

Introduction

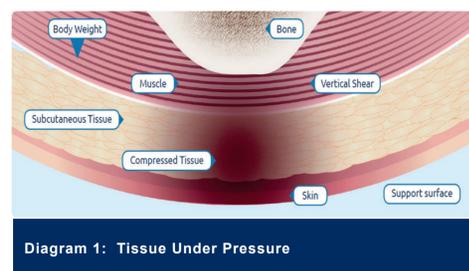
Pressure injury is a common chronic wound defined as "localised injury to the skin and/or underlying tissue usually over a bony prominence, as a result of pressure, or pressure in combination with shear". Pressure injuries can be distressing and may compromise many areas of the patient's life, and are an increasing burden on the healthcare system¹. In the United States, annual pressure injury treatment costs are estimated to be \$11 billion².

The causes of pressure injuries are complex. Extrinsic factors such as pressure, shear, friction and microclimate may all contribute to pressure injury occurrence³.

Pressure injury prevention focuses on reducing the impact of these extrinsic factors. Intelligently designed dressings are able to reduce pressure, friction and shear, and are able to manage moisture to address the microclimate. International guidelines state that clinicians should consider applying multi-layered silicone foam dressings prophylactically over bony prominences and this is supported by clinical evidence^{4,5}.

Advanced Medical Solutions Limited (AMS) has developed a silicone foam* wound dressing, which is indicated for use on moderate to heavily exuding chronic and acute wounds. It may be used as part of a prophylactic therapy for pressure injury prevention.

In order to demonstrate the product's ability to be an effective pressure injury prevention device, *in vitro* tests were performed against each of the above extrinsic factors.



Pressure

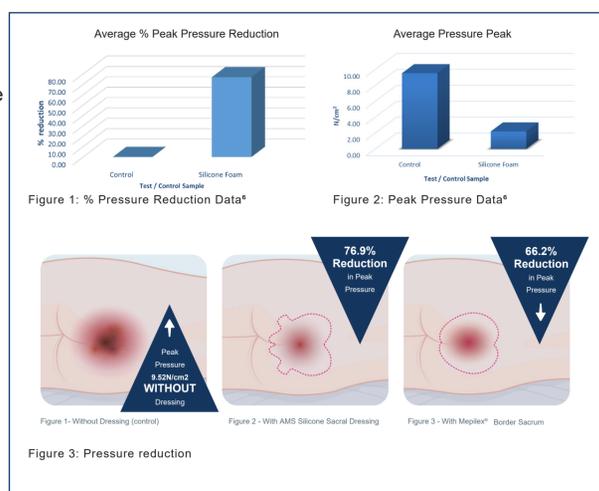
Pressure was assessed using a pressure sensing mat to visually (Figure 3) and quantitatively (Figures 1+2 and Table 1) monitor the pressure profile of a mass when applied directly onto the mat as a control measurement, and onto the dressing.

A 300g steel ball is used, which is representative of a bony prominence when applied directly on the pressure sensing mat.

The test measured the pressure of the steel ball directly onto the pressure sensing mat (control), and the pressure of the steel ball when the silicone foam dressing is applied between the ball and the pressure mat as a pressure deflection layer.

	Average Control	Average Silicone Foam
Peak Pressure (N/cm ²)	9.52	2.2
% Peak Pressure reduction	N/A	76.9%

Table 1: Peak Pressure and Peak Pressure reduction*



References
*Silicone foam - Silicone trilaminar foam border dressing
1. A patient-reported pressure ulcer health-related quality of life instrument for use in prevention trials (PU-QOL-P): psychometric evaluation. Claudia Rutherford et al Health and Quality of Life Outcomes volume 16, Article number: 227 (2018)
2. Lawrence, P., Fulbrook, P. and Miles, S., 2015. A survey of Australian nurses' knowledge of pressure injury/pressure ulcer management. Journal of Wound, Ostomy and Continence Nursing, 42(5), pp.450-460
3. World Union of Wound Healing Societies (WUWHS) Consensus Document. Role of dressings in pressure ulcer prevention. Wounds International, 2016
4. Prevention and treatment of Pressure Ulcer/Injuries: Clinical Practice Guideline, The International Guideline (2019)
5. NICE medical technology scope: Mepilex Border Heel and Sacrum dressings for preventing pressure ulcers (2018)
6. Data on File: P3844R, LD092-17, LD123-17, 6
7. AMS Data on File: LD127-17 and P3844R V1

Moisture Vapour Transmission Rate (MVTR)

MVTR is a measure of the total amount of fluid lost through the film of the dressing, allowing the wound to breathe.

Testing was performed in accordance with the standard procedure BS EN ISO 13726-1:2002 which assesses the fluid handling capacity of waterproof wound dressings under controlled conditions of temperature and humidity (Figure 4).

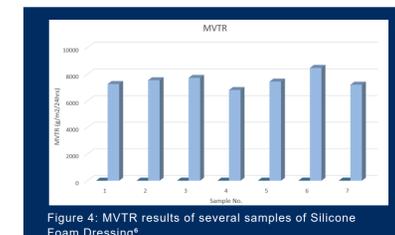


Figure 4: MVTR results of several samples of Silicone Foam Dressing*

Microclimate

The results suggest that AMS silicone foam and Mepilex® Border Sacrum can manage fluids effectively, and a comparison between the two dressings shows there is no significant difference between them. MVTR data suggests that AMS silicone foam allows for the evaporation of moisture away from the skin's surface.

	AMS Silicone Foam	Mepilex® Border Sacrum
MVTR (TFH)	9150 g/10m ² /24hr	10718 g/10m ² /24hr
MVTR Vapour in contact	1306 g/10m ² /24hr	1659 g/10m ² /24hr



Friction and Shear

Coefficient of Friction method:

For this test a sample of the dressing is wrapped around a metal plate and clamped in place with the surface to be tested on the outside of the plate. The test rig is set up on a Zwick tensometer, and a piece of non-extensible string links the metal plate with the dressing around a pulley system that attaches to the upper jaw. There is to be no tension in the string. Once the tensometer is started, the machine will pull the plate with the dressing along a plate which is covered in bedding cloth and the force required to move the plate is recorded (Figure 5).

The data generated suggests that AMS Silicone Foam and Mepilex® Border Sacrum are comparable, 0.47N ± 0.02 and 0.46N ± 0.15 respectively. There is no significant difference in the coefficient of friction values of the AMS dressings vs the competitor dressing.

Shear:

Shear may result from the application of a tangential force, i.e. a force that is parallel to the surface of the skin. When there is a high level of friction between the skin and a support surface and a tangential force occurs, the skin will tend to stay in place against the support surface while the layers of underlying tissues are deformed as they move with the patient.

Shear was measured using a pressure mat, whereby the test dressing was adhered to a slope at an angle; the pressure mat was applied over the top and a circular weight equivalent to 40mmHg was applied and measurements were taken after a 2 minute dwell time (Figure 6).

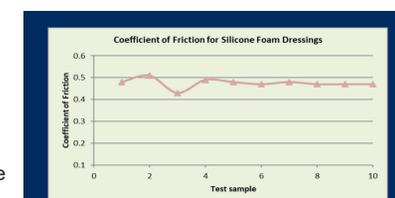


Figure 5: Coefficient of Friction Results*

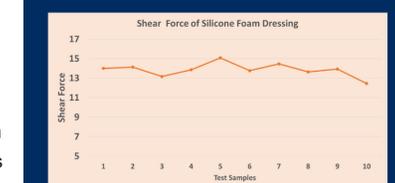


Figure 6: Shear Data*

The results indicate that AMS silicone foam limits the amount of shear force experienced when compared to Mepilex® Border Sacrum. This comparable data suggests that AMS silicone foam has a similar performance to that observed with Mepilex® Border Sacrum, a device which is indicated for pressure injury prevention.

	AMS Silicone Foam	Mepilex® Border Sacrum
Max Shear Force	Mean 26.27mmHg SD 4.98	Mean 29.18mmHg SD 5.14

Discussion and Conclusion

MVTR: The data demonstrates the product has excellent fluid handling properties which is an important factor in pressure injury prevention, as high moisture levels can contribute significantly to shear and increase the likelihood of tissue damage.

Pressure: The pressure mapping results demonstrate that a significant reduction of pressure is achieved when the AMS silicone foam dressing is applied, compared to the data obtained from the control. This is further observed in the pressure profile images (Figure 3).

Friction and Shear: The mechanisms of friction and shear often work together in the creation of pressure injuries. Therefore, examining both these properties is essential to determining the capabilities of the device. The results obtained indicate the dressing assists in reducing the degree of friction and shear exerted thus minimising tissue deformation.

Each of the tests performed assesses individual contributing factors to the development of pressure injury and results indicate the dressing reduces the level and intensity of these extrinsic factors.

Throughout these tests **AMS silicone foam** has demonstrated its ability to be fundamental in the prevention of factors linked to the cause of pressure injury.

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