Gel®	30	5	✓	✓✓✓
		Soft spacer fabric	15	3	✓	✗
		Firm spacer fabric	10	4	✓✓	✗
		Blue viscoelastic foam	25		✓	✗
		Dacron				
	Core	Deep Intelli-Gel®	60	9	✓	✓✓✓
		400 density polyurethane foam	40		✓	✗
		650 density polyurethane foam	40		✓	✗
	Base	Rigid flat				
	Other complete cushions	Inflatable air cushion		12	✓	✗

Figure 1. *Flat gel*

Figure 2. *Castellated gel*

Figure 3. *Firm spacer fabric*

Figure 4. *Soft spacer fabric*

Figure 5. *Red Intelli-Gel®*

Figure 6. *Blue Intelli-Gel®*

Figure 7. Core spacer fabric

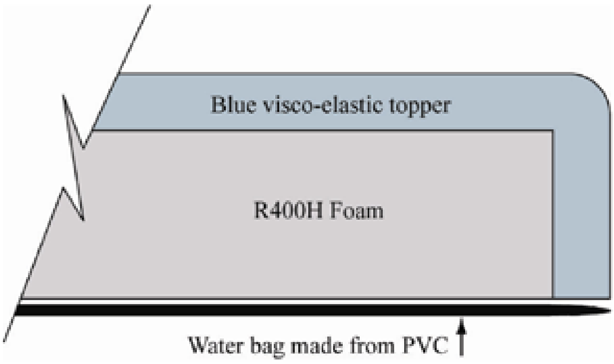

Figure 8. Water-cell cushion

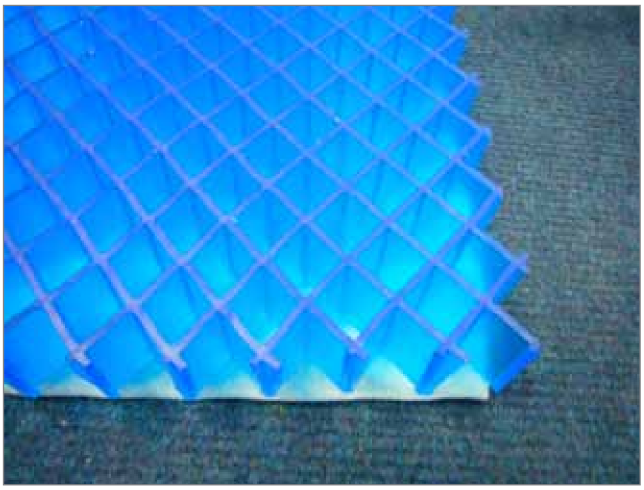

Figure 9. Deep Intelli-Gel®

Figure 10. Commercial viscoelastic cushion

Figure 11. Flexible contoured (elastomeric mesh)

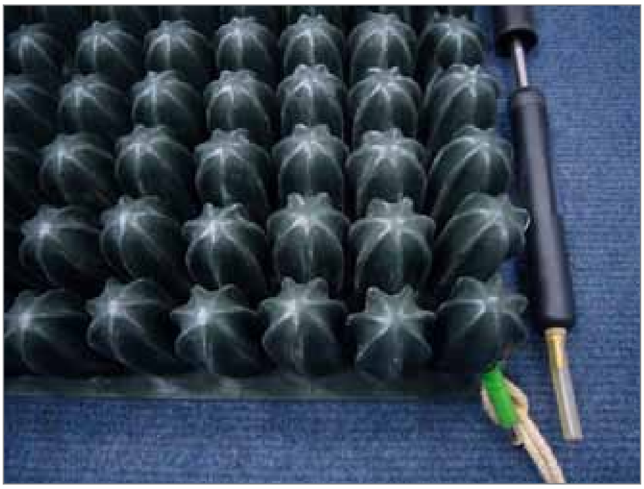

Figure 12. Air inflatable bladder cushion

Figure 13. Test-rig and XSENSOR Pressure Imaging system

2.2 XSENSOR Pressure Imaging System

The XSENSOR Pressure Imaging System was used to measure seat interface pressures (Figure 13). The system consists of a pressure mat and an X3 sensor platform to provide a communication relay function and power for the pressure mat. The XSENSOR 4.3 Industrial software was used for operating the system and collecting data.

The pressure mat is thin and flexible, and contains capacitive sensors. The mat consists of a 36 x 36 array of sensors (1296 measuring points in total) and covers a sensing area of 457 x 457 mm. The sensor spatial resolution is 12.7 mm, with no gaps between sensors. The advantages of capacitive sensors are high repeatability, high accuracy, low hysteresis, and no need for frequent calibration, as is the case for resistive sensors (Mootanah & Bader, 2006). In addition, the study by Pipkin and Sprigle (2008) suggested a low perturbation error with the XSENSOR mats. The pressure range is 10–200 mmHg, and the manufacturer claims an accuracy of 10%. Prior to the testing, the sensor mat was sent to the manufacturer for calibration.

2.3 Protocol

2.3.1 Stage 1

Thirty two cushion permutations were measured during the first stage of this research. Data were collected from one subject only due to the time required for completion. Once the cushion and sensing mat had been fitted to the test-rig, the subject sat for a 10 minute stabilisation period prior to data collection. This was to allow for creep in the cushion, sensors and body tissues to stabilise. 10 minutes was found to be necessary since viscoelastic foams had been included which require ‘warming up’ to reach their maximum benefit. Immediately following the stabilisation period, data were recorded for 36 seconds with the subject remaining as still as possible. This recording period was then repeated twice, with a 5 minute recovery period between measurements. Each data set therefore contained 3 recordings.

2.3.2 Stage 2

The second part of this research focused down on developing a cushion built around the Intelli-Gel® material. More samples of the Intelli-Gel® material varying in gel type, wall size, grid density, column height and manufacturing techniques were supplied for further investigation. The pressure distributions of material combinations incorporating these Intelli-Gel® samples, viscoelastic and polyurethane foams, and spacer fabrics were compared in an iterative process to filter down towards a final specification. This final specification was then benchmarked against a standard polyurethane foam cushion, a commercially available viscoelastic foam cushion (with a polyurethane core) and a commercially available air cushion. The results of the benchmarking tests are reported here.

The protocol underwent modifications during this second stage of research depending on the temperate and creep characteristics of the materials being compared. The base support was standardised to flat plywood. Two adult males, one mesomorph aged 30 and one ectomorph aged 58, and two children participated at different stages of this process. The benchmarking data on the final cushion specification are from the 30 year old male. The first comparison had a 5 minute stabilisation period for each cushion, with the subject repositioning between measurements. Each data set contained 3 recordings which were then averaged. A different protocol was used for the viscoelastic foam cushion. This had a 10 minute stabilisation period and the subject did not reposition between measurements. This was in an attempt to 'warm up' the viscoelastic foam. The Intelli-Gel® and air cushions were compared again in two subsequent test sessions. Interface pressure data is also reported for the air cushion where it was first maximally inflated, and then for each deflation level until eventually bottoming out.

2.4 Interpretation of interface pressure data

The interface pressure variable selected for comparing all data was Peak Pressure Index (PPI). PPI is the mean of the highest recorded pressure values within a 9-10 cm² area (approximately the contact area of an ischial tuberosity and other bony prominences) under one of the loading-bearing surfaces (ischial tuberosities, greater trochanters, and sacrum/coccyx). Analysing single sensor peak pressures proves problematic because it is an unstable measure that exhibits poor repeatability (Sprigle, et al., 2003). Average pressure is reliable but not very volatile because a lot of body weight is concentrated on only a portion of the surface area of the mat. Hence, calculating a mean pressure value loses much meaning (Sprigle, et al., 2003).

3 Results

The means and standard deviations for the stage 1 part of this research are presented in Table 2 and Figure 14. The data from the final cushion specification resulting from stage 2 are given in Table 3 and Figure 15. Figure 16 gives data on the effect of different inflation pressures for the air cushion on interface pressure.

Table 2. Mean Peak Pressure Index (mmHg) and Standard Deviations from Stage 1

Ref	Topper	Core	Base	Mean PPI	STDEV
A1	Red Intelli-Gel®	400 PU	Flexible Contoured	63.74	2.33
B1	Firm spacer fabric + red Intelli-Gel®	400 PU	Flexible Contoured	65.97	3.99
C1	Red Intelli-Gel®	Core spacer fabric	Flexible Contoured	67.42	3.69
D1	Red Intelli-Gel®	400 PU	Rigid Contoured	67.82	4.31
E1	Blue Intelli-Gel®	400 PU	Rigid Contoured	69.55	3.18
F1	Firm spacer fabric + red Intelli-Gel®	400 PU	Rigid Contoured	70.96	4.21
G1	Red Intelli-Gel®	650 PU	Rigid Contoured	72.52	3.72
H1	Water-cell cushion (used)		Rigid Contoured	73.05	1.8
J1	Castellated gel	400 PU	Rigid Contoured	74.25	2.32
K1	Firm spacer fabric + red Intelli-Gel® + soft spacer fabric	400 PU	Rigid Contoured	74.35	1.49
M1	No topper	400 PU	Rigid Contoured	74.78	4.76
N1	Yellow viscoelastic foam	400 PU	Rigid Contoured	75.05	1.91
O1	Red Intelli-Gel® + soft spacer fabric	400 PU	Rigid Contoured	76.65	1.9
P1	Water-cell cushion (new)		Rigid Flat	75.91	1.23
Q1	Blue viscoelastic foam	400 PU	Rigid Contoured	76.67	1.08
R1	Red Intelli-Gel®	Core spacer fabric	Rigid Contoured	77.52	1.04
S1	Water-cell cushion (used)		Rigid Flat	77.77	4.32
T1	Blue viscoelastic foam	400 PU	Flexible Contoured	77.81	2.48
U1	Soft spacer fabric	Core spacer fabric	Rigid Contoured	78	1.56
V1	Firm spacer fabric	400 PU	Rigid Contoured	78.91	1.55
W1	Water-cell cushion (new)		Rigid Flat	79.55	3.48
X1	Castellated gel	650 PU	Rigid Contoured	79.97	5.07
Y1	Soft spacer fabric	Core spacer fabric	Flexible Contoured	80.14	3.87
Z1	Red Intelli-Gel® + soft spacer fabric	Core spacer fabric	Rigid Contoured	80.92	1.79
A2	Blue viscoelastic foam	650 PU	Rigid Contoured	81.24	2.55
B2	Yellow viscoelastic foam	650 PU	Rigid Contoured	81.35	3.57
C2	Firm spacer fabric	650 PU	Rigid Contoured	82.52	1.62
D2	100% blue viscoelastic foam		Flexible Contoured	82.91	3.11
E2	Yellow viscoelastic foam	400 PU	Flexible Contoured	85.52	4.33
F2	Commercial viscoelastic cushion		Rigid Flat	89.43	1.69
G2	Flat gel	400 PU	Rigid Contoured	90.19	7.36
H2	100% yellow viscoelastic foam		Flexible Contoured	96.95	5.23

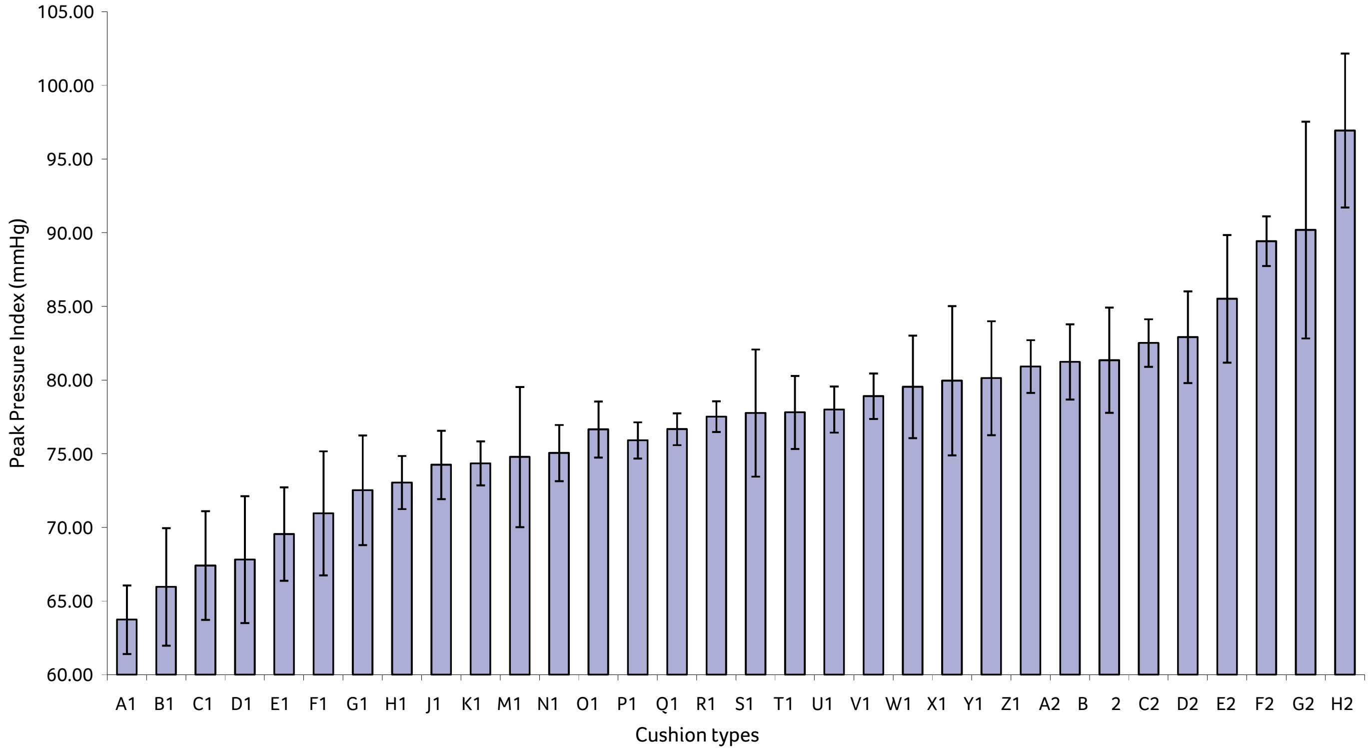

Figure 14. *Mean Peak Pressure Index (mmHg) and Standard Deviations from Stage 1*

Table 3. Mean Peak Pressure Index (mmHg) and Standard Deviations from Stage 2

		Average	STDEV
Comparison 1	Air cushion	169.1	0.8
	Intelli-Gel® cushion	163.41	1.53
	PU foam (650)	193.26	3.01
	Viscoelastic cushion	199.24	1.02
Comparison 2	Air cushion	159.13	2.11
	Intelli-Gel® cushion	166.26	1.36
Comparison 3	Air cushion	178.81	4.77
	Intelli-Gel® cushion	169.71	3.19

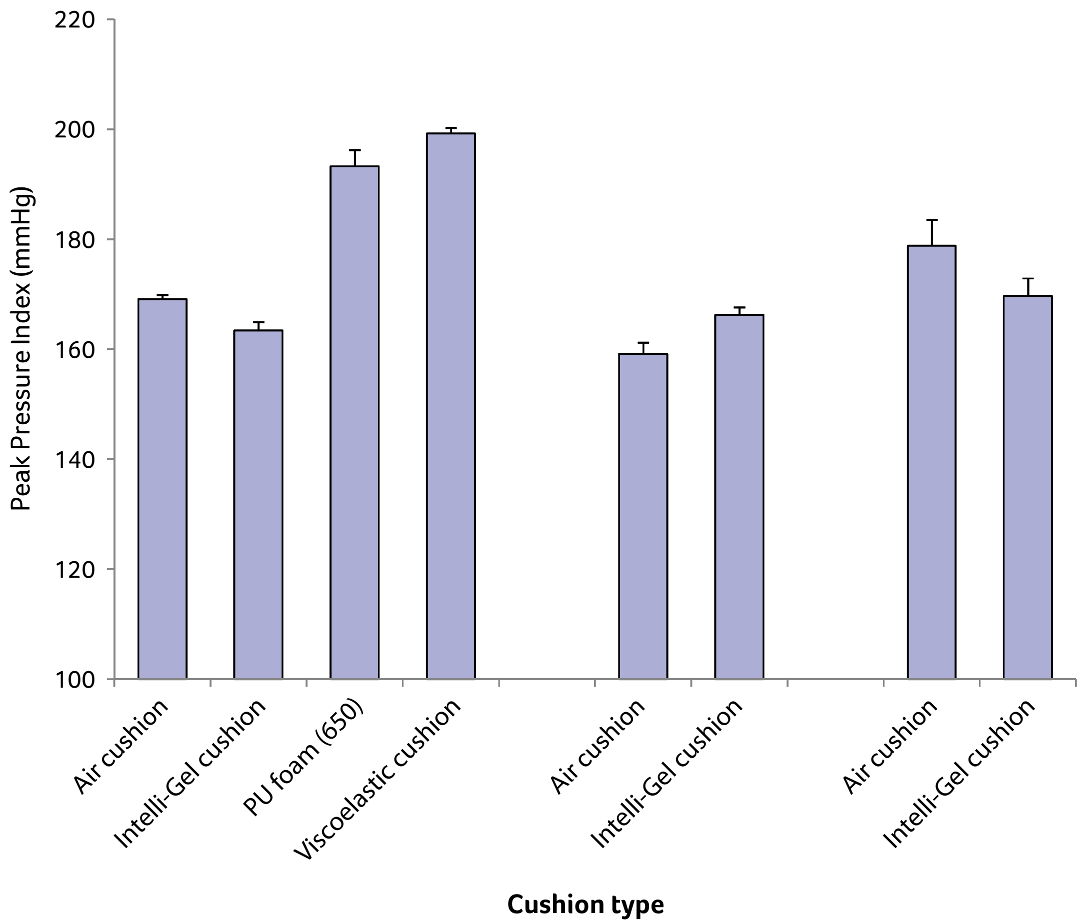

Figure 15. Mean Peak Pressure Index (mmHg) and Standard Deviations from Stage 2

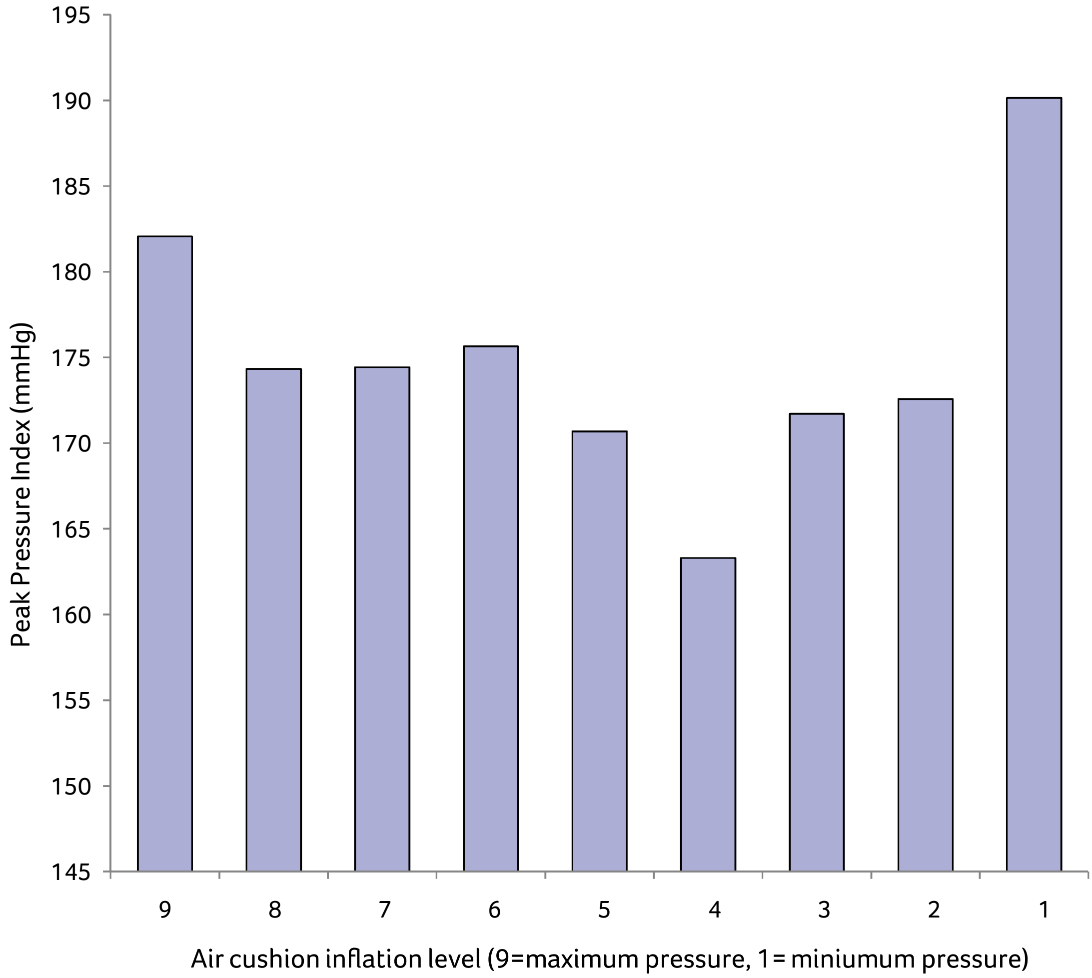

Figure 16. Peak Pressure Index values for an air cushion at various inflation levels

4 Discussion

Interface Pressure Imaging has been used by the R&D team at The Kirton Healthcare Group Ltd to help guide decision making through the development of advanced pressure redistributing seat cushions for long term care. Although Pressure Imaging provides useful data, there are limitations that need to be acknowledged when interpreting the results.

Firstly, the presence of the pressure mat at the body/support interface has an effect on the true pressures that would exist normally. This is known as the perturbation error. Pipkin and Sprigle (2008) evaluated the perturbation error for a number of different pressure mats using two artificial buttock models to collect data. They found that all pressure mats affected the readings, and in general most underestimated the baseline data which supports Diesing's conclusions (2002). The perturbation error was different for each mat depending on the cushion type, which suggests that different pressure mapping systems could rank cushions in different orders. Pipkin and Sprigle (2008) found that the two pressure mats that had the least perturbation error were the ConforMat and the XSENSOR mat. The authors also found pressure mapping to have limited repeatability.

During stage 2 of this research, data was collected from subjects that differed in body type which meant that inter-subject comparisons could not be made statistically (Swain and Peters 1997). It was considered important however to evaluate the cushion with a heterogeneous group in order to develop the best understanding of the cushion's characteristics with the resources available at the time. In addition to this the protocol was modified several times during stage 2 depending on the expected rate at which the cushion would stabilise which again made it not possible to draw statistical comparisons between different test sessions. Only the benchmarking on the final cushion specification is reported.

The results of stage 1 suggest that a trend may exist where all cushion combinations incorporating the Intelli-Gel® material result in the lowest Peak Pressure Index values. In addition to the pressure redistributing potential of this material, it appears to be beneficial for controlling skin temperature and moisture build up. Previous studies have shown that gel wheelchair cushions maintain a constant skin temperature (Fisher et al. 1978, Stewart et al. 1980) whereas foams and viscoelastic foams have been demonstrated to increase skin temperatures by 3.4C and 2.8C respectively (Stewart et al. 1980). Increasing skin temperature is undesirable because there is an accompanying increase in metabolism (Bruetman and Gordon, 1971). It has been shown that a 1° increase in temperature increases tissue metabolism by 10% (Ruch and Patton, 1965). Increasing tissue metabolism results in an increased demand for oxygen. If tissue demand for oxygen is not met cell necrosis can happen. This supply and demand relationship is central to pressure ulcer development. Therefore, the high specific heat capacity of gel makes it a very suitable material for use in seat cushions designed to reduce the risk of tissue breakdown. A problem with gels that are commonly available on the market is that they are impermeable to vapour. The study by Stewart et al., (1980) demonstrated that relative humidity at the skin/cushion interface increased by 22.8% with gels compared to 10.4% with foams. Increased humidity could compromise skin strength making it more prone to mechanical damage from shear stress or abrasion. Furthermore, dry skin offers less risk of infection. The Intelli-Gel® material is different from conventional gels in that it has an open lattice design which permits moisture to transport away from the skin/cushion interface and through the gel columns.

The manufacturers of Intelli-Gel® claim that the material is beneficial because of the 'column buckling' principle. Here, it is said that the gel columns buckle under areas of peak pressure such as bony prominences but under other areas where pressure is evenly distributed the columns remain structural and support the body. Thus, the Intelli-Gel® is said to eliminate high pressures. The R&D team at The Kirton Healthcare Group Ltd found however that the Intelli-Gel® did not always respond the same way under applied load. On some occasions the gel columns buckled as intended, but on other occasions there was more of a toppling over which can be likened to falling dominos. Intelli-Gel® had been previously used in bed mattresses where this problem may not exist due to a much larger surface area supporting the body when lying. However, in a seat cushion it appeared that the Intelli-Gel® needed more surface structure to help control how the columns responded to the higher pressures. This was achieved by inserting the Intelli-Gel® into a foam border and fusing a light weight non-stretch fabric to the face surface of the gel and foam surround. A foam base was also included which built up the cushion to the require 90mm thickness, and gave the additional cushioning necessary for occasions when the Intelli-Gel® began to bottom out. An additional advantage of this cushion design is that the foam border can be easily modified to produce a cushion of practically any size, which is particularly beneficial for supplying the extensive range of seat sizes common in long term care.

The results from benchmarking the final specification are presented in Table 3 and Figure 15. Here, it can be seen that there is a significant difference between the polyurethane and viscoelastic foam cushions compared to the Intelli-Gel® and air cushions. Of the three comparisons between the Intelli-Gel® and the air cushions, the Intelli-Gel® cushion scored better in two. The reason for the differences in these three comparisons is the inflation pressure of the air cushion. Figure 16 shows how the interface pressures change as the inflation pressure changes. This suggests that the air cushion has the potential to produce very low interface pressures but that it is difficult to hone in on the correct inflation pressure. During the benchmarking tests, the air cushion was tested three times but in only one of those three tests was the cushion inflated to its optimum for that subject.

5 Conclusion

Based on the work carried out by the R&D team at The Kirton Healthcare Group Ltd, the final specification for the Intelli-Gel® cushion showed potential to exhibit similar pressure redistributing characteristics to adjustable air cushions, and could therefore be positioned alongside the market leaders for pressure relief. An independent laboratory study would be the next logical step towards verifying these findings, before moving to a clinical study.

6 References

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Case Study 1

Anna has been suffering for as long as we can remember, with numerous visits to our GP and to Paediatricians. About two years ago she was diagnosed with Lichen Schlerosus and she was started on a regime of creams and steroids.

What is lichen sclerosus?

Lichen sclerosus is a chronic, usually itchy, skin disease of the genital skin. The most common groups to be affected by it are middle aged and older women but it can occur in children. The skin in the genital area appears as white skin patches.

What causes lichen sclerosus?

The cause of lichen sclerosus is unknown. It can be associated, in some patients (and/or their close relatives), with autoimmune diseases, such as thyroid disorders or vitiligo. These occur when the cells and proteins that the body uses to fight off infection start to damage the bodies own tissues and prevent their normal actions.
Lichen sclerosus is not an infection and is not contagious.

What are the symptoms?

- **Itching is the most common symptom and some people experience soreness and burning.**
- **The skin becomes pale and white in appearance. This may be patchy or involve all of the vulva extending down to the anus. The area may split causing stinging and pain.**
- **Children usually complain of itching and are constantly scratching and rubbing at their vulva. They may develop burning or pain with urination and with bowel movement and may even develop constipation.**
- **Small purplish/red areas may be seen on the white background. These are due to tiny areas of bleeding into the skin, often because of scratching.**
- **There may be scarring that causes loss of vulvar tissue (e.g. clitoris) or shrinkage of the vulvar areas, which can cause pain and interfere with sexual intercourse and even cause problems urination.**
- **It does not involve the vagina**

Anna has had a particularly bad few months with her skin. The Lichen schlerosus has moved further down and around her anus making it difficult for her to go to the toilet without pain, we had a hospital admission for faecal impaction, for which she received a phosphate enema. Anna takes movicol (a stool softener) every day and has for the last 2 years.

Anna never has a pain score below 2- 3 (0 being no pain 10 being unbearable pain) even on a day when her skin is ok. She finds it very difficult to sit still for any amount of time and before having her cushion from Kirton Healthcare would sit on the edge of a chair or with her foot under her so that her bottom does not take full pressure. The cushion has made a considerable difference to her a school and her teachers have seen a marked difference in her, she has had fewer absences from school also because she feels more able to cope at school on ' sore days'.

One of the most incapacitating effects of Lichen Schlerosus is broken sleep. As soon as Anna gets into bed the itching and irritation starts. The summer months are particularly bad as the heat at night seems to aggravate it also.
Anna is still receiving treatment from the dermatology department, we are using an emollient and a steroid every day, and although some days her skin looks fine and clear, the next day it is back. She has learnt to avoid things that hurt her bottom, like bike riding and swimming and pursue other interests.

Additional comments from a tissue viability specialist

During my last visit to Anna, Mum stated that the Intelli-Gel cushion (slim green material) had been an enormous benefit to Anna. She carries it everywhere in a special PE kit type cotton bag, so that it doesn't get damaged. Up until this point, Anna has transported the cushion from home to school and back each day. However, Kirton Healthcare has now kindly provided Anna with another sheet of Intelli-Gel – a blue deeper model.

Anna's mum informed Fiona that the cushion has transformed their ability to travel for long distances in the car – previously this was limited and traumatic due to Anna's discomfort. Holidays are now being considered!

One of Anna's main difficulties is the ability to sleep at night, particularly in the summer, as she becomes so hot – the trigger for her discomfort. We have therefore wondered whether the use of a deep Intelli-Gel insert built into a surrounding matrix of foam (not viscoelastic / memory foam as this will cause heat issues) will assist in improving her quality of sleep. A thin cotton sheet would be the only material that could cover the mattress however, in order to minimise heat. Anna's current mattress measures 35" x 74" (89cm x 188cm).

Anna is extremely excited at the prospect of trying an Intelli-Gel mattress – as is her mother and they are very happy to provide any feedback that is required! We have even wondered about publishing this as a single case study in a journal as it could help other lichen sclerosis sufferers.