An investigation into the conformability of wound dressings

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Abstract

Aims: Flexibility and conformability are key performance characteristics in dressing design and construction, which can have an impact on product suitability in the clinical environment. This study evaluated both quantitatively and qualitatively the conformability and comfort of a variety of wound dressings (Biatain® Soft/Ag/Non-adhesive (Coloplast), Allevyn® Gentle (Smith and Nephew), Mepilex®/Mepilex® Ag, Mölnlycke Health Care) using established laboratory-based methods. These were supported by a healthy volunteer study of Mepilex Border and Allevyn Gentle Border. *Results: In vitro*, Mepilex was found to be more conformable and able to mould to smaller radii than the other products tested. The volunteer study supported this finding and showed that Mepilex Border dressings were more comfortable and conformable than the comparator (Allevyn Gentle Border). Statistical analysis was not possible as more than 50% of the comparator products did not remain *in situ* over the study period. *Conclusions:* Mepilex and Mepilex Border were shown to achieve higher levels of conformability and comfort in the laboratory tests and volunteer studies respectively. This is an important feature in clinical use. *Conflict of interest:* This manuscript was supported by an educational grant from Mölnlycke Health Care, Gothenburg, Sweden.

KEY WORDS

Conformability
Flexibility
Body contours
Anatomical radii

Wounds appear on all aspects of the body. This fact, in itself, provides a challenge to healthcare professionals, as most dressings tend to be provided in the same almost two-dimensional format of a square, round or oblong sheet, not necessarily lending themselves to application to the multiple contours of the body. The conformability and flexibility of modern dressings is therefore a key element in their clinical usefulness. If dressings are not able to be flexible and conform, they may not be able to be applied to a wound/body area, or they may quickly detach, thus becoming ineffective. Conformability is an important aspect to measure, quantify and compare between dressings in order that healthcare professionals can identify dressings which best suit the needs of the wound and the patient.

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The conformability of wound dressings is a property that is often overlooked, despite being important both for patient comfort and wound management. Having a chronic or even an acute wound is discomfort enough for a patient, and so the conformability of a dressing that behaves as a second skin is desirable. There are many factors that influence the way a dressing conforms to a patient, i.e:

- Level of adhesion
- Isometric elasticity of the dressing
- Dressing thickness
- Shape of wound site
- Quantity of exudate held within the dressing.

In the context of a wound dressing, 'conformability' means that it should follow the contours of the surface of the wound, or the surrounding skin in such a way that there is close apposition of the interface of the dressing to the tissues.

This is important for a number of reasons, namely:

- Helps to maintain a moist wound environment at the interface of the dressing and the wound (Mouës et al, 2009)
- Avoids dead space where wound fluid and bacteria can accumulate to the detriment of healing and may promote infection (Sibbald et al, 2000)
- Prevents leakage of wound exudate onto surrounding skin or into the external environment, thereby reducing the risk of maceration (Adderly, 2010)

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- Allows greater patient mobility, especially in areas where movement is required, e.g. over joints (Tustanowski, 2009) — flexibility being, in the authors' opinion, one of the components of conformability
- Increases comfort factor for the patient (Wasiak et al, 2008).

However, a clear distinction needs to be drawn between those products which, by their construction, only interact with the wound interface (primary contact dressings), and those which incorporate both wound interface components and periwound adherence. The former dressings require secondary products to maintain wound interface contact and to augment their wound management properties (e.g. moisture vapour transmission, bacterial barrier and wound bed protection). The latter are designed to provide optimised dressing functionality within a one-piece construct.

Conformability prevents blisters

Dressings with aggressive adhesives, be they one-piece constructions or secondary type designs that do not exhibit viscoelastic properties and are not conformable to contours and or movement, may lead to skin blistering. This is a common problem and has been thought to be due to the shear forces within the tissue at the dermal/epidermal junction (Morris, 2008). Blisters associated with dressings can be detrimental to the patient, as they delay overall healing, decrease quality of life, increase the potential for infection and costs (Gupta et al, 2002).

Assessment of dressing conformability

The difficulty in assessing the conformability of dressings during their development is making measurements that relate to body contours. This may be carried out using volunteer studies, but that, of course, is no substitute for the clinical situation. Laboratory-based *in vitro* studies that provide quantitative data allow direct comparisons between different dressings, without relying completely on subjective judgements on conformability, that are generally provided from volunteer studies and clinical trials.

Bowler et al (2010) have tested the wound bed conformability of dressing products within the confines of simulated wounds. However, here the testing of a primary wound care product (Aquacel Ag®, ConvaTec), retained with a thin hydrocolloid dressing, was compared to one-piece or purpose-built composite

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dressings (Mepilex Ag®, Mölnlycke Health Care; Allevyn® Ag Adhesive, Allevyn® Ag non-adhesive, Allevyn® Ag Gentle Border, all Smith and Nephew Healthcare). However, this was designed to investigate contact with the wound bed alone, without considering the effect of the dressing on body contour and shape. Thus, there is doubt regarding the comparability of the findings of the study relating to conformability. Little data, other than anecdotal, is generally provided by manufacturers to support statements that indicate high levels of conformability.

Few manufacturers have given laboratory evidence that provides quantitative or comparative data. In fact, the only referenced laboratory investigations of conformability of wound film dressings was undertaken by Queen at al (1987). In this study, an *in vitro* assessment technique was employed, based on an inflation technique which provides a measurement of the minimum radius of curvature which a specific dressing will adopt under pressure. An inflation pressure of 40mmHg was chosen, as this had been shown to be the maximum tolerable pressure before the occurrence of tissue breakdown (Reswick and Rogers, 1975). This radius was matched to the natural radii of the body surfaces to assess conformability. In addition to the development and validation of this technique, a number of commercially available films were assessed with respect to their conformability, and the enhancement of their conformability due to viscoelastic creep behaviour.

The study presented in this paper initially examined the *in vitro* conformability of different wound dressings using a standard methodology of surgical materials testing laboratory (SMTL) and the method developed by Queen et al (1987), which directly linked body shape to dressing performance. Additionally, the subjective results from an *in vivo* volunteer study are reported, and finally some clinical observations are made.

Materials

The materials used in the study included:

- Biatain® Soft (Coloplast Ltd)
- Biatain® Ag (Coloplast Ltd)
- Biatain® Non-Adhesive (Coloplast Ltd)
- Mepilex Ag (Mölnlycke Health Care)
- Allevyn Gentle (Smith and Nephew)
- Mepilex (Mölnlycke Health Care).

Methods

In vitro conformability

The *in vitro* methods evaluated attempted to create the distortion that occurs in the clinical situation by holding the dressing in a fixed position and applying pressure to distort the dressing. The response to that distortion then being measured. Both methods attempt to recreate the *in vivo* situation by measuring the change to distortion in all directions. These two methods were selected over another method using a universal testing machine, which is only able to test the conformability in one direction at each measurement

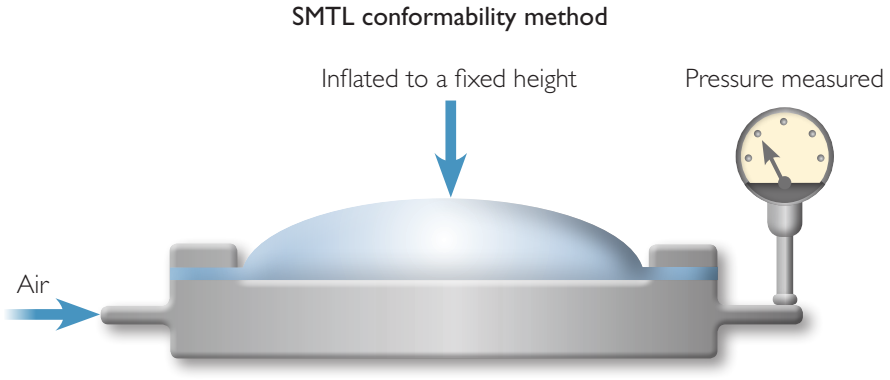

Figure 1. Diagram representing the SMTL apparatus.

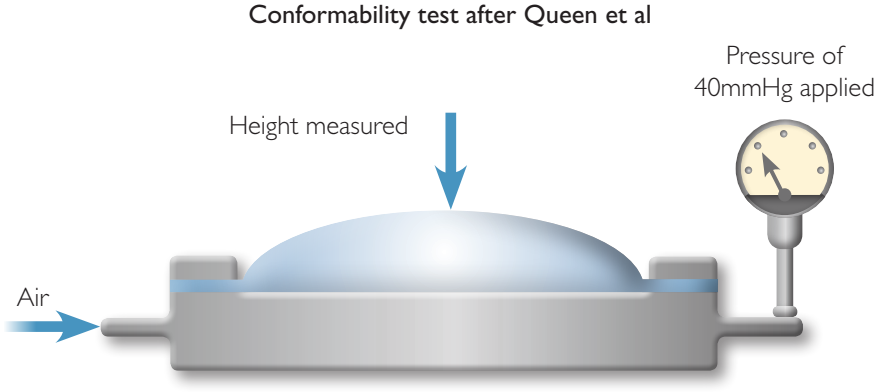

Figure 2. Diagram representing the Queen method apparatus.

(European standard EN 13726-4 Test methods for primary wound dressings - Part 4 Conformability). Therefore, each dressing is required to be tested in one direction, and then again normal (i.e. 90˚ to that direction to overcome the differences in elasticity that is often observed as a result of the manufacturing process). The difficulty, however, is to interpret both measurements and to understand how they contribute to the conformability of the dressing.

Both of the methods that evaluate the dressing simultaneously in two directions can prove problematical with island dressings, depending on the size of the island and the clamped area. These two methods are ideally suited for dressings such as films, foams and hydrocolloids that do not have islands.

Surgical Materials Testing Laboratory (SMTL) method

This test involves utilising a modification of the waterproofness apparatus (British Pharmacopoeia and British Standard EN 13726-3 referenced) to identify the pressure required to distort a dressing to a set height of 20mm (*Figure 1*).

Queen method

This methodology was developed by Queen et al (1987) and, although the dressing is pressurised in a similar manner to the SMTL method, in this case a fixed pressure is applied (40mm Hg) and the height of the distorted dressing is measured (*Figure 2*). This has a distinct advantage over the SMTL method in that as the dressing is pressurised, it creates a shape, the radius of which can be calculated and then directly related to body curvature.

The following calculation is used to convert the height (x) in cm to radius of curvature, where
D = diameter of the sample holder in cm

$$R = \frac{D^2}{8X} + \frac{X}{2}$$

Volunteer study

In addition to the *in vitro* methods, a separate volunteer study was undertaken at proDERM Institute for Applied Dermatological Research, Schenefeld, Hamburg, Germany. The aim of the study was to assess skin tolerance and cosmetic acceptance of two dressings, Mepilex® Border (Mölnlycke Health Care) versus Allevyn® Gentle Border (Smith and Nephew) (test products 7.5cm x 7.5cm). The data relating to conformability and comfort are presented in this article. In total, 22 female volunteers were tested, aged 42.5 +/- 15.4 years (mean, standard deviation).

The study was conducted in accordance with a study protocol and approximating the main principles of good clinical practice (GCP). On day 1, subjects came to the study site and were informed about the study, giving their written consent. A subjective and objective dermatological evaluation of the skin was carried out. The test products were applied by a trained

Table 1
Conformability and comfort assessment during wear

Subjective assessment	Score
Very good	2
Good	1
Neither good nor bad	0
Bad	-1
Very bad	-2

Table 2
Pressure measurements using SMTL conformability method

Dressing	Pressure/mmHg n=5 (S.D.)
Allevyn Gentle	150 (3.5)
Mepilex	88 (4.2)

Table 3
Height and radius of curvature using Queen method

Dressing	Height (mm), n=5 (S.D.)	Radius of curvature (cm)
Biatain Soft	20.25 (0.37)	4.96
Biatain Ag	14.66 (0.84)	6.19
Biatain Non-adhesive	21.59n(0.38)	4.78
Allevyn Gentle	15.14 (0.48)	6.04
Mepilex Ag	20.70 (0.46)	4.90
Mepilex	21.95 (1.23)	4.74

technician to the inner forearm, according to a randomisation scheme. While this was a flat area and thus not a challenge to conformability, the area in question was constantly moved and distorted during wear time.

On day 8, subjects came to the study site. Before removal of the dressings the technician estimated the percentage of the dressing still adhered to the skin, adherence being an important part of conformability. After removing the dressing, a subjective and objective evaluation of the skin was performed. The technician assessed the area covered with the adhesive and the dressing itself, the conformability and comfort during the application time. The assessments were scored from values of 2 to -2 according to *Table 1*.

Table 4
Natural radii of body surfaces (cm) from Queen et al, 1987

Buttocks	14.5
Head	10.2
Shoulder	7.8
Knee	5.7
Heel	5.0
Chin	4.1
Elbow	3.9
Knuckle	1.5
Finger joint	1.0

Results

Surgical Materials Testing Laboratory (SMTL) method

The results for the two dressings tested using the SMTL method are shown in *Table 2*. These show that Allevyn Gentle requires higher pressure to distort to a height of 20mm than the Mepilex dressing and, as such, is less conformable.

Queen method

Table 3 shows the heights measured for each of the dressings tested and the value when converted to radius of curvature. The radius of curvature is then able to be compared to the natural radii of body surfaces shown in *Table 4*. These results, from the *in vitro* methodology, show that Mepilex distorts to the greatest height and will conform to the smallest radius of all the dressings tested, followed by Biatain Non-adhesive, Mepilex Ag, Biatain Soft, Allevyn Gentle, and finally Biatain silver.

Volunteer study

The results presented are for comparison with the *in vitro* data, although in this instance Mepilex Border was used instead of Mepilex. The results consistently show that the Mepilex Border dressings were more conformable and comfortable than the Allevyn Gentle Border (*Figures 5* and *6*). During this study, approximately 50% of the Allevyn Gentle Border dressings were not retained in place for the period of the study (Data on file – proDERM Study Report 09.0282-11). Due to this lack of adhesion and the subsequent small sample size, a statistical analysis of the data was not undertaken.

Discussion

Modern wound dressings should follow a number of criteria. One, which is frequently quoted and often considered during clinical evaluations, is that of conformability (Thomas, 2003; Young, 2007; Vowden, 2004; Stephen-Haynes, 2011). Subjective opinions on conformability achieved from clinical studies or volunteer trials can make it difficult to spot subtle differences between dressings. However, *in vitro* laboratory methods allow definite values to be given to

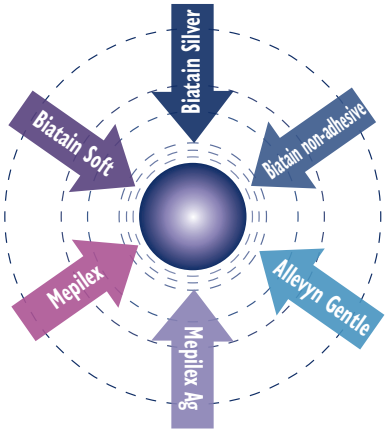

Figure 3. Diagram representing the conformability of the different dressings using the Queen method values from *Table 3*.

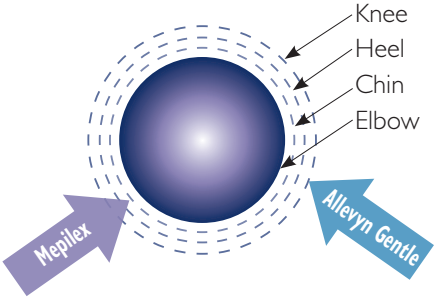

Figure 4. Diagram representing the conformability of Mepilex and Allevyn Gentle equated with experimentally derived radii of curvatures of the body.

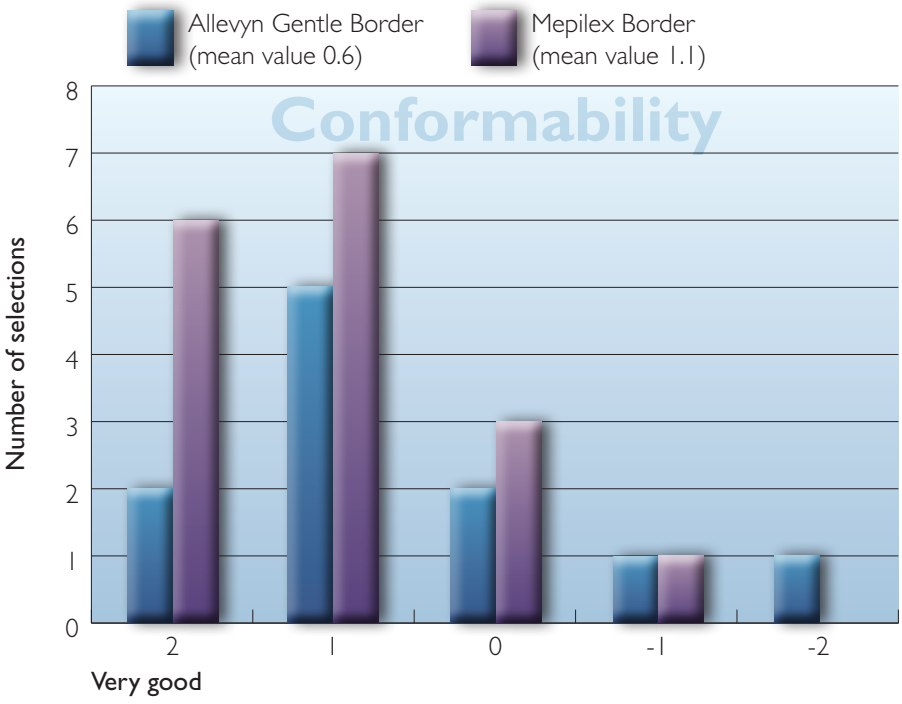

Figure 5. Scores on conformability from the volunteer study.

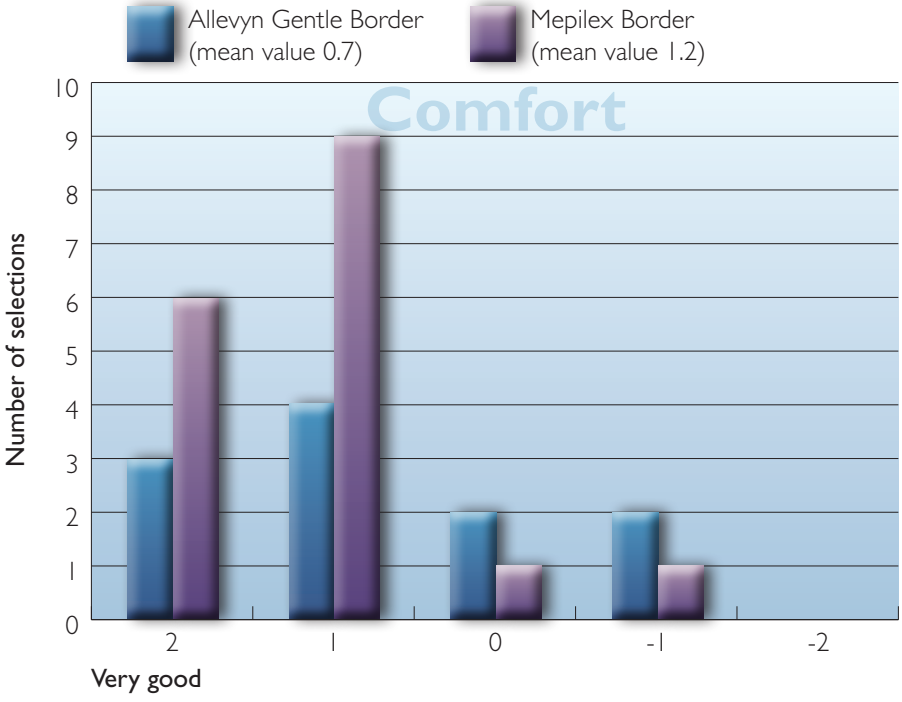

Figure 6. Scores on comfort from the volunteer study.

dressing conformability, providing more accurate dressing selection when conformability is important.

In this laboratory study, two methods were used to evaluate the conformability of dressings commonly used in the treatment of a variety of different types of wounds.

The first method is fairly simplistic in that it measures the pressure that is required to inflate a dressing to a fixed height: the lower the pressure required, the greater the flexibility/conformability of the dressing. Two dressings were evaluated, Allevyn Gentle Border versus Mepilex Border and the results showed greater conformability for the Mepilex dressing (*Table 2*), with the t-test giving $p=8.2\times10\text{-}9$.

The second method developed by Queen et al (1987) is a more complex laboratory test that allows measurement of the conformability of the dressing to be equated with experimentally derived radii of curvatures of the body. This provides a quantitative measure that allows comparisons of dressings, as well as identifying on which body surfaces they can be used, for example, on developable surfaces of fixed geometry, i.e. curvature of the torso or non-developable surfaces such as joints.

Table 3 and *Figures 3* and *4* show the results obtained using this technique. The radii of the concentric circles relate to the surfaces on which the dressings are conformable, from outer (less complex) to inner (more complex and requiring greater conformability). Hence, outer to inner concentric circle — buttock, head, shoulder, knee, heel, chin, elbow, knuckle and finger relate to radii that might be expected on these anatomical positions respectively.

Of the six dressings studied with this method, Mepilex shows the most conformability with Biatain Ag the least. It can be seen that both Mepilex Ag and Biatain silver have lower conformability properties than their non-silver containing equivalents. This may be due to the processing of the silver dressings affecting the physical properties. In the case of Biatain Ag, the difference is significant ($p<0.01$). However, it is not significant for Mepilex Ag ($p=0.0524$) which can still conform to small anatomical radii such as the chin and possibly the elbow, and so would be useful when the antibacterial properties of a silver-containing dressing are required.

From a clinical perspective, more conformable dressings are more versatile, in that they can be applied to varied body locations that would generally be challenging to dress. It is also likely that these dressings will be

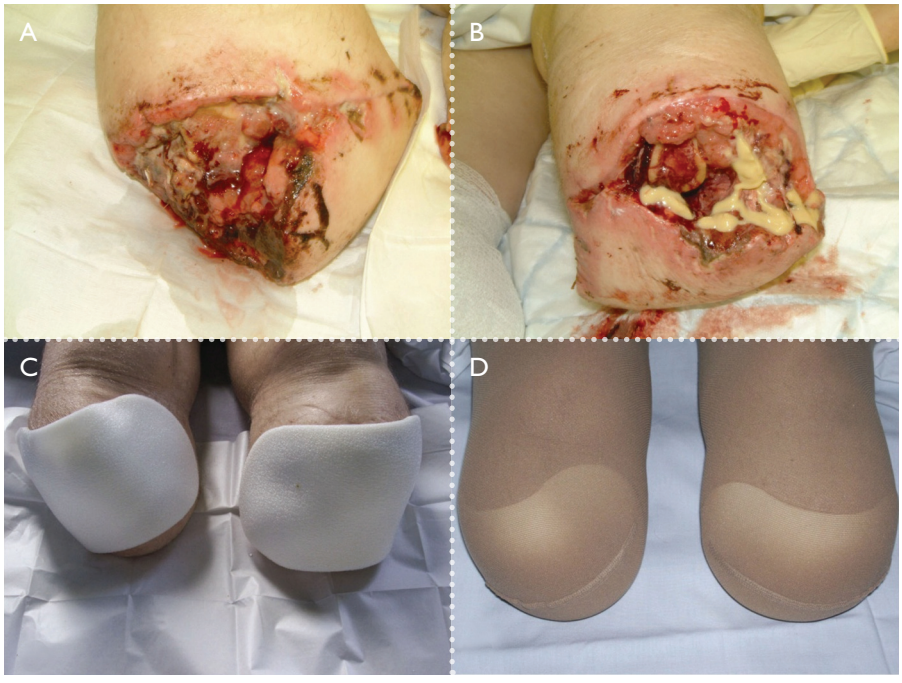

Figure 7. Leg amputation wounds treated with Mepilex.

Figure 8. Diabetic foot ulcers treated with Mepilex Ag.

retained. Data from the volunteer study demonstrated that 50% of Allevyn Gentle Border dressings were not maintained in place at the end of the study.

Figures 3 and *4* represent examples of how Mepilex dressings conform to the contours of the body and can be used in difficult to dress anatomical locations. In support of this laboratory evidence, other investigators have also shown in the clinical environment that Mepilex is conformable to wounds that are awkward to dress. For example, leg amputations, which provide a large, generally irregular but convex stump area (Weaver and Crawford, 2007), diabetic wounds (Young, 2002), venous leg ulcers and pressure ulcers (Dubois, 2004).

An example of the use of Mepilex in the treatment of leg amputation wounds can be seen in *Figure 7*. The dressing conformed well to the wounds (*Figure 7 C* and *D*) and assisted in the healing progression.

Mepilex Ag, the antibacterial silver-containing dressing, also shows conformability in the treatment of diabetic wounds and foot ulcers, as shown in *Figure 8*.

It is interesting to note the differences between Mepilex and Allevyn Gentle with the SMTL conformability method compared to the Queen method; although further dressings need to be tested using the SMTL method to see if it is more discriminatory. The clear advantage of the Queen method is the ability to relate the measured conformability of the dressing to a body shape.

Comfort of the dressing is important in that pain and discomfort reduces patient compliance (Douglas, 2006; Briggs, 2005), impacting upon the effectiveness of the dressing. Both conformability and flexibility of a dressing contribute to comfort (Aindown and Butcher, 2005). This is especially important if dressings are *in situ* over a joint or area of the body where movement occurs. A number of studies have identified comfort as being a key component of Mepilex dressings (Young, 2002; White, 2005; Meaume, 2009).

It is important to stress that the results of laboratory studies should not generally be assumed to accurately reflect outcomes in clinical settings. However, this particular study employed a validated *in vitro* method

that correlates curvature with areas of the body. The results presented here could, therefore, be considered more clinically relevant in terms of overall conformability than the findings of previously reported work which did not adopt the same methodology (Bowler et al, 2010).

Volunteer study

The results presented are for comparison with the *in vitro* data, although in this instance Mepilex Border was used instead of Mepilex. The results consistently show that the Mepilex dressings were more conformable and comfortable than the Allevyn Gentle Border dressing (*Figures 5* and *6*). During this study, 50% of the Allevyn Gentle Border dressings were not retained in place for the period of the study (Data on file – proDERM Study Report No. SP5146-V01). Due to this lack of adhesion and the subsequent small sample size, a statistical analysis of the data was not undertaken.

Conclusion

The human body with its irregular contours and shapes can be challenging when applying dressings that need to be in contact with the wound and the skin, but are situated in awkward places. Dressing conformability and flexibility will aid in maintaining contact and keeping the dressing in place, thereby overcoming this clinical challenge.

This study provides quantitative measures of conformability of dressings that are commonly used in treating a variety of wounds, and helps to correlate the dressings showing those best able to deal with different anatomical topographical features such as bony prominences and joint curvatures. Overall, Mepilex dressings were seen to have higher levels of conformability and comfort than the other dressings tested. WUK

Key points

- The human body consists of irregular contours and shapes that sometimes makes application of dressings to wounds difficult.
- Dressings need to maintain intimate contact with the body and the wound in order that they are effective.
- Conformability and flexibility are key components of the dressing that enable intimate contact with surrounding skin and wound tissue.
- Quantitative measures of conformability are useful in identifying these characteristics in dressings that can be correlated with clinical requirements.

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