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Evaluation of Prolevo Heelsafe & Solesafe

Pressure Redistribution Pads

Report compiled by

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Evaluation of Prolevo Heelsafe Pressure Redistribution Pad

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Introduction

This report evaluates the performance of the **Prolevo HeelSafe Pressure Relief Pad**, which is a leg-section inflatable overlay aimed at reducing interface pressures on the heels. High interface pressures are known to be associated with the onset of pressure ulcers, and these commonly occur on the heels. The report also evaluates the effect of the product on the skin microclimate, as this is also known to be a factor in the aetiology of pressure ulcers.

Aims

- To evaluate the effect of the **HeelSafe** overlay on peak interface pressures on the heel and lateral malleolus.
- To establish the optimum pressure setting for the **HeelSafe** product at a range of different leg weights representing different patient bodyforms.
- To evaluate the heat and water vapour transfer properties of the **HeelSafe** overlay.

Methods

Peak interface pressures

These are assessed using the UCL Phantom (developed by the RAFT Institute), a full technical description of which is published in the scientific literature.1. This is a life-sized articulated dummy with soft tissues, and bony prominences within. The Phantom has an automated positioning system, which places it in exactly the same way on every mattress. Pressure measurements are made using a highly flexible pressure-mapping array, to locate the peak pressures (which occur in different anatomical regions on different mattresses). The surface of the Phantom is warmed to 35°C using special heated and temperature-controlled skin.

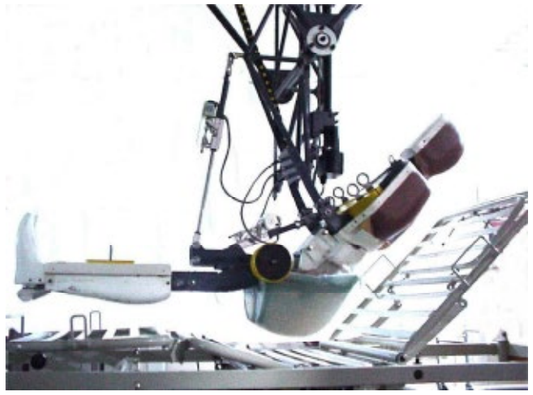


Figure 1 UCL Phantom

Multiple measurements are made, to obtain confidence intervals for the peak pressures in the pelvic and heel regions. Low peak interface pressure is deemed to be the most valid measure of pressure reducing properties according to current evidence at the time of publication.2

Pressure maps reveal visually much information besides peak pressure about the way pressure is distributed. A picture of the pressure map is therefore also provided, to allow readers to judge features of the pressure distribution that may be of particular interest to them (eg contact area). The pressure maps are provided with a sidebar scale to the colour map.

In the case of the **HeelSafe** overlay, the interface pressure under the heels is the relevant measurement. The phantom has a calcaneus insert based on a 50th percentile female heel, with a thin covering of gel material based on rheological measurements of hospital patients.

After positioning on the bed, the knee joint and ankle joint is released to allow natural movement.

Pressures were compared on a Softform Premier mattress, with and without the **HeelSafe** overlay.

Interface pressures were measured using three different setting valves (10mmHg, 20mmHg, and 30mmHg inflation settings), at different body weights of 40kg, 60kg, 80kg, 100kg, 150kg and 200kg.

Since a side-lying position is frequently adopted, this position was modeled using a live female subject age 71, weighing 62kg, and of height 1.67m.

1 Bain DS, Nicholson N, Scales JT.A Phantom for the Assessment of Patient Support Systems. Journal of Medical Engineering and Physics. 21 (1999).293-301

2 Bain D, Ferguson-Pell M, McLeod A. Evaluation of mattresses using interface pressure mapping. Journal of Wound Care Vol 12, No. 6, June (2003) 231-235

Results

Heel pressures on flat bed with **HeelSafe**

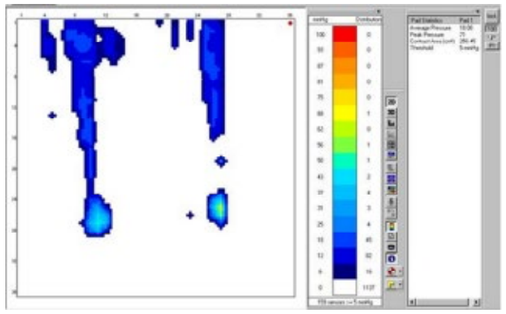


Figure 2 Interface pressure on heels,with **HeelSafe**, 10mmHg inflation, 60kg body type

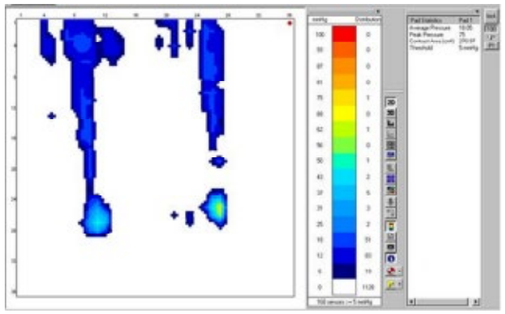


Figure 3 Interface pressure on heels, 20mmHg inflation, 60kg body type

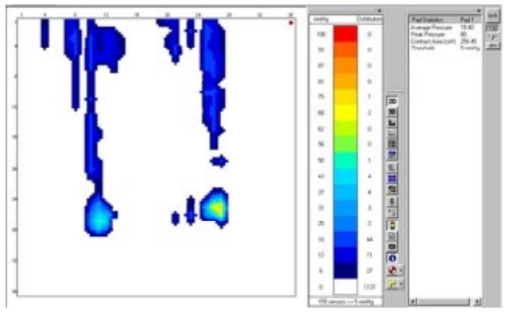


Figure 4 Interface pressure on heels,with **HeelSafe**, 30mmHg inflation, 60kg body type

Example pressure maps are shown in figures 2-4 of the effects of inflation pressure on the pressure distribution with Heelsafe. The large array of variables (6 different patient weights x 2 different knee break angles x 3 different inflation pressures x 3 different surface combinations x 2 anatomical sites) gives too many permutations to show every combination tested. The pressure maps shown are selected for illustration. Overall results are collated graphically. It can be seen that increasing the inflation pressure reduces the overall contact area, as expected. However, this does not result in an increase in peak interface pressure. In this orientation, we see that the middle pressure value gives the lowest value of interface pressure. No 'bottoming out' was observed with the lowest pressure, so it is assumed that the slightly elevated pressure was a result of increased surface 'hammock' tension associated with greater penetration.

Leg break activated with **HeelSafe**

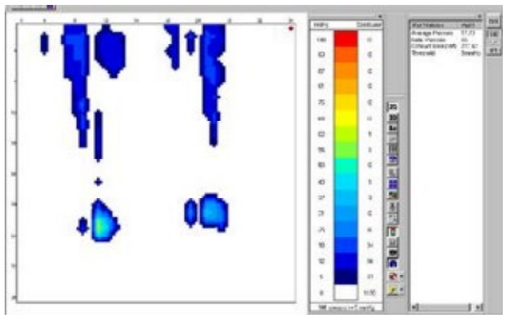


Figure 5 Interface pressure on heels,with **HeelSafe**, 10mmHg inflation, 60kg body type with leg break

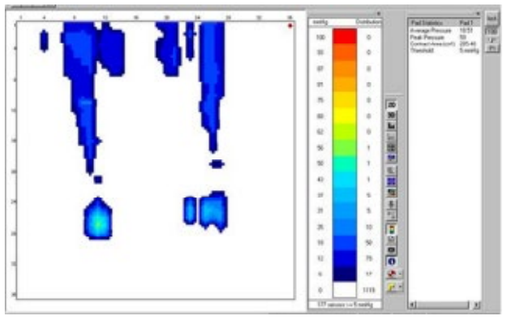


Figure 6 Interface pressure on heels,with **HeelSafe**, 20mmHg inflation, 60kg body type with leg break

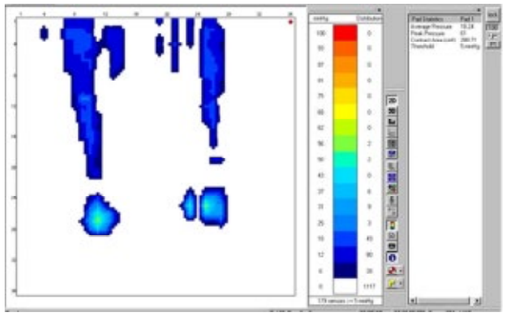


Figure 7 Interface pressure on heels,with **HeelSafe**, 30mmHg inflation, 60kg body type with leg break

Figures 5-7 show the same procedure with the bed adjusted to allow a 10 degrees flexion of the knee.
Again, the middle pressure setting proves to be the optimum for pressure reduction. Generally, lower interface pressures were observed with the bed adjusted to allow knee flexion. This is as expected, since the **HeelSafe** product lifts the foot slightly from the level of the mattress, causing more leg weight to be transferred through the knee in extension. Flexion at the knee removes moment transferred through the joint, thus removing this extra weight.

Figures 8 and 9 show the peak pressures for all body weight models. It can be seen that, although a trend exists for higher peak pressures at different weights, the middle pressure setting is optimal in most cases. At very light weight, 40kg, the lowest pressure setting gave a lower peak interface pressure, but this was marginal.

It is recommended that the md setting is used across all patient weights, to simplify the decision making process.

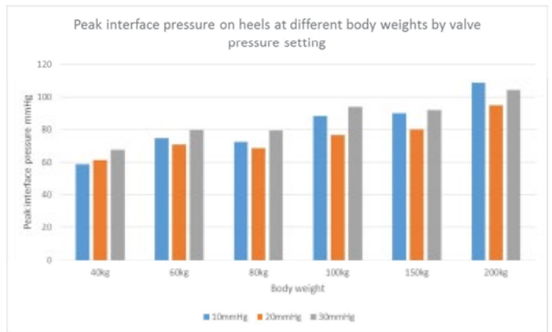


Figure 8 Peak pressures for all body weight models

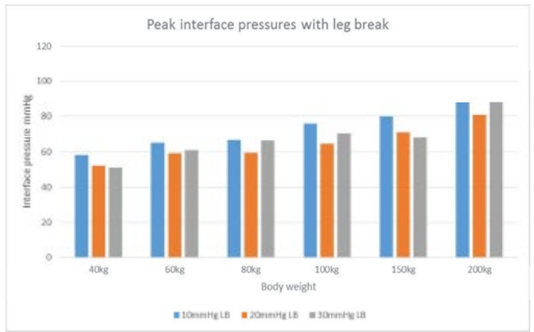


Figure 9 Peak pressures for all body weight models with leg break.

Side Lying

Side lying pressure was mapped using a live subject, as the biomechanics of this position are too complex to model realistically with a phantom. In this case, the subject lay on the bed on her left side in foetal position with the upper (right) leg extended beyond the pressure map. The pressure map shows the interface between the lateral side of the left foot and the bed.

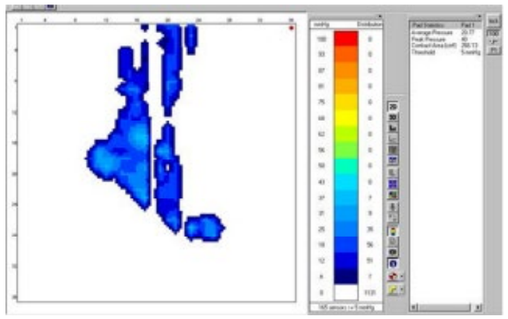


Figure 10 Side lying pressure,with **HeelSafe**, 10mmHg valve

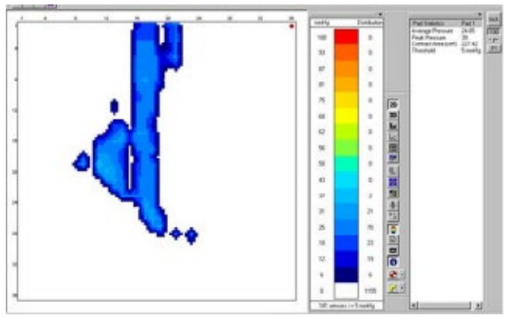


Figure 11 Side lying pressure,with **HeelSafe**, 20mmHg valve

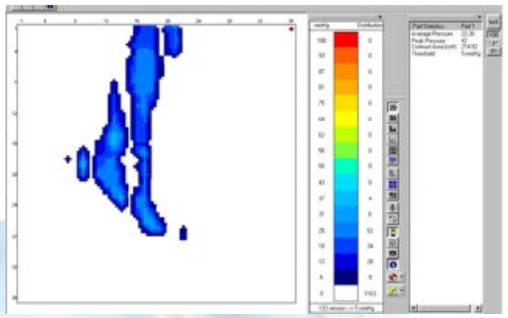


Figure 12 Side lying pressure,with **HeelSafe**, 30mmHg valve

Also in the side-lying position, the mid-range valve appears to be the optimum setting. The interface pressure seems to be remarkably insensitive to inflation pressure, although it can be seen that there is greater contact area at lower pressure.

Surface comparison: Softform Premier, Domestic mattress (Sealy Pearl Contour), Softform with **HeelSafe**.

Figures 13-15 show the 60kg articulated phantom respectively on the domestic mattress, the Softform Premier, and the Softform Premier with **HeelSafe** in the optimal setting of 2ommHg inflation. It can be seen that the lowest peak pressures occur on the **HeelSafe**. This appears to be due to increased contact area, with an almost continuous contact along the Achilles tendon area.

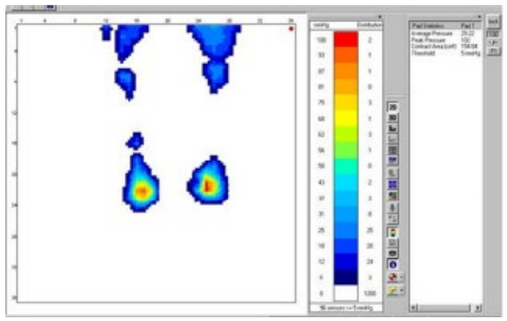


Figure 13 Peak interface pressure, 60kg phantom domestic mattress

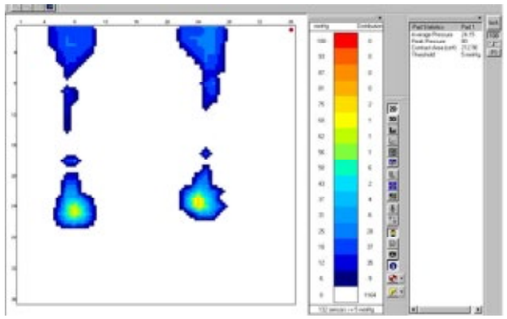


Figure 14 Peak interface pressure, 60kg phantom Softform Premier mattress

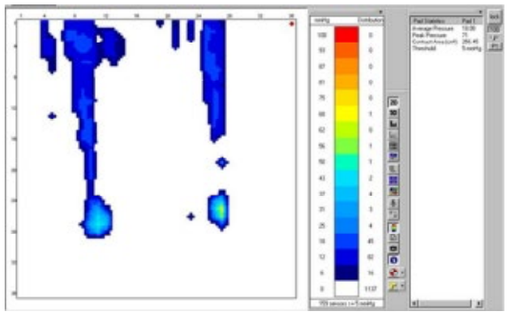


Figure 15 Peak interface pressure, 60kg phantom Heelsafe

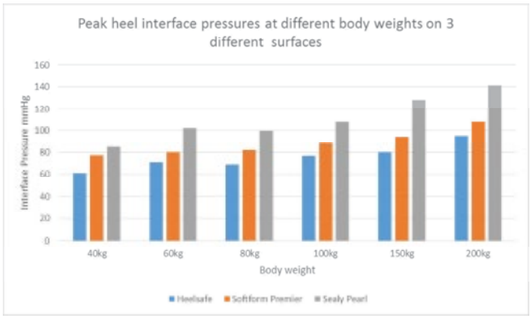
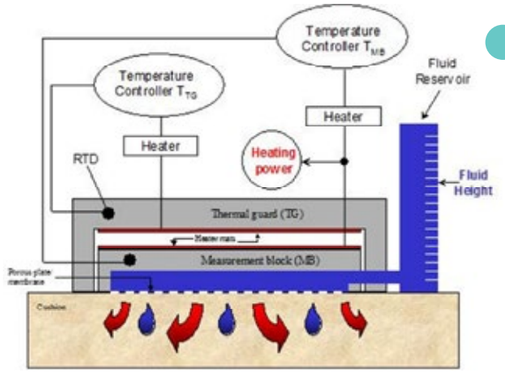


Figure 16 Figure 16 summarises the results at different modelled body weights. It can be seen that in every case the peak pressure was lowest on the **HeelSafe** compared to the other 2 surfaces.

Microclimate

The ability of a surface to dissipate body heat and moisture makes an important contribution to comfort. Excessively moist conditions at the skin/mattress interface are also known to macerate the skin, exacerbating the risk of mechanical damage to the skin.



Heat and water vapour transfer test rig schematic.

Tests were done in a controlled environment testing facility with a thermalguarded sweating hot-plate 3. This permits accurate measurements to be made of both heat transfer rates and water-vapour transfer rates through the product.

The hot-plate is maintained at constant temperature and humidity at the interface to the mattress, and losses of heat and water vapour into the mattress are electronically monitored simultaneously.

Test Heat/Vapour permeability with or without cover.

Conclusions

HeelSafe provides effective reduction in heel pressure across all body weights tested, relative to both a Softform Premier mattress and a Sealy Pearl Contour mattress.

Optimum inflation pressure appears to be the mid setting (20mm Hg) of the 3 valves provided, and this seems to be the case across all body weights. This favours a simple approach to inflation, whereby patient weight need not be considered prior to inflating the product.
Heat and water vapour transfer rates through the product are within expected norms, and no adverse effect on skin microclimate are foreseen, compared to existing pressure reducing mattresses.

Evaluation of Prolevo Solesafe Bed End Pressure Redistribution Pad

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Introduction

This report evaluates the performance of the **Prolevo SoleSafe Bed End Pressure Relief Pad**, which is an inflatable pad for placing under the plantar surfaces of the foot, between the foot and the bed base.

Aims

To map the interface pressure between the sole of the foot and the bed foot board, with and without the **SoleSafe** at 2 different pressure set-points.

Methods

A pressure mapping array (Xsensor) is used to measure the interface pressure distribution under the sole of the foot.

The subject was a 71 year female, 62kg, 1.67m. This pressure distribution is measured 10 times to establish a 95% confidence interval for the peak value.

Results

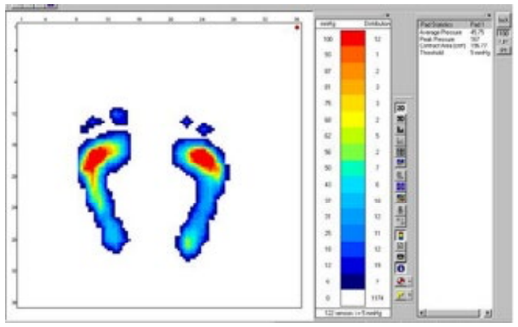

Figure 1 Plantar pressure on bare foot board

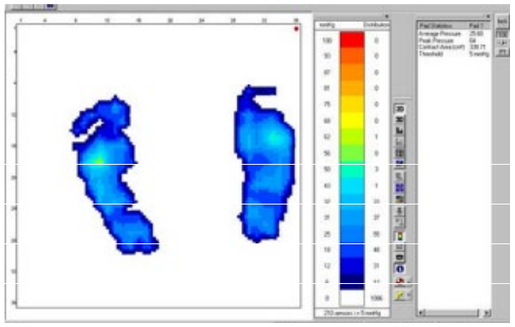

Figure 2 Plantar pressure on foot board with **SoleSafe** at 10mmHg

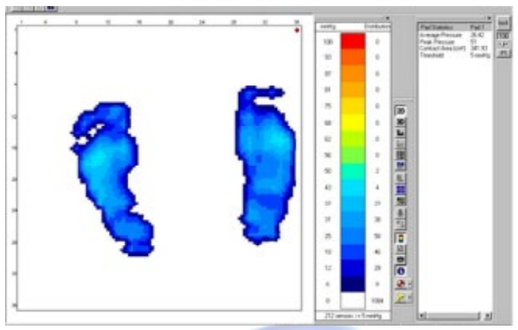

Figure 3 Plantar pressure on foot board With **SoleSafe** at 20mmHg

Figures 1-3 show the pressure distributions of the 3 different comparator conditions.

It can be seen that the lowest peak pressure in these instances occurs with the **SoleSafe** inflated to 20mmHg.

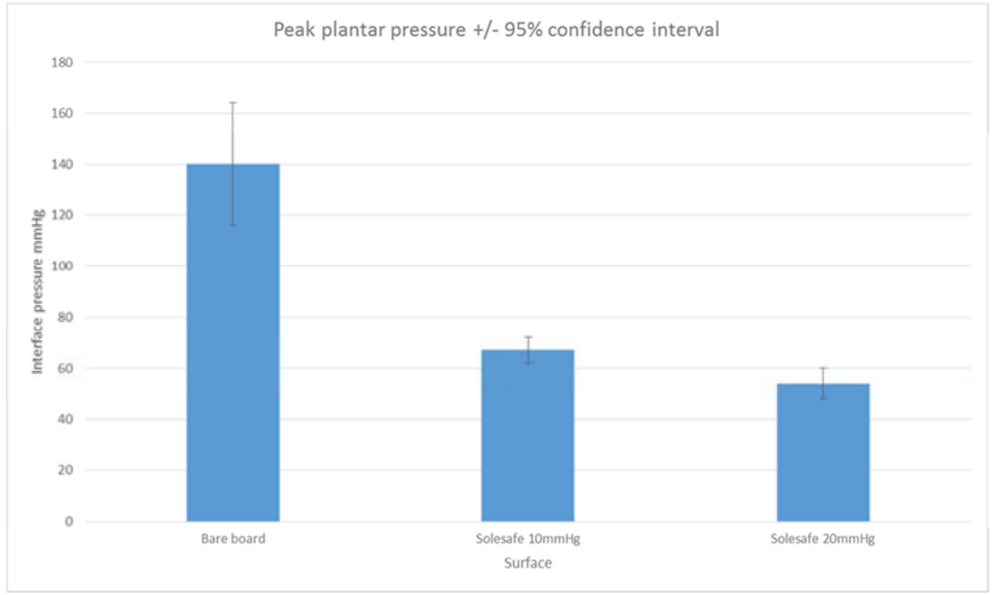

Figure 4 Summated results after 10 repeats, showing 95% confidence intervals.

Figure 4 shows the mean and 95% confidence interval range of ten repeated measures on each surface. Clearly, the peak pressures are consistently lower with **SoleSafe** than without. It also appears that the 20mmHg setting is more effective than the 10mmHg setting.

Conclusions

It appears that substantial interface pressures are encountered between the sole of the foot and the foot board of the bed. In this evaluation, the subject was regularly arranged in a supine position, and laid straight with respect to the orientation of the bed.
It might be anticipated that in less regular lying positions other parts of the foot might come into contact with the foot board, and these parts may be less able to withstand pressure than the sole of the foot.

Measurements of the pressure distribution reveal that the **SoleSafe** product, especially when set to 20mmHg inflation pressure, significantly reduces the peak pressures.

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