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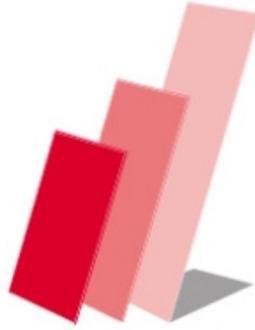
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**Independent clinical evaluation of Stimulite cushions
conducted on behalf of Gerald Simonds Healthcare by
Wounds Healing Centres UK Ltd. and Dr Steve Young.**

April 2013

 **StimuLITE[®]**

The logo icon consists of a stylized, three-dimensional cube-like shape made of brown lines, representing the Stimulite cushion technology.



woundhealingcentres

Report on a Clinical Evaluation of the Stimulite Classic XS Cushion

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Executive Summary

- The Stimulite[®] Cushion was evaluated by 5 Subjects in a Registered Nursing Home for Elderly Mentally Ill (EMI) People over a 2 week period, in order to examine its effect on contributing to the prevention and reversal of pressure injuries in vulnerable adults. The average age of the Subjects was 86 years, with the oldest Subject being 90 years and the youngest 83 years.
- The Waterlow Score Range was 19 – 33, with the average Waterlow Score being 25. One of the Subjects was in a “High Risk” category with the remaining 4 in a “Very High Risk” category.
- All five Subjects had pressure injuries of up to Category 2 (EPUAP / NPUAP, 2005), although only four of the five had visually evident pressure injuries; all Subjects were provided with a Stimulite[®] Cushion to use in their armchair, but other than this their usual pressure injury prevention care plans remained unchanged during the evaluation. The use of the cushion resulted in substantial improvement in the pressure injuries of all of these Subjects.
- The Nursing Home staff all reported that the Stimulite[®] Classic Cushion appeared to provide significantly more comfort than the cushions that the subjects were using prior to the evaluation. The comments made by the staff with regard to each subject were most powerful and these are included under the profile of each Subject.

Introduction

Preventing and healing pressure injury is difficult, due to the large number of potential aetiological factors involved, although it is recognised that the largest single causative factor is unrelieved pressure. Concomitant to this are other predisposing factors which may be intrinsic or extrinsic. These include, intrinsically malnutrition, incontinence, altered level of consciousness and altered level of sensation, and extrinsically, friction and shear forces (NICE, 2005). Many of these factors are often involved simultaneously, and for those patients who are extremely immobile, appropriate

pressure redistributing equipment needs to be considered. Pressure injuries occur across the age spectrum from pre-term infants through to the very old (Benbow, 2008). The vast majority of people at risk of pressure injury are provided with a suitable profiling bed frame and pressure relieving mattress appropriate to their needs. However many of these people, particularly if they sit in armchairs, are left vulnerable to pressure injury due to inadequate provision of suitable pressure relieving cushions (Collins 2008). Evaluating the contribution of pressure reducing cushions to preventing and remedying pressure injury is challenging due to the complexity of factors involved, such as length of time the person sits for, their sitting posture, their ability to withstand gravitational forces and the reaction of the person's skin to pressure, shear forces and friction.

The Stimulite® Classic Pressure Redistributing Cushion

Stimulite® lightweight cushions use a soft, flexible 'honeycomb' form to distribute weight uniformly, giving exceptional comfort and excellent postural stability. A unique ventilation system allows air to circulate horizontally and vertically, creating an ideal micro-climate for long-term sitting comfort and skin protection. Stimulite cushions have had a proven track record among wheelchair users since 1994. They are hygienic, safe and offer total comfort and, uniquely, both cushions and covers are machine washable. They are naturally antibacterial, antifungal and allergen free making them long lasting, durable and cost effective in use. There is a full range of Stimulite cushions, including standard, paediatric, sport and bariatric models, specifically designed to accommodate a wide range of disabilities.

The **Stimulite Classic** cushion is designed for people who are at high risk for skin breakdown, providing excellent pressure relief, unsurpassed comfort and exceptional stability.

Project Objectives:

The primary objectives of the clinical evaluation were to:

1. Formally evaluate efficacy in preventing and healing pressure injury

2. To evaluate the comfort, patient experience, and ease of use of the Stimulite® Classic Cushion in 5 people in the community who were using a pressure redistributing cushion in their armchair, which for various reasons were unsuccessful.

Methodology

The Subjects for the evaluation were residents in an EMI Nursing Home, all of whom on examination had existing pressure injury and were vulnerable to further development of pressure injury. Prior to the evaluation, the Subjects had been identified by Nursing Home staff as being at very high risk of pressure injury or with existing pressure injury, and were using pressure relieving cushions on top of their existing armchair seats, which they were finding uncomfortable.

Subject profile

All Subjects had profiling bed bases and replacement deep cell alternating mattresses. One of the Subjects had a privately owned riser recliner chair, one Subject used a 'bucket' style chair and three of the residents used a conventional high seat chair (all of which had the original seat cushions removed and replaced with a memory foam pressure redistributing cushion). Two of the Subjects had been provided with an alternating air cushion, but had rejected this on grounds of discomfort and instability.

Two out of the five Subjects required hoisting for their moving and handling needs. Two Subjects could transfer with assistance, but were extremely immobile. One Subject needed assistance with transfers but once standing was ambulant.

All of the Subjects were doubly incontinent.

Two of the Subjects had a MUST score (Malnutrition Universal Screening Tool) of 1 (medium risk) and the remaining three had a score of 2 (high risk).

Day 0

All Subjects remained in bed prior to assessment.

Baseline demographic data was collected for each of the Subject.

The skin of each Subject was examined for signs of pressure injury.

Photographs were taken of any areas of the skin exhibited signs of pressure injury.

High definition ultrasound was used to examine firstly normal skin and then the skin of each person's buttocks and sacrum for signs of pressure injury

Comments were sought from the Subject (where possible) on the comfort of their existing cushion. Comments from staff relating to perceived Subject comfort were also sought.

The Subjects were then provided with a Stimulite Classic cushion which was the same size as their armchair seat. This cushion was positioned into the armchairs instead of the existing pressure reducing cushions already in situ.

Day 14

The skin of each Subject was examined for signs of pressure injury.

Photographs were taken of any areas of the skin exhibited signs of pressure injury.

High definition ultrasound was used to examine firstly normal skin and then the skin of each person's buttocks and sacrum for signs of pressure injury

Comments were sought from the Subject (where possible) on the comfort of Stimulite[®] Classic Cushion. Comments from staff relating to perceived Subject comfort, and ease of use of the Stimulite[®] Classic Cushion were also sought.

Results

Visual examination of the skin demonstrated that the Stimulite Classic Cushion had maintained skin integrity in all five Subjects. In the four Subjects with visually evident pressure injury on Day 0 there were significant visible improvements to the skin condition by Day 14. The photographs presented for each Subject at the end of this report demonstrate the positive effect of the Stimulite[®] Classic Cushion on extremely vulnerable individuals. The results of the High Definition Ultrasound Scans obtained on each of the subjects provides substantive quantitative data, which strongly supports the efficacy of the Stimulite cushion in preventing and healing Pressure Injuries up to Category 2, when comparing scans from Day 0 and Day 14. Dr Steve Young has provided a separate report on High Definition Ultrasound Scanning for the Stimulite Evaluation, which will be presented alongside this report. However, the summary graph from his report with associated comments, is presented at the end of this section. The individual case studies, with photographs, are presented at the end of this report.

Due to all of the subjects suffering from Dementia, it was not possible to gain verbal feedback on comfort directly from them. However, qualitative summary feedback was provided by the Nursing

Home Matron on each subject, including feedback on length of time sitting, the subjects' posture and perception of comfort. There were many positive comments and these have been recorded in the details on each Subject's profile below. No negative comments were made by the Matron with regard to the Stimulite Classic cushion.

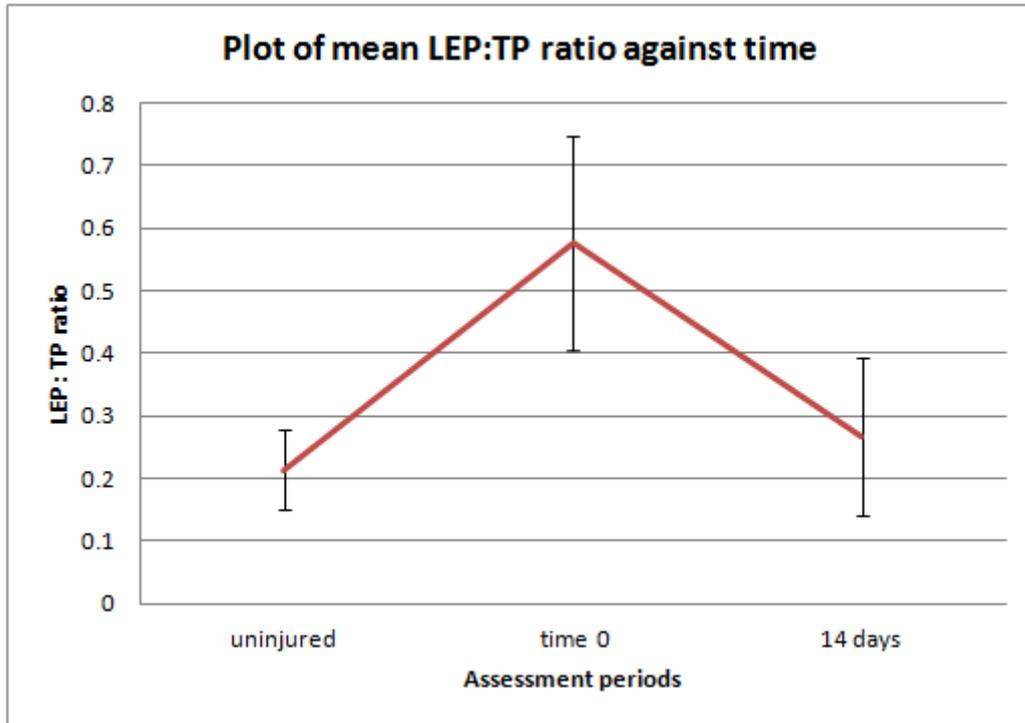


Figure 1: Graph showing LEP: TP ratio

Figure 1 Interpretation: Using the scanners image analysis software, it was possible to measure the amount of oedema within the dermal tissue of each subject. 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.

The analysis of the ultrasound images from the uninjured skin of the subjects shows that the mean LEP: TP ratio is 0.214. This is therefore the level we would wish to get the affected skin to if our therapy (i.e. use of the Stimulite Classic Cushion) works.

As the graph shows, the damaged skin at time 0 is 0.58 which is approximately twice the uninjured skin level, which indicates high levels of oedema present. By 14 days, the ratio is almost at normal/uninjured levels.

Conclusion

The results obtained during the evaluation of the Stimulite Classic Cushion are extremely positive and would suggest that the use of this cushion has a significant role to play in both preventing and healing pressure injuries up to Category 2 (EPUAP / NPUAP, 2005) in extremely vulnerable people. The comments received by the Matron were overwhelmingly positive, particularly relating to visually improved comfort, improved posture and reduced agitation. This evidence and feedback would indicate that the Stimulite Classic Cushion has a very effective part to play in the prevention and management of pressure injuries for vulnerable people who wish to sit in conventional armchairs for controlled periods of time.

References

Benbow, M (2008) Pressure ulcer prevention and pressure relieving surfaces. *British Journal of Nursing*. 17 (13): 830-5

Collins F (2008) An essential guide to managing seated patients in the community. *Br J Community Nurs*. Mar;13(3):S39-40, S42-3, S45-6.

EPUAP / NPUAP (2009) Treatment of Pressure Ulcers: Quick Reference Guide

National Institute for Health and Clinical Excellence (2005) *The Management of Pressure Ulcers in Primary and Secondary Care. A Clinical Practice guideline*. CG029

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| Subject 1: (AJ) | |
| Age: | 83 years |
| Gender: | Male |
| Waterlow Score: | 20 (very high risk) |
| MUST Score: | 1 (medium risk) |
| Medical history: | Dementia, Diabetes Type 2, Hypertension, Angioplasty |
| Contenance: | Doubly incontinent |
| Transfers: | Standing transfers with the assistance of care staff using a patient handling belt |
| Mobility status: | Ambulant |
| Repositioning status: | Can reposition a little in bed, but predominantly relies on staff for assistance |
| Length of time sitting | Sits for 2-3 hours during the day in a bucket style chair with a memory foam cushion. Staff reported that this gentleman was often agitated when sitting, constantly attempting to slide down in the chair, hence the provision of a bucket style chair in order to try and prevent this |
| Existing bed frame and mattress | Subject has a profiling bed with a deep cell alternating mattress replacement |
| Day 0 Observations | A full skin assessment was undertaken. There was generalised erythema in the sacral region and three separate broken areas of skin, all of which were defined as Category 2 (EPUAP, 2005) pressure injuries. |
| Day 0 Photograph |  |
| Day 14 Observations | There was visible improvement of this Subject's pressure injuries. Much of the surrounding erythema had dissipated and there was evidence of epithelialisation in the broken areas |

**Day 14
Photograph**



**Matron's Comments on Effect of
Stimulite® Classic Cushion**

The Matron felt that AJ had made a 'marvellous improvement' since using the Stimulite Classic cushion in his armchair. She reported that his perceived agitation when sitting and sliding up and down in the chair was much reduced. This she felt, had resulted in his posture being improved and had contributed to his skin integrity being improved.

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| Subject 2: (WL) | |
| Age: | 90 years |
| Gender: | Male |
| Waterlow Score: | 33 (very high risk) |
| MUST Score: | 2 (high risk) |
| Medical history: | Dementia, Arthritis, Diabetes Type 2, Frailty |
| Contenance: | Doubly incontinent |
| Transfers: | Hoisted for all transfers |
| Mobility status: | Non weight bearing |
| Repositioning status: | Unable to reposition independently |
| Length of time sitting | Sits for 2-3 hours during the day in a high seat armchair with a memory foam cushion. This gentleman had been provided with an alternating seat cushion, which he did not tolerate and which staff reported made no difference to his skin integrity. This gentleman had a tendency to rock forwards and backwards when sitting |
| Existing bed frame and mattress | Subject has a profiling bed with a deep cell alternating mattress replacement |
| Day 0 Observations | A full skin assessment was undertaken. Some of the redness observed in the photograph below was caused by a skin reaction to the sacral dressing used to cover an abrasion. This dressing had immediately been discontinued. However, there was generalised non blanching erythema in the sacral region and a graze slightly above and to the right of the natal cleft which was defined as a Category 2 (EPUAP, 2005) pressure injury. |
| Day 0 Photograph |  |

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| <p>Day 14 Observations</p> | <p>There was significant visible improvement of this Subject's pressure injury. The surrounding erythema had dissipated and the graze the above left of the natal cleft had epithelialised</p> |
| <p>Day 14 Photograph</p> |  |
| <p>Matron's Comments on Effect of Stimulite® Classic Cushion</p> | <p>The Matron was extremely pleased that the graze on this subject's sacrum had made such progress. She noted that this client had reduced his tendency to rock in the chair and appeared more comfortable.</p> |

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| Subject 3: (BH) | |
| Age: | 85 years |
| Gender: | Female |
| Waterlow Score: | 24 (very high risk) |
| MUST Score: | 2 (high risk) |
| Medical history: | Dementia, Left and Right Cerebrovascular Accidents leading to bilateral hemiparesis, Arthritis, Angina |
| Contenance: | Doubly incontinent |
| Transfers: | Hoisted for all transfers |
| Mobility status: | Non weight bearing |
| Repositioning status: | Unable to reposition independently in the bed or chair |
| Length of time sitting | This lady has her own riser recliner armchair onto which staff had placed an alternating seat cushion, as they were concerned about her risk of developing a pressure injury (this lady has a history of pressure injuries); however, the lady refused to sit on the alternating seat cushion due to discomfort and feeling unstable. As a consequence, due concerns about her vulnerability, and as she had no alternative cushion to use, the lady had been placed on enforced bed rest in her best interests, despite her preference to be sat out of bed. However, staff felt that provision of a Stimulite cushion offered the lady an opportunity to sit out of bed, in a controlled situation, on an alternative cushion which it was hoped would meet her needs. |
| Existing bed frame and mattress | Subject has a profiling bed with a deep cell alternating mattress replacement |
| Day 0 Observations | A full skin assessment was undertaken. Visually the skin in the sacral region and between the buttocks was darkened. It was difficult to note any reddening of the skin although there was clear scarring from previous pressure injuries. However the ultrasound scan determined evidence of Category 1 (EPUAP, 2005) pressure injury in the upper left sacral region |
| Day 0 Photograph |  |

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| <p>Day 14 Observations</p> | <p>Much of the darkening of the skin in the sacral region had dissipated, leaving paler skin, clearly demonstrating the scarring from previous pressure injuries</p> |
| <p>Day 14 Photograph</p> |  |
| <p>Matron's Comments on Effect of Stimulite® Classic Cushion</p> | <p>The Matron reported that she had been extremely concerned when allowing the lady to be sat out of bed using the Stimulite Classic cushion, due to her previous history of pressure injury and the inability of the lady to tolerate the alternating seat cushion previously provided. The Matron reported that this lady's posture had not specifically improved throughout the duration of the evaluation due to her fixed kyphosis, which would not necessarily have been affected by the use of the cushion.</p> |

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| Subject 4: (CM) | |
| Age: | 87 years |
| Gender: | Female |
| Waterlow Score: | 19 (high risk) |
| MUST Score: | 1 (medium risk) |
| Medical history: | Dementia, R hemiarthroplasty 2012, L dynamic hip screw 2011 |
| Continance: | Doubly incontinent |
| Transfers: | Assisted by two to undertake standing transfers |
| Mobility status: | Unable to take more than 2-3 steps |
| Repositioning status: | Unable to reposition independently in the bed, but can reposition a little in the chair |
| Length of time sitting | This lady sits in a conventional high seat armchair for 2-3 hours with a memory foam cushion, but regularly requires enforced bed rest due to a tendency to develop sacral pressure injuries |
| Existing bed frame and mattress | Subject has a profiling bed with a deep cell alternating mattress replacement |
| Day 0 Observations | A full skin assessment was undertaken. There was generalised non blanching erythema in the sacral region and between the buttocks. There was a graze at the top of the buttocks on the right hand side which was defined as a Category 2 (EPUAP, 2005) pressure injury. There was a small reddened area to the lower right buttock, but the ultrasound scan determined that this was not a pressure injury. |
| Day 0 Photograph |  |
| Day 14 Observations | There was a substantial improvement visually; the erythema was no longer present and the graze had healed, with a small area only remaining |

**Day 14
Photograph**



Matron's Comments on Effect of Stimulite® Classic Cushion

The Matron reported that this lady seemed far more comfortable using the Stimulite Classic cushion rather than the original memory foam cushion that she had been using. This she felt was evident in the lady's improved posture, the improvement in skin integrity and her ability to sit out of bed for increased periods of time.

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| Subject 5: (SD) | |
| Age: | 85 years |
| Gender: | Male |
| Waterlow Score: | 29 (very high risk) |
| MUST Score: | 2 (high risk) |
| Medical history: | Dementia, breathlessness, repetitive urinary tract infections, Type 2 Diabetes |
| Continence: | Doubly incontinent |
| Transfers: | Assisted by two to undertake standing transfers |
| Mobility status: | Unable to take more than 1-2 steps |
| Repositioning status: | Relies on staff for all repositioning in the bed and chair |
| Length of time sitting | This gentleman sits in a conventional high seat armchair for 3-4 hours with a memory foam cushion |
| Existing bed frame and mattress | Subject has a profiling bed with a deep cell alternating mattress replacement |
| Day 0 Observations | A full skin assessment was undertaken. There was no evidence of erythema in the sacral region; however the ultrasound scan confirmed evidence of oedema within the tissues confirming the presence of tissue injury |
| Day 0 Photograph |  |
| Day 14 Observations | The Subject's skin remained intact with no erythema |

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| <p>Day 14 Photograph</p> |  |
| <p>Matron's Comments on Effect of Stimulite® Classic Cushion</p> | <p>The Matron felt that this particular subject's skin had remained in good integrity despite the fact that he had become increasingly frail during the period of the evaluation. She felt that there was no change in terms of postural improvement, but did feel that he seemed more comfortable using the Stimulite Classic cushion.</p> |