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An evaluation of properties related to wear time of four dressings during a five-day period

This study evaluated skin tolerance and other properties relating to wear time, such as conformability and comfort, pain on dressing removal, adhesion and premature detachment, of four advanced hydrated dressings applied to the knees and elbows of 22 healthy volunteers over a fixed five-day period. The dressings all incorporate silicone-based adhesives and are designed to provide a moist wound environment while managing exudate. Skin tolerance was good for all four dressings but there was variation in regards to wear time and fluid-handling properties. Conflict of interest: this work was supported by a grant from Mölnlycke Health Care, Sweden

KEY WORDS

- Conformability
- Dressing-related pain
- Exudate management
- Silicone-based adhesives
- Wear time

In the 1960s, Winter (1962) identified that moisture was required to provide an optimum environment for reepithelialisation (and hence healing) to occur. Since then, further research has added to our knowledge and now the broad criteria for an ideal wound dressing includes:

- Provision of a moist environment
- Protection from the external environment (including the prevention of ingress of foreign particles/microorganisms)
- Removal of wound exudate (through absorption, retention and moisture vapour transmission)
- Promotion of tissue regeneration
- Prevention of damage to the fragile wound bed or surrounding skin on removal, and minimisation of dressing-related pain (Moura et al, 2013).

Fundamentally the dressing also has to stay in place for a reasonable amount of time to enable healing to occur. Frequent removal and reapplication of dressings may delay healing due to:

- Trauma to the wound bed and surrounding skin that disturbs the healing process (Rippon et al, 2012)
- Temperature loss at the wound site, which affects the cellular processes of healing (Romanelli et al, 2002; McGuiness et al, 2004)
- A greater opportunity for pathogenic bacteria to infect the wound (Lawrence, 1994; Bowler et al, 1999)
- Psychological stress and pain suffered by the patient at dressing change that has been shown to delay healing (Solowiej and Upton, 2012).

Dressings that incorporate silicone-based adhesives (such as the ones evaluated in this study), generally cause less trauma and pain on removal compared with dressings that use traditional adhesives.

Wear time of the dressing is dependent upon many factors related to the patient (such as mobility, type and frequency of bathing, and interference with the dressing), the characteristics of the wound (such as location, size, level of exudation, condition of peri-wound skin and level of microbial contamination) and the actual properties of the dressing itself.

Two of the key factors that determine how long a dressing can be left in place are adhesion of the dressing to the wound or surrounding skin and the ability of the dressing to manage wound exudate. If the level of adhesion is too low then the dressing will fall off, too high and there is a higher propensity to cause damage to either the wound bed or peri-wound skin (Dykes, 2007; Waring et al, 2011), leading to pain and, as a result of the skin damage, possible infection (Charlesworth et al, 2014). Good conformability will aid dressing adhesion. If the dressing cannot manage the level of wound exudate (through

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absorbance, retention, fluid transmission or a combination of these properties), then maceration can occur, which may also delay healing, exacerbate the wound condition and increase the risk of infection (Benbow and Stevens, 2010). Thus, a wound dressing should provide a balance in relation to both adhesion and exudate management. It should be sufficiently adhesive to stay in place without causing tissue damage and it should also be able to prevent the extremes of desiccation or moisture-related damage (Menon, 2012; Milne, 2013).

Some dressing components — such as adhesives — may induce skin sensitisation and allergic reactions (Renner et al, 2011). Increases in the moisture content of the skin caused by these adverse reactions may also influence the wear time of a dressing by reducing adhesion and increasing pain and discomfort, which may cause the patient to interfere with the dressing.

This study evaluated skin tolerance and other properties relating to wear time of four advanced hydrated dressings applied to the knees and elbows of healthy volunteers in order that they may be compared and the results extrapolated to clinical use.

Table 1. Test schedule.

Day	1	2	4	5
Objective dermatological evaluation of erythema, dryness, barrier disruption, papules, swelling (by trained technician)	X			X
Application of test materials (by trained technician)	X			
Subjective assessment of conformability and comfort (by subjects)		X	X	X
Subjective dermatological evaluation of itching, burning, tickling (by subjects)	X	X	X	X
Percentage of adherence (by trained technician)		X	X	X
Removal of test materials; objective assessment of removal (by trained technician)				X
Subjective assessment of pain (by subjects)				X

Table 2. Test products used in the study.

Test products	Description	Fluid load (ml)	Area of entire dressing including adhesive surface (cm)	Area of absorbent wound dressing section excluding adhesive surface (cm)
A	Mepilex Border Flex (Mölnlycke Health Care)	29.5	13x16	9x12
B	Mepilex Border (Mölnlycke Health Care)	25.1	12.5x12.5	8.5x8.5
C	Allevyn Life (Smith & Nephew)	17.5	12.9x12.9	7.6x7.6
D	Biatain Silicone (Coloplast)	25.1	12.5x12.5	8.5x8.5

METHODS

Inclusion and exclusion criteria

All subjects were healthy volunteers and they were required to provide written informed consent before enrolment in the study. Participants could be men or women aged between 18 and 70 years who were willing to avoid water contact and the application of cosmetic products in the test areas throughout the course of the study. Participants had to have uniform skin colour and no erythema or dark pigmentation in the test areas. Exclusion criteria included:

- Participation, or being in the waiting period after participation, in similar cosmetic and/or pharmaceutical studies
- Pregnancy or lactation
- Active skin disease at test area
- Documented allergies to adhesive products
- Moles, tattoos, scars, irritated skin or hairs at the test area
- Systemic therapy with immunosuppressive drugs, such as corticosteroids and/or antihistamines, within the previous seven days
- Systemic therapy with antiphlogistic agents within the previous three days
- Unmedicated asthma or hypertension
- Known AIDS or infectious hepatitis.

Test procedure

The study was conducted over a five-day period. On day one participants were informed of the study procedure and asked to give written consent (*Table 1*). Before the start of the study, participants were instructed to avoid applying any cosmetics to test areas on the morning before the start of the study. Following randomisation of dressing to test area using a Latin square method, four different adhesive dressings were applied on the randomly assigned test areas on each of the subject's knees and elbows by a trained technician. The test products assessed are summarised in *Table 2* and were Mepilex Border Flex (Mölnlycke Health Care) (dressing A), Mepilex Border (Mölnlycke Health Care)

"Exudate-handling abilities were determined using an artificial exudate preparation made up from sodium chloride and calcium chloride dihydrate preparations dissolved in de-ionised water"

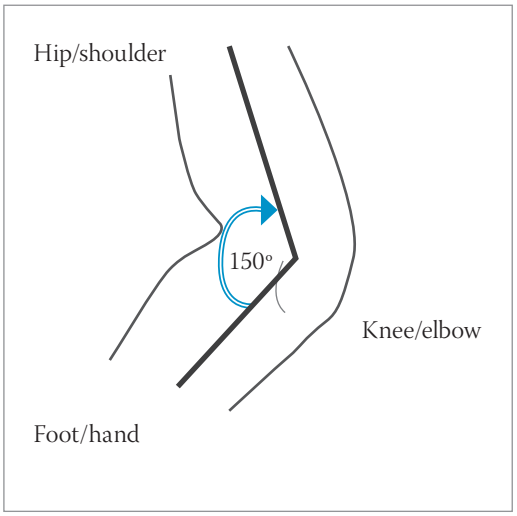

Figure 1. Diagrammatic representation of dressing application over knee/elbow.

(dressing B), Allevyn Life (Smith & Nephew) (dressing C), and Biatain Silicone (Coloplast) (dressing D). These dressings were chosen for comparison as they all have a similar function.

Exudate-handling abilities were determined using an artificial exudate preparation made up from sodium chloride and calcium chloride dihydrate preparations dissolved in de-ionised water. Each of the four dressings was applied in a wet state to both knees (outer sides) and both elbows with the dressings being positioned directly above the elbow. Dressings were applied by the technician on day one of the five-day study as depicted in *Figure 1*. These angled locations are generally considered to be particularly challenging when it comes to dressing adhesion. The artificial exudate fluid was applied directly to the padded area of the dressings using a Finn® pipette. The volume of fluid added to each dressing was determined from the maximum absorbency of dressing A (the largest dressing) and calculated for the other dressings to give an equivalent quantity per unit of the pad area (about 0.3 ml/cm²). All dressings were loaded with a comparable amount of fluid per area of the wound pad. A was loaded with 0.27 ml/cm², B with 0.35 ml/cm², C with 0.30 ml/cm² and D with 0.35 ml/cm² and the total fluid-loading for each of the dressings was A = 29.5 ml, B = 25.1 ml, C = 17.5 ml and D = 25.1 ml.

Assessments

At baseline (day one) and on the final day (day five), the technician made an objective assessment of dermatological parameters, which included erythema, dryness, barrier disruption, papules, and swelling. At the same time, participants made subjective assessments of itching, burning and tickling in the test areas; they also made these subjective assessments at visits two and four. Both the technician's objective assessment and the participants' subjective assessments were graded according to a numerical score which was then interpreted into categories of no result (score = 0), very slight (score = 0.5), slight (score = 1), moderate (score = 2), and strong (score = 3).

Participants made a subjective assessment of conformability and comfort on days two, four, and five of the study, using the descriptors very good (score = 2), good (score = 1), neither good nor bad (score = 0), bad (score = –1), or very bad (score = –2). They also undertook a subjective assessment of pain at removal of dressings on day five of the study, using the responses no pain (score = 0), slight (score = 1), moderate (score = 2), strong (score = 3), or very strong (score = 4).

The percentage of adherence of the dressing to the skin and tendencies toward premature detachment were assessed by the technician on days two, four, and five of the study. Ease of removal of dressings was assessed objectively by the technician on day five in terms of the actual process of removing the dressings, using responses of very easy (score = 2), easy (score = 1), neither easy nor difficult (score = 0), difficult (score = –1), or very difficult (score = –2) and in relation to the degree to which adhesive residues were left on the skin following removal of dressings using the responses of none (score = 0), barely (score = 1), some (score = 2), many (score = 3), or great many (score = 4).

Analysis of data

Statistical data was analysed using SPSS for Windows. Valid subjects were defined as enrolled subjects who had finished the study without major deviations from the protocol and who had not withdrawn consent. Descriptive statistics were used and included mean values, standard deviation, median, minimum and

maximum values, as well as the number of subjects evaluated.

Literature review

In conducting this review, the bibliographic database PubMed/MEDLINE was searched to identify systematic reviews and primary studies addressing the background related to skin complications in patients with wounds and other studies involving wear time of dressings. Google Scholar was used as a search engine to find supporting information.

RESULTS

A total of 22 subjects (male $n=7$, 32%; female $n=15$, 68%) with a mean age of 57.1 ±12.0 years were recruited from the general population of Schenefeld/Hamburg in Germany. The findings from all 22 subjects were valid for analysis with no exclusions. However, it was noted that from day one to day two, the inlays of some dressings had loosened and shifted position and the dressings were unable to maintain an effective seal with the skin and were prone to leaking or falling off. This was the case for all dressings except dressing D (three cases for dressing A, two for dressing B, and one for dressing C). In one case, leakage of the hydrating fluid was noted in dressing A. Some of the dressings fell off before the end of the five-day period — five for dressing A, three each for dressings B and C, and eight for dressing D.

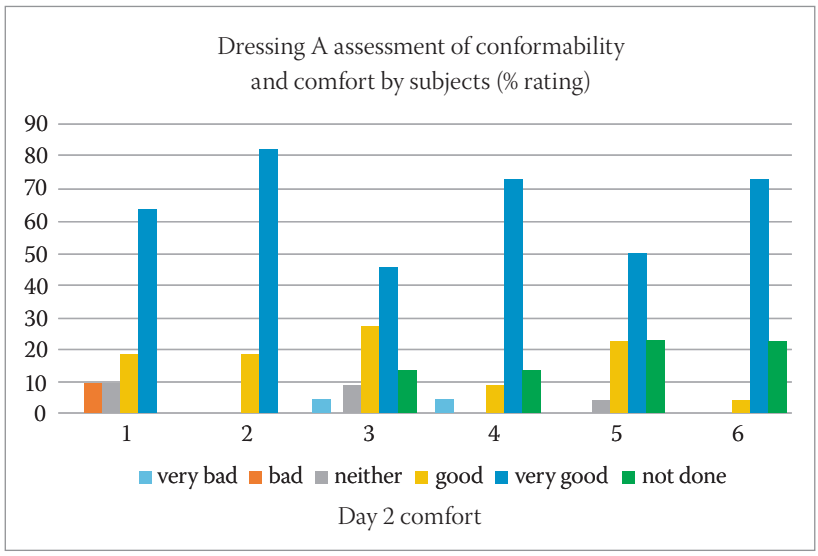

Figure 2. Dressing A assessment of conformability and comfort by subjects (% rating).

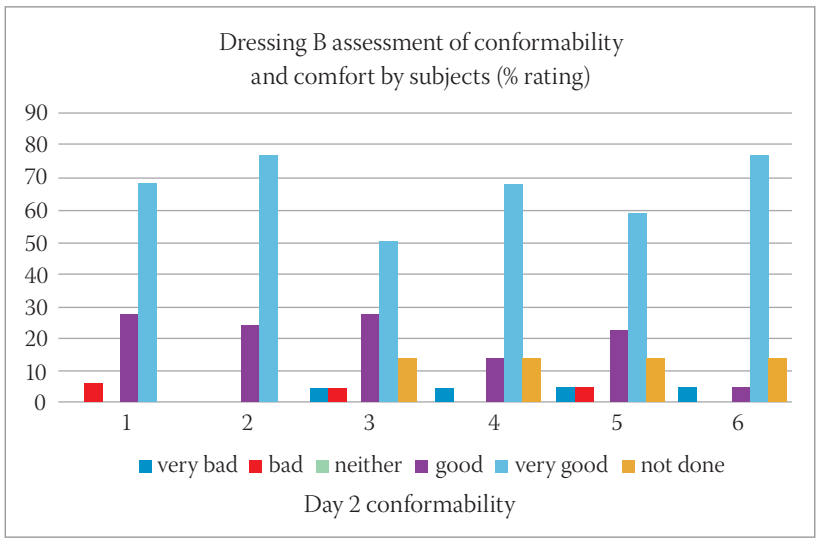

Figure 3. Dressing B assessment of conformability and comfort by subjects (% rating).

Skin tolerance

Objective dermatological evaluation

Barrier disruption, papules and swelling were not observed at all during the study period. The occurrence of erythema stayed more or less unchanged from the baseline evaluation to the final evaluation on day five for all test products. The mean scores remained unchanged except for a slight increase in relation to dressing C on day five (*Table 3*). With respect to skin dryness, the number of affected participants and the corresponding mean scores slightly increased from baseline to day five for dressings A, B and D. For dressing C, the number of affected participants and the corresponding mean scores were lower on day five compared with baseline.

Table 3. Mean occurrences of objective dermatological parameters at day 1 (baseline) and day 5 (study end).

Dressing	Assessment	Mean value at Day 1	Mean value at Day 5
A	Erythema	1.5	1.5
	Dryness	2.0	2.5
B	Erythema	1.5	1.5
	Dryness	2.5	3.5
C	Erythema	1.5	2.0
	Dryness	2.5	2.0
D	Erythema	1.0	1.0
	Dryness	2.0	3.0

* 0 = no result; 0.5 = very slight; 1 = slight; 2 = moderate; 3 = strong

Subjective dermatological evaluation

- Dressing A: very slight itching was reported on day four and day five by one participant. Tickling was not mentioned at all.
- Dressing B: six cases of very slight itching were reported (one case on day two, two cases on day four and three cases on day five) and one case of slight itching on day four. Slight tickling was reported by one participant on day four.
- Dressing C: very slight itching was noted by one participant on day four and by two participants on day five; furthermore, one subject reported slight itching on day four. Slight tickling was recorded by another participant in relation to essing C on day four.
- Dressing D: one participant recorded very slight tickling on study days two and five. Itching was not mentioned at all.

Burning was not reported by any of the participants during the study.

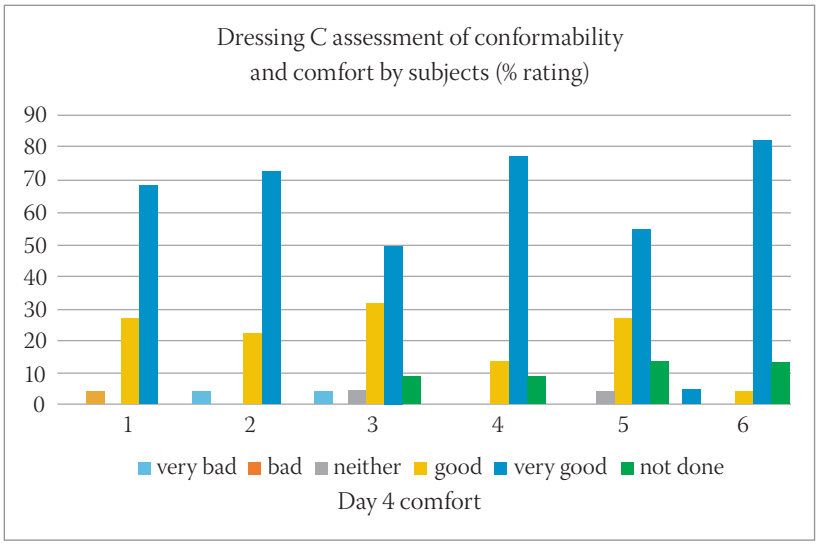

Figure 4. Dressing C assessment of conformability and comfort by subjects (% rating).

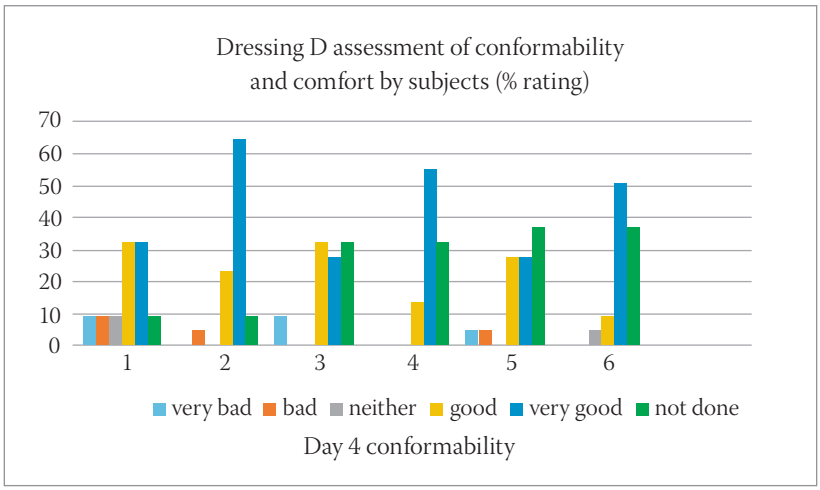

Figure 5. Dressing D assessment of conformability and comfort by subjects (% rating).

Other properties relating to wear time

Conformability and comfort

The subjective assessment of conformability and comfort of the dressings during wear was judged to be good or very good by the majority of study participants. No significant differences were identified between the different dressing types, although the conformability of dressing D was rated lower than that of the other dressings tested (*Figures 2–5*). It is noteworthy that a large number of dressings ($n = 8$) detached prematurely with dressing D.

Objective assessment of removal

None of the dressings tested were assessed to be very difficult to remove.

- Dressing A: no cases of difficult removal were recorded and 10 out of 17 dressing removals were rated as neither easy nor difficult. In four cases, dressing A was rated as easy to remove from participants' skin and in three cases it was very easy.
- Dressing B: two dressing removals were rated as difficult. For six of the participants, dressing removal was evaluated to be neither difficult nor easy; for seven participants it was rated as easy. In four cases, the removal of dressing B was rated as very easy.
- Dressing C: one case of difficult removal, six cases of neither difficult nor easy removal, seven cases of easy removal and five cases of very easy removal were recorded.
- Dressing D: an easy removal was noted in the majority of cases (nine out of 14 dressings), whereas in two further cases the removal was documented to be very easy. In one case, the removal of dressing D was neither difficult nor easy, whereas in two cases it was deemed to be difficult.

Subjective assessment of pain during removal

Pain was assessed on a scale of 0–4 from no pain to very strong pain. The pain data is summarised in *Figure 6*. None of the participants mentioned

very strong pain during dressing removal.

- Dressing A: none of the participants noted strong pain, seven participants noted no pain, a further seven noted slight pain and three noted moderate pain during dressing removal.
- Dressing B: two participants noted strong pain and four noted moderate pain. Slightly less than half of the participants described slight pain during removal of the dressing and five of the participants felt no pain at all.
- Dressing C: two cases of strong pain, four cases of moderate pain, seven cases of slight pain, and six cases of no pain were recorded.
- Dressing D: eight out of the 22 participants experienced premature detachment of the dressing. However, in seven of the remaining participants, no sensations of pain were reported during removal of the dressings and four of the other subjects noted slight pain, with three noting 'moderate' pain.

Objective assessment of adhesive residues on the skin after dressing removal

- Dressing A: in the majority of cases no adhesive residues following removal of the dressing were seen. In two cases there were barely any residues and in only one case was there a great many adhesive residues.
- Dressings B and C: generally there were no adhesive residues left on the skin following removal of the dressings, but in four cases for both dressings B and C, adhesive residues left on the skin were reported as being 'barely' present. However, in one case, many adhesive residues were noted on the skin following removal of dressing B.
- Dressing D: left no adhesive residues on the skin in two out of 14 dressings, in six cases adhesive residues were reported as 'barely' left on the skin, and in four cases there were some adhesive residues left. Many adhesive residues were noted in two cases following removal of dressing D.

Percentage of adherence and premature detachment of dressings:

The number of dressings that showed premature detachment and percentage adherence for each of the dressings was as follows. A = 5 (22.7%), B = 3 (13.6%), C = 3 (13.6%), D = 8 (36.4%), respectively. The distribution of these detachments in terms of study visit day are presented in *Figure 7*. The highest number of premature detachments and the lowest percentage adherence values in the mean were detected for dressing D followed by dressing A. Dressings B and C demonstrated the highest mean percentage adherence values and the lowest number of premature detachments (*Table 4*).

DISCUSSION

With regards to skin tolerance, none of the dressings evaluated were associated with any notable adverse effects such as erythema or dryness (*Table 3*); furthermore, reported itching was generally rated as very minor and not considered to be of clinical significance.

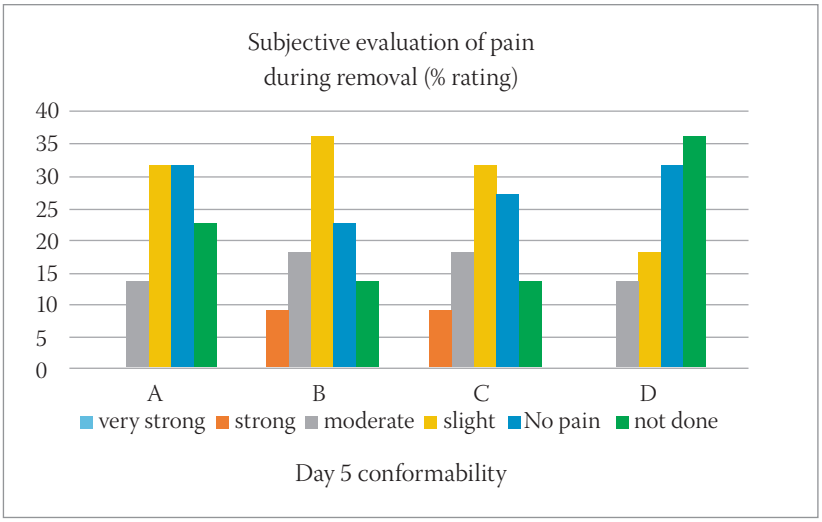

Figure 6. Subjective evaluation of pain during removal (% rating).

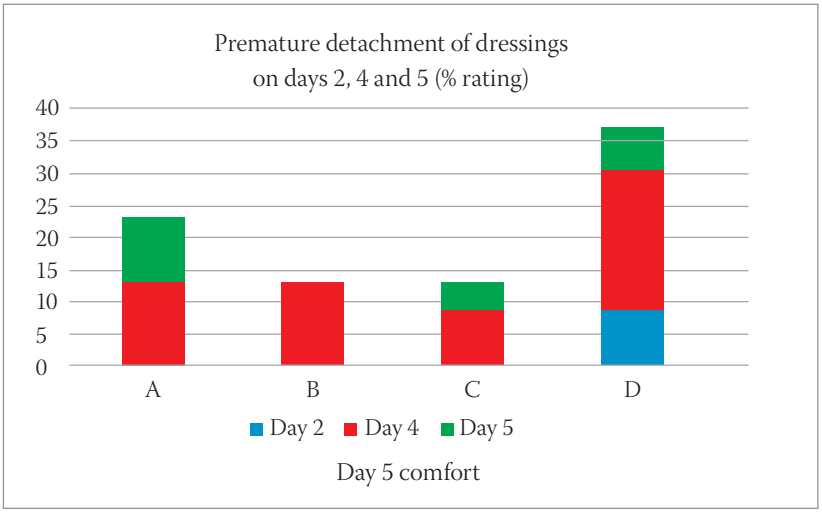

Figure 7. Premature detachment of dressings on days 2, 4 and 5 (% rating).

"Wear time is an important consideration for clinicians, not least because of the cost implications related to the number and frequency of dressing changes that can impact heavily on resources."

This is noteworthy because, since the advent of advanced dressings, allergic reactions to their constituents (mainly the adhesives) have been problematic and a considerable clinical challenge (Newton, 1999; Conway and Whettham, 2002; Foti et al, 2007; Freise et al, 2008; Renner et al, 2013). Recent studies have shown this still to be the case and some dressings have been shown to cause significant allergic reactions in volunteers undergoing sensitisation testing (Renner et al, 2011).

The propensity of adhesive dressings to induce skin reactions in patients with chronic wounds and sensitised peri-wound skin is also much greater, for example, in people with leg ulcers (Tavadia et al, 2003). This was highlighted in a recent study of 70 patients with chronic wounds, which demonstrated significant positive allergic responses to dressings (Renner et al, 2013). The researchers concluded that patients with recalcitrant ulcers of prolonged duration showed a significantly higher number of skin reactions to wound dressings than patients with shorter ulcer duration. This should be taken into consideration when choosing dressings and the probability that this will also affect wear time because the longer dressings are in contact with the skin, the greater the chance of an allergic reaction (Renner et al, 2013).

Wear time is an important consideration for clinicians, not least because of the cost implications related to the number and frequency of dressing changes that can impact heavily on resources (Harding et al, 2001; Panca et al, 2013). Frequent dressing changes can also reduce patients' quality of life due to heightened pain, dressing-related trauma and psychological stress, all of which have the potential to delay healing (Ravenscroft et al, 2006; Charlesworth et al, 2014).

Table 4. Mean percentage of adherence.

Dressing	Assessment time		
	Day 2	Day 4	Day 5
A	86.4%	72.7%	75.8%
B	90.9%	73.6%	83.2%
C	91.4%	80.9%	84.5%
D	70.0%	49.0%	62.7%

In this study, the wear properties of each of the dressings were assessed by a number of parameters during the fixed period of wear, including conformability and comfort. The results showed no clear differences between them, other than dressing D faring worse than the others (dressing D had the highest proportion of bad or very bad conformability scores) (*Figures 2–5*). Flexibility and conformability are key performance characteristics in wound dressings and can have an impact on product suitability. If a dressing is not able to conform to contours and features of the human body then adhesion is not optimised and the dressing will inevitably become detached.

No significant differences were seen between pain values recorded for each of the dressings (which were generally very low) upon removal. Pain is an important issue to consider. Some wound dressings have been shown to have very aggressive adhesives that can damage both the wound and peri-wound skin on removal (Hollinworth, 2009; Waring et al, 2011; Charlesworth et al, 2014). Patient quality of life may also be significantly affected as a consequence of this pain, which may, in turn, lead to delayed wound healing caused by psychological stress (Gouin et al, 2011; Upton and Solowiej, 2012; Upton et al, 2012a) and mood disorders (Upton et al, 2012b).

The percentage of dressings that demonstrated early detachment was evaluated and the results are presented in *Figure 7*. The ranking (highest to lowest percentage of premature detachments) was D>A>C=B (36.4, 22.7, 13.6, 13.6 respectively). In respect of wear time, the fluid absorption capabilities of the dressings should also be taken into consideration. If only small volumes of fluid can be absorbed by the dressings then they will have to be changed more frequently. In this study, the fluid-loading of the dressings was ranked (highest to lowest) A>B=D>C (29.5 ml, 25.1 ml, 25.1 ml, 17.5 ml, respectively). Thus, of the four dressings tested, dressing A would appear to be the one that has a low level of detachments coupled with the highest wound exudate absorption capability based on the total volume of fluid immobilised by the dressing. Generally

the dressings left only small amounts of adhesive residue on the skin of the volunteers. However, dressing D did show 'some' and 'many' residues left; this might explain why this dressing showed a greater degree of detachment, perhaps due to delamination of the adhesive component.

The ability of a dressing to manage wound exudate relates to its absorption, retention and moisture vapour transmission capabilities. A number of *in vitro* and *in vivo* studies have been undertaken by other researchers to quantify wear time in terms of physical characteristics of the dressing, e.g. moisture vapour transmission rates (MVTR) (Zehrer et al, 2013), fluid absorption (Young et al, 2007; Thomas, 2010) and the number of days a dressing can be retained in place (Lutz et al, 2011). Most relevant to this study was a recent evaluation undertaken involving human volunteers, which compared the MVTR and wear time or fluid-handling capacities of six adhesive foam dressings versus a reformulated control dressing (Lutz et al, 2011). A similar methodology to this study was adopted whereby artificial wounds were constructed on the lower backs of the volunteers, dressings placed over them and 12 x 1ml aliquots of artificial wound fluid were intermittently infused into the models at intervals no less than one hour apart to give a total daily dose of 12 ml of fluid. The results showed marked differences between the dressings both in terms of MVTR and wear time or fluid-handling capacity. But importantly, the authors concluded that this volunteer model could not be used to predict exact dressing wear time or fluid-handling capacity, but rather relative performance of the dressings when used on wounds with similar clinical conditions. The main benefit of this volunteer model is that direct comparison of dressing performance can be undertaken on a much smaller population of subjects than can be obtained in a clinical environment (Zehrer et al, 2013).

This then supports the premise on which the current study is based, in relation to developing a model in which many parameters of different dressing types can be compared under controlled conditions. In order to further substantiate the findings of this study, a review of the literature was undertaken; however, it became clear that, due to the disparity of test methods in published articles, it is difficult to undertake any comparisons. However, a significant and unambiguous conclusion drawn from such studies was that leakage due to poor fluid absorption characteristics of dressings was one of the main causes for their changes outside of the routine procedures and that both *in vitro* and *in vivo* comparative experimental studies could be used to gain data that could be extrapolated to give an idea of effectiveness in the clinical environment.

STUDY LIMITATIONS

The main limitation of this volunteer study model is that it does not take account of the fact that real wounds on patients are heterogeneous in nature. This is especially true when considering the amounts of exudate that can vary enormously between different types of wounds, their position, healing/non-healing status and bioburden. A large number of volunteers/model environments would be required to provide an accurate portrayal of this. On the other hand, the lack of confounding factors and the ability to control the environment, fluid volume (and potential flow rates) makes this a valid model for comparing different dressing types in a simulated environment.

CONCLUSION

The purpose of this study was to assess skin tolerance and wear properties of four dressings: Mepilex Border Flex, Mepilex Border, Allevyn Life and Biatain Silicone. The results showed that skin tolerance in all dressings was equivocal. However, when taking into account the combined results of fluid absorption and dressing adhesion over a period of five days, dressing A (Mepilex Border Flex) would appear to have the best overall properties related to wear time (fluid-handling and dressing retention) of the four dressings tested in this study. Conversely, Biatain Silicone fared poorly, having moderate absorptive capacity (with a high number of dressings becoming prematurely detached), the lowest percentage of adherence and poor conformability in this test model. WUK

"The lack of confounding factors and the ability to control the environment, fluid volume (and potential flow rates) makes this a valid model for comparing different dressing types in a simulated environment."

"Mepilex Border Flex would appear to have the best overall properties related to wear time (fluid-handling and dressing retention) of the four dressings tested in this study."

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