A new silicone foam dressing* fit for pressure injury prevention and wound treatment with strong in vitro performance

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Introduction

Dressings' original purpose is to ensure an optimal wound healing environment by absorbing exudate in a way that keeps the wound moist.[1] In recent years, silicone foam dressings have become an integral part of standard protocols for prevention of pressure injuries in patients at risk by contributing to redistributing pressure, reducing friction and shear and enhancing microclimate control.[2,3,4]

When used for wound treatment, dressings should effectively manage exudate while providing moist wound healing conditions.[1] As many wounds are characterized by an irregular wound bed, it is also important that dressings match the shape and depth of the wound bed to avoid pooling of exudate in the cavity which can lead to maceration, infection and delayed healing.[5]

A new five-layer silicone foam dressing* indicated for pressure injury prevention (PIP) and wound management was developed through extensive user research with more than one thousand healthcare professionals and hospital staff across the US.

The silicone foam dressing* was designed to address their clinical needs and perform highly on key parameters for PIP and wound treatment. The aim of this test series was to evaluate these important performance parameters of the new silicone foam dressing*.

Methods

Pressure injury prevention key parameters

Pressure redistribution: the pressure redistribution performance was determined by performing Interface Pressure Mapping (IPM) using a pressure sensor type 5051 from Tekscan™. The samples were placed on the pressure sensor with the top film side downwards facing the pressure sensor (silicone adhesive upwards). A predefined compression load was applied to the dressing, and the pressure sensor recorded the force distribution. Data analysis of the recorded force distributions results in the evaluation of pressure redistribution performance with two parameters; peak pressure and coefficient of variation (COV). The peak pressure is an indicator of the maximum pressure, and the COV is an indicator of how evenly the pressure is distributed.

Static and dynamic friction coefficients on whole wound care products: the friction test was performed by attaching and folding the dressings around a steel sledge. The sledge with the dressing on will then be attached to the tensile testing machine by a string.

The force required to pull the sledge with the top film side of the dressing facing a Teflon substrate is measured. The static friction is measured as the force that prevents initial motion between the top film and the Teflon substrate while the dynamic friction is the force measured when the object is already in motion.

Peel adhesion: was evaluated by determining the force needed to remove the adhesive border part of the dressings in a 180° pull angle from the steel plate. The test is repeated 5 times to achieve a total of 6 measurements. (initial adhesion and adhesion after 5 reapplications)

Waterproofness: dressings were tested for waterproofness according to the method described in EN 13726-3, Test methods for primary wounds dressings – Part 3: Waterproofness.[6] Testing was performed at the external lab Danish Technological Institute.

Wound treatment key parameters

24h fluid handling: dressings were tested for fluid handling capacity according to the method described in EN 13726-1, Test methods for primary wounds dressings – Part 1: Aspects of absorbency, section 3.3.[7] Five samples of each dressing were tested. Testing was performed at the external lab Surgical Materials Testing Laboratory (SMTL).

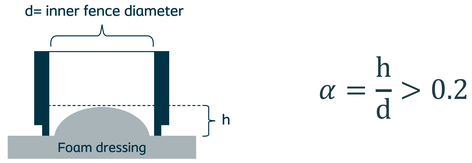
Retention: Retention capacity was tested according to Annex C of the updated EN 13726.[8] The method quantifies the dressing's ability to retain test fluid after being pressurised for one minute at 40 mmHg in fully wetted condition. The retention was determined by weighing the sample and comparing the pressed weight with the dry weight of the sample and the result given as g/cm2.

Relative swelling rise: The test quantifies the conformability of a wound dressing to the wound bed by measuring the bubble height of foam products after swelling. The dressing's ability to form a bubble is inferred to demonstrate the conformability capacity of the dressing – into e.g. a wound cavity – by expanding swelling property. The conformability is reported as the bubble height relative to a circular diameter.

Initially the thickness of the dressing at the absorbing area of the dressing is measured. Hereafter, a specific amount of fluid is applied to the absorbing surface. The amount is defined by percentage of maximum absorption capacity of the tested dressing.

To avoid the fluid spreading around the surface of the dressing, test fences with specific diameters are used to control the fluid.

When all the fluid is absorbed into the dressing, the fence is removed, and the height of the dressing is measured. Based on the initially measured thickness, the height of the dressing after fluid absorption and the specific diameter of the fence, the relative swelling rise can be determined.



$$\alpha = \frac{h}{d} > 0.2$$

Figure 1: measured entities for relative swelling rise

Results

Pressure redistribution (Pa/N) - n=29	Peak pressure 38,36 +/- 3,73	Coefficient of Variation 2,84+/-0,15
Friction absorption n=29	Static Friction Coefficient 0,23 +/- 0,04	Dynamic Friction Coefficient 0,21+/-0,04
Microclimate	n=5	24h fluid handling capacity (g/10cm2) 30.2 +/- 1.1
	n=3	Waterproofness - pass
Peel adhesion and reapplication (N/25mm) - n=44	Peel adhesion no.1: 2.4 - no.2: 1.52 - no.3: 1.44 - no.4: 1.39 - no.5: 1.35 - no.6: 1.28	
Shear	Reduction of shear forces is provided through good adhesion to the skin, high loft and lateral movement of the dressing layers[2]	

The new silicone foam dressing* is designed with a special polyurethane foam that upon contact with exudate expands to match the shape and depth of the wound.

To quantify wound bed conformability, we measure how the dressing increases in height upon fluid absorption relative to the width or diameter of the wound. This relationship between height and diameter is defined as alpha value (α)= h/d and must be >0.2 for a wound bed conforming dressing.

The new silicone foam dressing* demonstrated a mean α value of 0.38 with a fence size of 60mm, and mean bubble height of 23mm.**

Exudate absorbed vertically through microcapillaries in the foam is retained inside the dressing, even under compression, reducing the risk of leakage and maceration. (mean retention capacity: 1.3 g/cm3)

Conclusion

These results show that the new five-layer silicone foam dressing* has strong in vitro performance on key parameters for PIP and wound treatment. With its special foam layer, it will match the shape and depth of a wound bed up to 2 cm** deep, leaving minimal dead space where exudate can pool.

The new dressing is developed in a full portfolio of 12 different sizes and shapes indicated for both pressure injury prevention and wound treatment, meeting the demands of acute care settings.

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*Biatain® Silicone Fit (Coloplast) ** Coloplast data on file 2023. Conformability may vary across product design

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