

Novel Clear Sacral Dressing to Address Microclimate, Peak Pressure, and Skin Checks

Martha Roman, B.S., Brenda Curtis, Ph.D., Jessica Campbell, B.S., Anthony Frei, Ph.D., and Laura Giesey, Ph.D.

Medline Industries, LP, Northfield, IL USA

INTRODUCTION

Pressure injuries occur from a variety of factors, such as the amount and duration of pressure, shear and frictional forces, microclimate, and overall patient health. Rotating/ re-positioning at-risk (bedridden or minimally mobile) patients can reduce the likelihood of pressure injury development. The NPAIP recommends dressings for prophylactic use that have the following properties¹:

- Ability to manage the microclimate
- Ease of application and removal
- Ability to maintain the dressing in situ
- Ability to regularly assess the skin under the dressing
- Potential benefit of using a dressing

Multi-layered foam dressings provide more insulation, potentially trapping heat up against the body. They are also opaque which requires removal of the dressing to inspect the sacral area for skin checks. The goal of this study was to evaluate microclimate management, peak pressure, and ease of skin checks using a novel clear sacral dressing.

METHODS

Thermal Trapping

Each dressing was applied to the skin substitute (heated by a hot plate set to body temperature, (37°C)) allowed to stabilize at temperature for 5 minutes then the dressing was removed. The temperature of the skin substitute was monitored over time using a thermal gun camera.

Peak Pressure Mapping

A 2.1 kg weight, with a 4-inch diameter spherical contact surface, was used to mimic a bony prominence. The weight was then placed on top of the adhesive side of the dressing (facing up), and pressure distribution data was collected by a surface pressure mapping system over approximately 5 minutes.

Translucency Testing

Simulated bruises on a skin explant from an African American subject were created by applying a combination of methylene blue and safranin dyes to 9 test sites. Images were obtained with and without dressing application using a scanner and analyzed for signal intensity using Image-Pro software. There was no manipulation of raw images, including enhancements or auto coloration.

STATISTICAL ANALYSES

Thermal Trapping

At all time points, independent sample t-tests with Tukey-HSD correction for multiple comparisons for both mean and temperature change over time were performed (n=10).

Peak Pressure Mapping

The peak pressure was monitored and averaged over 5 minutes then the difference between dressing and control were calculated.

Translucency Testing

Paired sample t-test comparisons were performed. *Intensity Max data points were not normally distributed. The median and mean values were nearly identical and the non-parametric equivalent Wilcoxon rank test was also significant at p=0.03 (n= 9 per group).

Table 1: Test Articles

Product	Composition	Prophylactic Usage
Dressing 1	Transparent HydroCore™ sacral dressing with waterproof backing and silicone adhesive	• Designed to be used as part of a pressure injury prevention protocol and is ideal to reduce pressure over intact skin to help maintain the skin integrity.
Dressing 2	5 layer foam sacral dressing with waterproof backing and silicone adhesive	• May be used as part of a prophylactic therapy to help prevent skin damage, e/g/ pressure ulcers, postoperative blistering
Dressing 3	5 layer foam sacral dressing with shower proof backing and silicone adhesive	• Pressure ulcer prevention on intact skin as part of a pressure ulcer prevention protocol

Figure 1

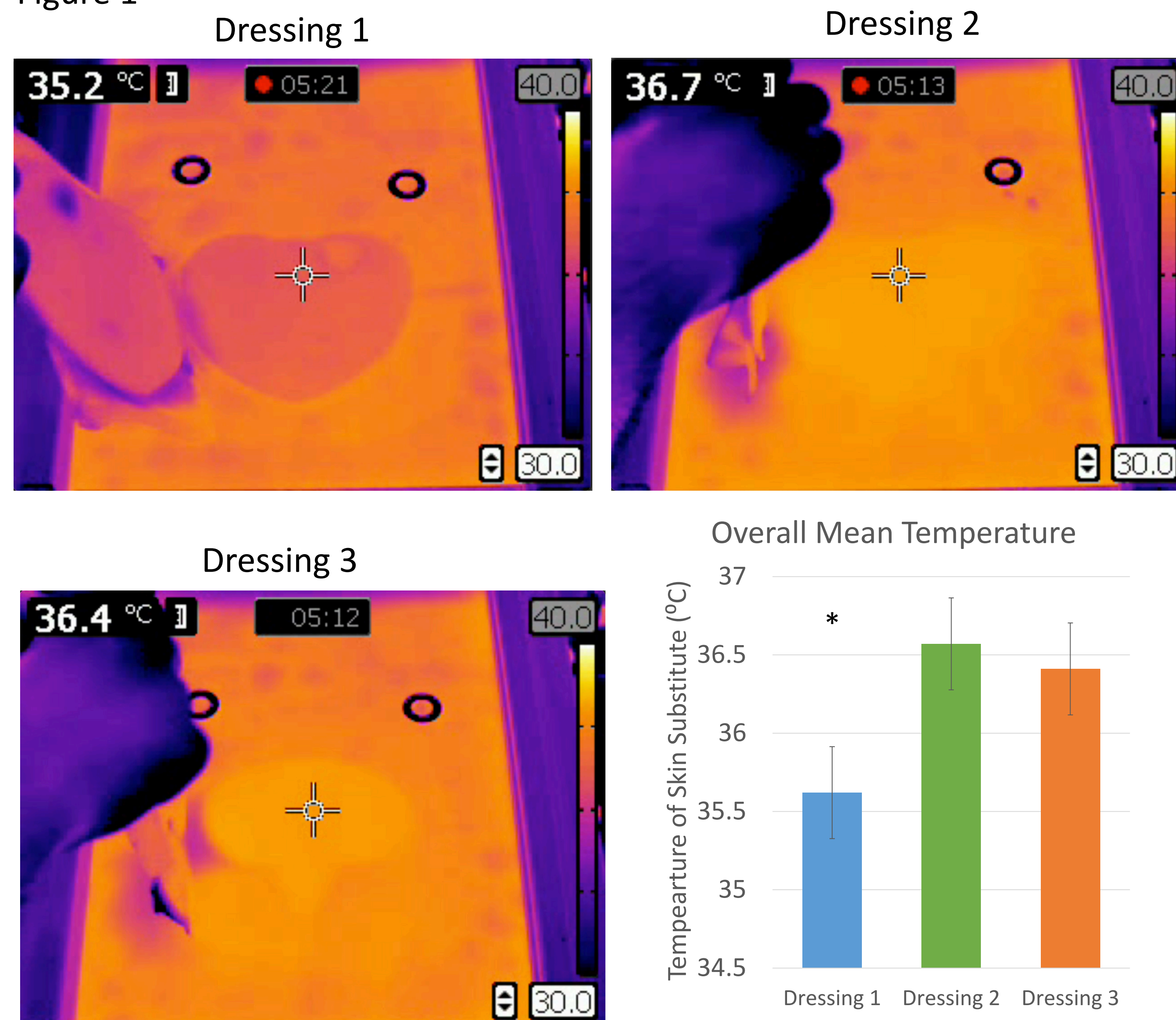


Figure 1: Each dressing was applied to heated skin substitute and then the temperature was monitored. Above images show the heat index of the skin substitute after application. Below graph shows the temperature readings over time after application. Data are presented as the mean ± standard deviation. *Dressing 1 has p<0.05 compared to Dressing 2 and Dressing 3.

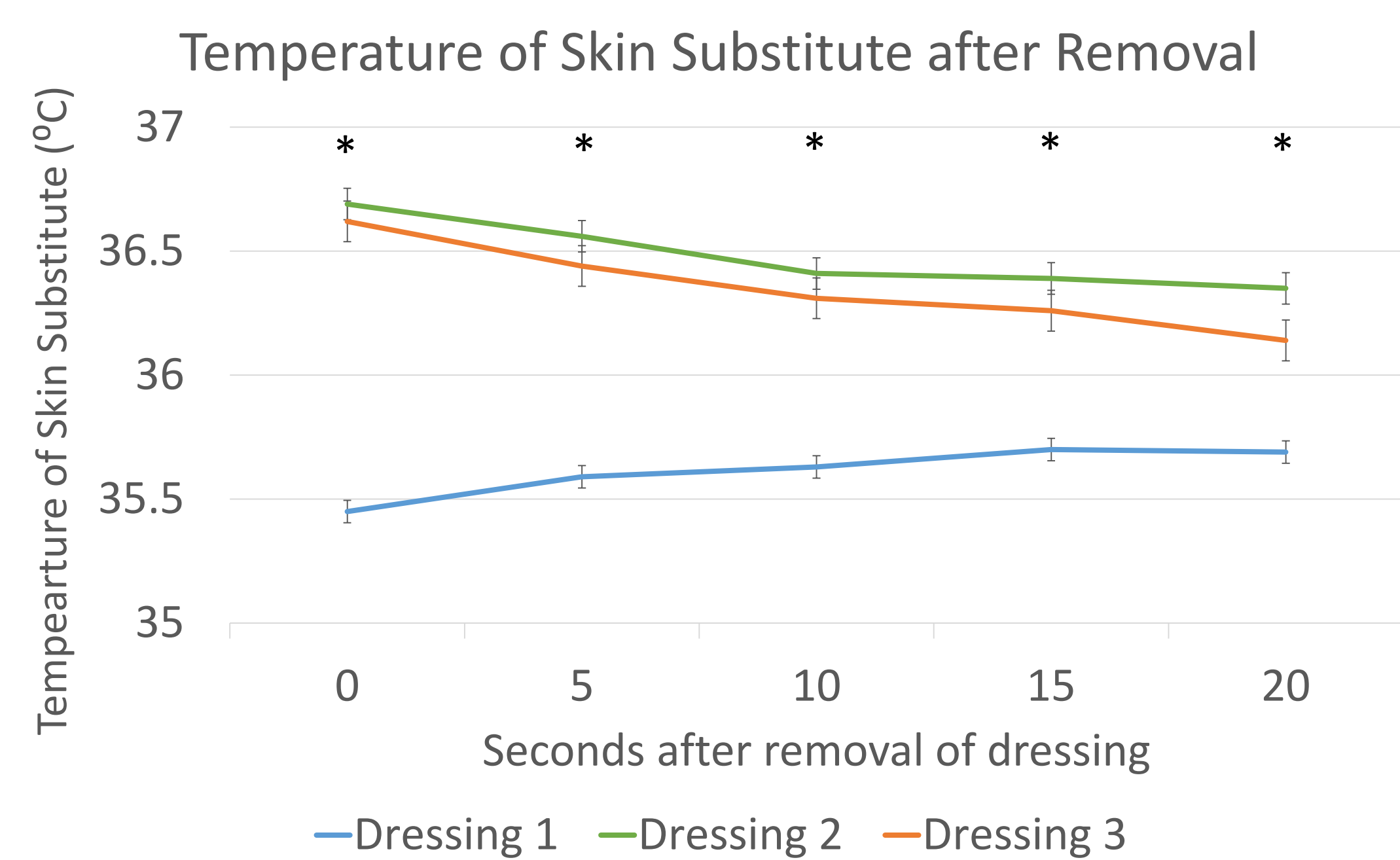


Figure 2

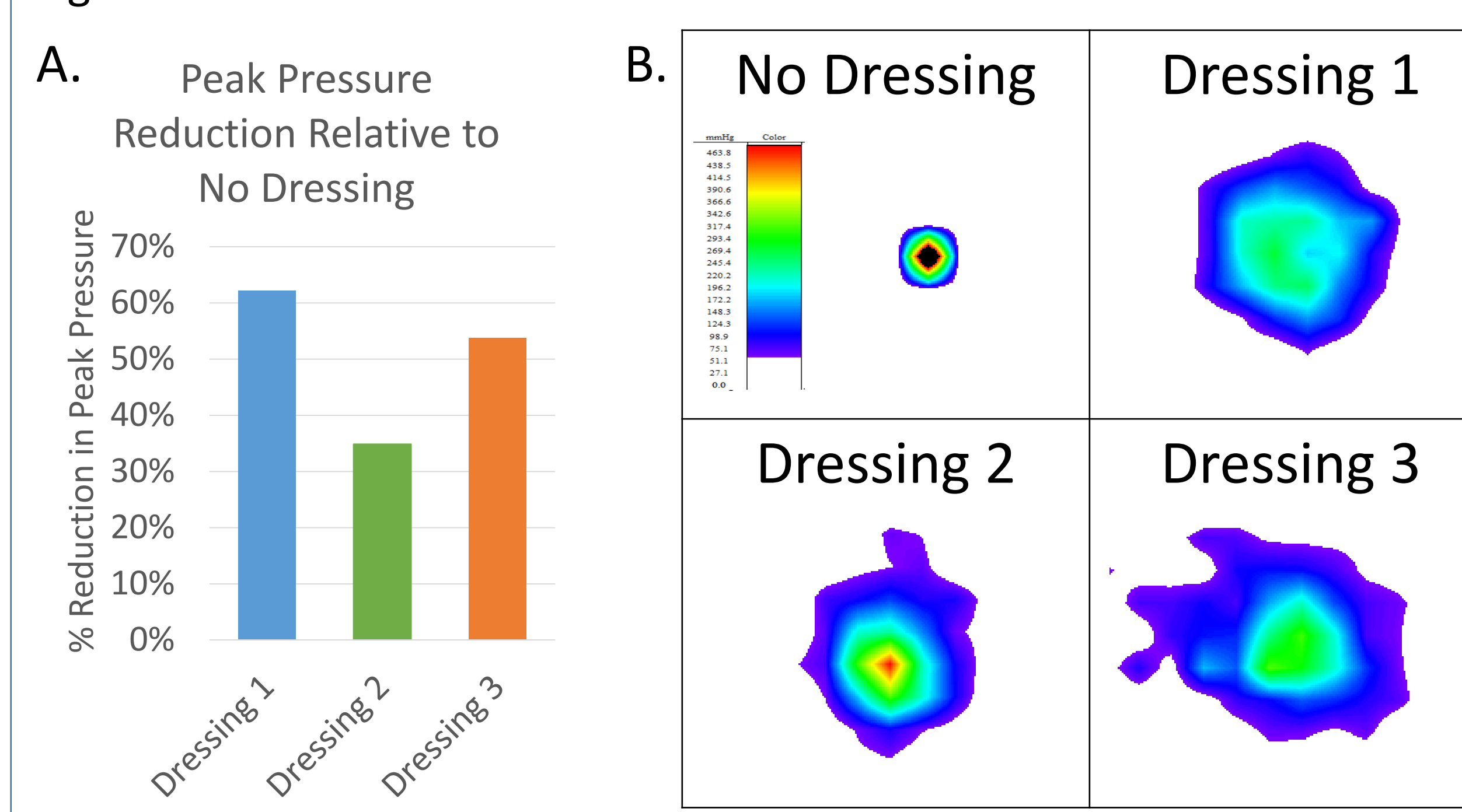


Figure 2: In this *in vitro* test method, a 4 inch diameter spherical contact surface was used to mimic anatomical features. Peak pressure was monitored for 5 minutes and then averaged. Dressings were compared to no dressing peak pressure. A) Shows the reduction in peak pressure with each dressing compared to no dressing. B) Shows the pressure map for each dressing over the 5 minute period of testing. Red indicates higher pressure while blue/purple indicates lower pressure readings.

Figure 3

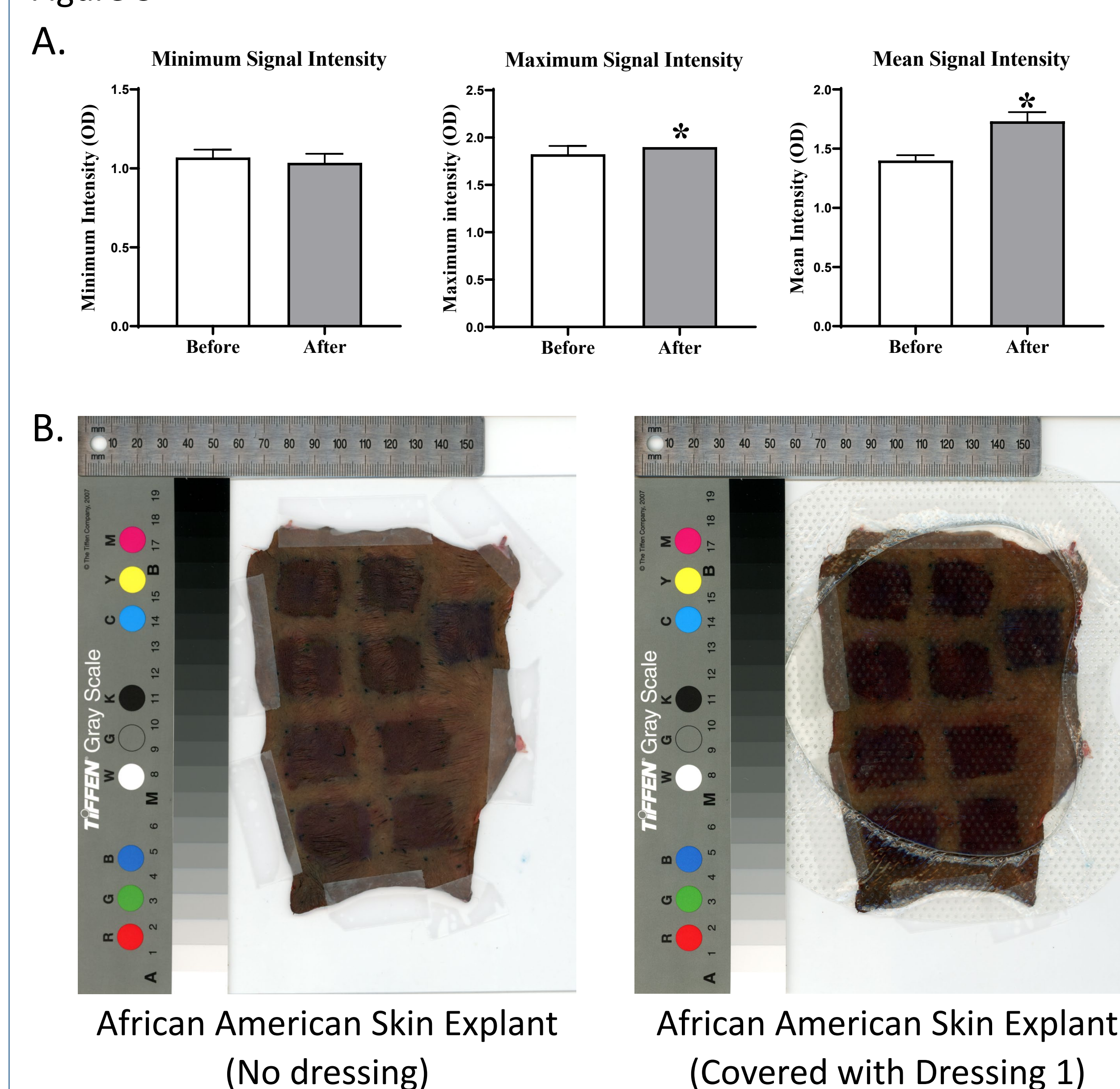


Figure 3: A) Signal intensity graphs of greyscale-converted images before and after dressing application. *p<0.05 compared to no dressing. B) Left: Image of the human skin explant with simulated bruising. Right: Image of the human skin explant with simulated bruising covered with the transparent HydroCore™ dressing.

RESULTS

Thermal Trapping

Dressing 1 had significantly lower thermal heat trapped as shown by the thermal camera. Dressing 2 and Dressing 3 had equivalent thermal readings of the skin substitute after removal of the dressing.

Peak Pressure Mapping

Dressing 1 had the highest peak pressure reduction between all the dressings. All three dressings reduce peak pressure: Dressing 1 reduces peak pressure by 62%, Dressing 2 by 35% and Dressing 3 by 54%.

Translucency Testing

Ex vivo testing of human skin explants showed Dressing 1 application significantly enhanced the maximum and average (+23.6%) signal intensities associated with simulated bruising. Dressing 1 in no way impeded detection of color intensity changes beneath the dressing.

CONCLUSION

This set of experiments show that Dressing 1 meets multiple clinically valuable needs:

- Dressing 1 manages microclimate by helping to maintain a lower skin temperature by easily transmitting heat away from the simulated sacral model.
- Dressing 1 reduced peak pressure by 62% compared to no dressing in a lab test.
- Dressing 1 enhanced the ability of the camera to detect the simulated bruising on a skin explant from an African American subject.

Further testing on other aspects that affect pressure injuries are needed.

REFERENCES

1. European Pressure Ulcer Advisory Panel, National Pressure Injury Advisory Panel and Pan Pacific Pressure Injury Alliance. Prevention and Treatment of Pressure Ulcers/Injuries: Clinical Practice Guidelines. The International Guideline. Emily Haesler (Ed.). EPUAP/NPEIP/PPPIA: 2019.

PROPRIETARY INFORMATION

Dressing 1: Optiview™, Medline Industries, LP, Northfield, USA
 Dressing 2: Mepilex Border Sacrum, Molnlycke, Inc., Gothenburg, Sweden
 Dressing 3: Allevyn Life Border Sacrum, Smith & Nephew Medical Limited, Hull, England