Cilguard

A review of clinical literature relating to the use of foam/film dressings and soft-silicone adhesives.

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1. EXECUTIVE SUMMARY

- Simple dressings made from polyurethane foam sheet bonded to a semipermeable polyurethane film backing layer possesses many of the attributes of the 'ideal dressing' and as such they have become a mainstay of modern wound management, used in the treatment of virtually all types of exuding wounds.
- The addition of a discontinuous layer of a suitable adhesive to the wound contact surface of these dressings facilitates placement and retention. It also helps to prevent leakage of exudate thereby reducing maceration and helping to prevent infection.
- Laboratory and clinical studies have shown that dressings with a soft-silicone adhesive system have advantages over those with conventional adhesives because they produce less pain and trauma upon removal.
- Products coated with soft-silicone adhesives have made a major impact on the dressings market as annual sales are estimated to exceed nine million units, worth around £27m.
- The technical information provided for review suggests that dressings in the new Cilguard® range are comparable in design and structure with pre-existing commercial foam/film products coated with a soft-silicone adhesive. It is therefore not unreasonable to assume that they will function in a similar way to existing materials and be suitable for a similar range of clinical indications

2. INTRODUCTION

2.1. Study sponsor

This report was commissioned by Graham Collyer, Executive Chairman of Sumed International (UK) Ltd based in Integrity House, Units 1-2 Graphite Way, Hadfield, Glossup, Derbyshire SK13 1QH.

2.2. Aim of study

The author was asked to undertake a review of published literature relating to foam/film dressings, particularly those coated with a soft-silicone adhesive.

The principal aim of this review was to determine if it is appropriate to claim that products in new 'Cilguard' range of dressings are likely to be suitable for use in the management of exuding wounds, and to comment on whether they are equivalent in terms of their design characteristics, safety, performance and intended use, to other products identified during the review that are used extensively in wound management throughout the United Kingdom and beyond.

2.3. Documentation provided for review

The documents provided by the client included copies of packaging and labelling information for the new product range together with the results of a Medline literature search, completed on December 9th 2010, which covered the period 1949 to date. The various search criteria employed and the numbers of publications relevant to each are summarised in an appendix attached to this report.

2.4. Additional data sources

In addition to the material supplied by the client, the author has made extensive use of the results of an earlier extensive review of the literature which was undertaken to facilitate the production of a new textbook entitled Surgical Dressings and Wound Management[1] sections of which have been incorporated into this document.

2.5. Timescales

The documentation for review was received on December 11th and the report was produced between December 14th and December 20th. 2010.

2.6. Author contact details

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2.7. Declaration by author

This review was undertaken by the author for a professional fee in his capacity as an independent medical device consultant and medical writer. The author has no interest, financial or otherwise, in Sumed Ltd or any of the products produced or marketed by that organisation.

3. PRODUCT INFORMATION

3.1. Product description

Three versions of the dressing are described.

The standard device consists of a 5 mm thick, heat-bonded, polyurethane foam/film laminated sheet the patient-contact surface of which is coated with a discontinuous film of soft-silicone adhesive. Based upon the information provided, it is the view of the author that the resulting dressing pad, which is available in a range of sizes, is very similar in design, construction and appearance to other commercially successful products in current use, and might therefore be expected to function in a similar fashion.

In a second form of the device the film backing layer, which is bonded to the foam with an acrylic adhesive, extends past the margin of the foam by approximately 20 mm on one or more adjacent sides. It is suggested that in this embodiment two or more dressings can be placed edge to edge over a wound, held together by the film border which should also act as an effective liquid seal and bacterial barrier at the interface between the two adjacent dressings.

In a third form of the dressing the adhesive margin, formed as above, is present on all four sides resulting in an 'island dressing' which is retained securely in place by the acrylic adhesive on the dressing border. In this presentation the foam layer is substantially thinner than that of the standard dressing.

3.2. Product claims

The product literature provided suggests that the dressing, which is claimed to be waterproof and vapour permeable, is designed to 'gently but firmly' adhere to the periwound skin absorbing exudate whilst minimising the risk of maceration. The dressing is indicated for a range of wounds including pressure ulcers, venous and arterial leg ulcers, diabetic foot ulcers and traumatic wounds such as skin tears.

3.3. Legal status

In accordance with European Directive 93/42/EEC, each form of Cilguard is classified as a Medical Device, Class IIb. (22)

4. LITERATURE REVIEW

4.1. Structure of review

As previously indicated the dressings which form the subject of this review consist of a foam-film laminate coated with a discontinuous 'soft-silicone' adhesive wound contact layer.

The individual components used in the production of the dressings are not novel either when used alone or in combination, and for this reason the review has been divided into three parts.

The first part briefly summarises the wealth of literature on foam/film dressings, the second describes the development and clinical benefits of soft-silicone, and the final part relates to existing products which make use of these technologies used in combination.

In the absence of published data on Cilguard the review has, of necessity, been based upon literature relating to alternative branded products which share a broadly common structure with the new development. Although some of the clinical indications described in the studies cited may not currently appear in the range of indications identified in the product literature for Cilguard, they have been included here because they illustrate the clinical benefits of this type of product and therefore make a significant contribution to the value of this review.

4.2. Part 1: Polyurethane foam/film dressings

1.1.1. Key properties of foam-film dressings

Foams in various forms have a long history in wound management. Over time these have evolved and resulted in the formation of a hydrophilic polyurethane (HPU) which is now the most commonly used foam used in wound management.

Dressings consisting solely of HPU satisfy some, but not all, of the requirements of the 'ideal dressing' originally proposed in 1956 by Scales[2] and subsequently modified in 1975 by Winter[3] and updated by Thomas in 1985 [4] and again in 2010.[1]

Amongst other requirements all these publications agree that the 'ideal dressing' should be:

- Capable of providing good absorption of blood and exudate
- Free of toxicity
- Conformable
- Able to create ideal microclimate for most rapid and effective healing (prevents dehydration and maceration)
- Capable of protecting against secondary infection (bacterial barrier)
- Non-adherent
- Fibre-fast (does not shed loose material into wound)
- Capable of providing mechanical protection to wound

The principal disadvantage of HPU foam when used alone, is that it may be excessively permeable to moisture vapour, resulting in undesirable drying of the wound bed. Furthermore, as open cell foam does not form an effective bacterial barrier, exudate 'strikethrough' may occur. This results in the formation of a liquid pathway from the wound surface to the

external environment by means of which microorganisms can either gain access to, or be liberated from, the surface of the wound.

The application of an intact polyurethane membrane to the outer surface of an HPU foam sheet overcomes both these problems, forming an effective bacterial barrier whilst exerting some degree of control over the evaporation of exudate through the back of the dressing.

The fluid handling capacity of an uncoated non-adhesive composite foam/film dressing pad is determined by its absorbent capacity, a function of the porosity, density and thickness of the foam, the moisture vapour permeability of the film, and the nature of the process used to bond the two components together.

The combination of foam and film used in this way has lead to the development of arguably some of the most useful dressings currently available on the market. Many leading manufacturers and distributors of surgical dressings sell products of this type, among the most commercially successful of which is the Allevyn range marketed by Smith and Nephew.

The first non-adhesive form of Allevyn was launched around 1985 followed in 1995 by the adhesive version. In 2006 the dressings were improved by the introduction of a more permeable outer film which further enhanced their fluid handling capacity.

Foam/film dressings are used in enormous quantities, both as simple absorbent pads and as components of more sophisticated products such as adhesive island dressings, including those shaped specifically to suit the sacral region, and products preformed to dress particular anatomical sites such as heels and elbows. Despite the widespread use of these dressings, the author is unaware of any reports of adverse events associated with the use of these materials.

A comprehensive review of the fluid-handling and bacterial barrier properties of different foam/film dressings has been published previously.[1]

Key properties of polyurethane foam/film dressings

- Polyurethane foam bonded to a semipermeable film backing layer possesses many of the attributes of the 'ideal dressing'.
- Available as simple pads and as adhesive island dressings
- Used since the late 1980s they have become a mainstay of modern wound management throughout much of the world.
- Commercial brands vary in their ability to absorb exudate and transmit moisture vapour according to the thickness of the foam, the method of construction and the permeability of the outer backing layer.

1.1.2. Clinical use of foam/film dressings

An early reference to the use of a foam/film dressing (Allevyn) was published in Germany in 1988 by Friederich,[5] but the first clinical study to be identified was not published until some years later when foam/film was compared with petrolatum gauze dressing in a prospective

randomized controlled trial involving patients with donor sites.[6] Wounds were examined 14 days after surgery when the degree of epithelialization was recorded. Of the 68 patients recruited, 14/38 (37%) vs 5/30 (17%) achieved full closure in the foam/film and petrolatum gauze treated groups respectively. This difference just failed to reach significance ($p = 0.06$). Donor site and operative site pain were also assessed using a visual numeric scale which revealed that the mean maximum pain intensity scores were statistically lower for foam on postoperative days one to three ($p < 05$). Pain levels were elevated in larger donor site dressed with petrolatum gauze but not in wounds dressed with foam.

An adhesive version of the Allevyn dressing was compared with a standard form of treatment, paraffin gauze, in 50 patients with donor sites. Half of each wound was dressed with one of the products under examination and thus each patient acted as his/her own control. After four days, the wounds of 52% of 44 evaluable patients dressed with foam/film had completely reepithelialized and by seven days this figure had risen to 93%. By the tenth day all wounds dressed with the foam were completely healed. After seven days, the first assessment point for the control group, only 36% of wounds had healed, rising to 59% by Day 10. The difference in healing rates was statistically significant. Patients reported slight or no pain on removal of the trial dressing but 'unbearable pain' with the paraffin gauze. The results of this study were published twice.[7-8]

The performance and safety of a foam/film dressing was compared with that of a hydrocolloid dressing (Granuflex), in a prospective, multicentre randomized clinical trial involving 61 patients with Grade II or Grade III pressure ulcers.[9] Dressings were changed in accordance with the manufacturers' instructions and at each change assessments were made of the condition of the wound and surrounding skin, comfort, ease of use and leakage from the dressing. Treatment continued for a maximum of 30 days or until the wounds healed. Ease of application of the two dressings was comparable, but the foam dressing was found to be significantly easier to remove with superior fluid handling properties.

Allevyn was similarly compared with an alginate dressing, Kaltostat, in the treatment of 20 consecutive patients with split-thickness skin-graft donor sites.[10] The dressings were applied to equal halves of each wound and a secondary dressing of gauze, cotton wool and crepe bandage was applied over both products, it not being possible to dress them individually. Wounds were examined and dressing changed weekly in accordance with normal practice. Four patients were lost to follow up. In the remaining patients Allevyn showed a tendency to earlier healing, 12 patients healed at two weeks compared with ten dressed with alginate, but this difference was not statistically significant. However, Allevyn was found to be significantly more comfortable than Kaltostat, leading the authors to recommend it as a donor site dressing because of increased patient comfort, lower cost and reduced time to healing.

The management of leg ulcers is potentially a major indication for all modern dressings. The non-adhesive form of a foam/film dressing (Allevyn) was evaluated for the treatment of this condition in an open, observational multicentre study in 24 patients.[11] In the 22 patients who completed the study, 17 (77.3%) had ulcers caused by venous disease, one leg ulcer was of mixed aetiology, and one followed an amputation. In three instances the cause of the ulcer was not specified. Seven wounds healed completely and the remainder reduced in area. The dressing was found to be easy to use and was well tolerated by patient with no evidence of any adverse events.

The largest study ever published on Allevyn was that described by Verdu Soriano et al.,[12]

which involved 441 elderly patients 63% of whom had pressure ulcers, 27.2% leg ulcers of venous origin and 9.8% wounds of some other aetiology. Each wound was subjected to a maximum of 20 dressing changes unless closure was achieved during the treatment period. The wounds, which had been present for 6.1 months, had an average area of 30.4 cm^2 at the start of the study. During the study period 126 wounds (28.8%) healed in an average of 47.3 days. Of the 315 lesions which remained open at the end of the study, 90.5% showed evidence of improvement. Whist the numbers included in this investigation are impressive and the results appear positive, as with the previous study, the absence of a control group greatly limits the value of this publication.

Allevyn Adhesive was compared with Versiva, in the management of venous leg ulcers in a multicentre randomized, controlled 12-week study involving 15 centres in the US, Canada, France, Germany, and the UK.[13] Within this publication Versiva is described as a 'foam composite' but this is probably something of a misnomer. The absorbent core of the dressing consists of a layer of sodium carboxymethylcellulose fibres which is located centrally upon a larger piece of a thin sheet consisting of a polyurethane foam/film laminate which is present as a backing layer. The dressing may be more accurately described as an absorbent gel-forming island dressing rather than a foam dressing.

Patients with venous ulcers ≥ 2.0 cm^2 but no larger that 11×15 cm were randomized to treatment for 12 weeks with Allevyn (n = 52) or Versiva (n = 55). Dressings were changed and compression bandages applied in accordance with the manufacturers' recommendations. Dressing performance was assessed at every dressing change and at the final evaluation. Healing rates in the two groups were not statistically different, 36% in a mean of 66 days for Versiva and 39% in a mean of 73 days for Allevyn Adhesive. However, the Versiva performed significantly better than Allevyn with regard to improvement in the condition of the periwound skin, 55% vs 37% respectively, ($p = 0.03$). Versiva was also more conformable than Allevyn, rated 'very good' to 'excellent' in 87% vs 75% of instances ($p = 0.05$). It was also more highly rated in terms of ease of application, 93% vs 81% ($p = 0.01$). The authors concluded that Versiva offers significant improvements in the quality of life of patients with venous leg ulcers as well as for their caregivers.

Sometime dressings are used with no expectation of achieving wound closure. Young[14] described how Allevyn Adhesive was used to cover a severe meningocele in a terminally ill infant and, by so doing, enabled the parents' focus of care to be diverted away from the problems of the wound during the baby's short life.

Most Allevyn references cited above relate to the original formulation of the dressing, not the version with the moisture reactive (high permeability) film backing layer introduced in 2006. White *et al*.[15] reported the results of the clinical in-market evaluation of this new preparation which took the form of an on-going multinational study with a target treatment population of 250 individuals. At the time of publication of the review 82 patients had been treated with various presentation of the new form of the dressing the performance of which equalled or exceeded that of the original, particularly in terms of absorbency and durability.

Young[16] also reported the results of an uncontrolled assessment of the new form of Allevyn which involved 113 patients 94% of whom expressed a favourable opinion of the dressing relative to their impressions of the original formulation.

Key points: clinical use of foam/film dressings

- Compared with traditional dressings such as paraffin gauze, polyurethane foam/film dressings reduce wound pain and decrease healing times in a variety of wound types.
- Foam/film dressings also compare favourably with alginate dressings in the treatment of drying wounds and against hydrocolloid dressings in exuding wounds.
- Clinical experience suggests that the dressings are also of value in the treatment of leg ulcers and pressure ulcers although much of the data available in not well controlled.
- One study suggests that when used in the treatment of leg ulcers, a foam/film dressing is slightly less effective than an alternative product (Versiva®) in terms of its fluid-handling characteristics.

4.3. Part 2: Soft-silicone technology

1.1.3. Role of adhesive dressings

In order to function effectively, a surgical dressing must be held in intimate contact with both the wound surface and the intact periwound skin.

Good contact with the wound bed is required to prevent exudate pooling beneath the dressing and good skin contact is required to prevent exudate escaping from the immediate vicinity of the wound and spreading over the adjacent healthy tissue.

The escape of wound fluid in this way may produce maceration, leading to infection, or even cause the wound to increase in size due to the activity of proteolytic enzymes sometimes present in chronic wound fluid. A dressing which forms an effective adhesive bond with the intact skin around the wound margin may inhibit or prevent the lateral spread of fluid altogether and thereby facilitate fluid uptake into the absorbent component of the dressing structure.

Historically, a variety of different adhesive systems have been used in the production of adhesive dressings and bandages including zinc oxide and acrylic-based systems. More recently, adhesives based upon ‘soft-silicone’ technology have become very popular as these can be tailored to provide vary degrees of adhesion. The principal benefit of this material is that it adheres readily to intact dry skin but does not stick to the surface of a moist wound. More importantly it does not cause damage upon removal.[17]

In a wound management context, the terms ‘adherent’ and ‘adhesive’ are sometimes incorrectly used interchangeably. This causes confusion and can lead to a misunderstanding of the properties of the products concerned. The term ‘adherence’, describe the interaction between a dressing and the wound, whilst the description ‘adhesive’ should be used to describe the interaction that takes place between the dressing and the intact periwound skin. Some products, such as island dressings, have a low-adherent pad located in the centre of an

adhesive retention layer, and can therefore be described as both low-adherent and adhesive.

To overcome the confusion sometimes caused by the inappropriate use of the two terms, a new category of dressings was proposed to describe products which, on removal, do not cause trauma either to newly formed tissue or to the periwound skin. It was suggested that such dressings be described as 'atraumatic dressings', a term that can be applied both to adhesive and non-adhesive dressings and one that more accurately reflects the overall characteristics of this product group.[18] Products coated with soft-silicone fall into this classification.

Key points: role of adhesive dressings

- Adhesive dressings facilitate dressing retention and reduce leakage of exudate.
- Adhesive dressings that adhere effectively to periwound skin may reduce maceration and may help to prevent infection.
- Products coated with a soft-silicone adhesive offer benefits over conventional adhesive systems because they can be removed without causing pain or trauma.

1.1.4. Products that incorporate soft-silicone technology

Although soft-silicone technology is now most commonly associated with adhesive dressings, the first product to exploit soft-silicone technology was Mepitel (Mölnlycke) a porous, semi-transparent, non-absorbent, wound contact layer consisting of a flexible polyamide net coated with soft-silicone. This material was initially designed to act as a non-adhesive, low-adherent wound contact layer as an alternative to the widely used paraffin gauze and knitted viscose fabric dressings in use at that time.

Although designed not to stick to the wound bed, the dressing was slightly tacky which facilitated its application. By modifying the composition of the silicone coating to increase its 'tackiness' it was found that soft-silicone could be also used as a skin friendly adhesive.

The first absorbent dressing to make use of this new adhesive system was Mepilex, an absorbent polyurethane foam/film dressing with a perforated soft-silicone adhesive wound contact layer. Subsequently Mepilex Border was introduced in form of an absorbent island dressing. The absorbent core of the bordered dressing consists of three components: a thin sheet of polyurethane foam, a piece of non-woven fabric, and a layer of super-absorbent polyacrylate fibres. The absorbent core is located centrally upon a larger piece of polyurethane film and is held in place by the perforated soft-silicone adhesive layer that extends to the outer margins of the dressing.

Although several other manufacturers have introduced similar products with soft-silicone adhesives, selling a total of approximately nine million dressings a year, Mölnlycke remain the major supplier with approximately 90% of a growing market currently estimated to be worth around £27m per annum. This widespread usage has largely resulted from the very effective marketing strategies of the companies concerned, in particular their emphasis upon

the ability of soft-silicone adhesives to reduce patient pain and discomfort.

Key points: usage of soft-silicone adhesives

- Products coated with soft-silicone adhesives have made a major impact on the dressings market and sales are estimated to exceed nine million units and be worth around £27m per annum.
- Their success is based upon the belief that the dressings reduce or eliminate the pain experienced by patients at the time of dressing changes.
- Such products have been described as 'atraumatic' dressings.

1.1.5. Results of experimental studies involving soft-silicone

When evaluating the performance of wound dressings insufficient attention is frequently given to parameters such as pain, maceration, trauma, and patient comfort. This is reflected in the results of a survey of 3,918 practitioners from 11 countries[19] which showed that the majority considered trauma prevention the most important factor to consider when changing dressings with pain prevention the second most important consideration. Those who responded considered that adherent products were considered the most important contributory factor to trauma caused during dressing changes.

The 'skin-friendly' properties of soft-silicone adhesives were investigated by Dykes and colleagues who described their results in a series of publications in which they compared the effects of removal of dressings bearing a soft-silicone adhesive with those bearing alternative adhesive systems on the structural integrity and function of the skin of volunteers.

The force required to detach samples of different dressings from the skin together with the degree of resultant damage was assessed in a two part study.[17] The first compared the effects of applying Duoderm Extra Thin, Mepiform Safetac (a product with a soft-silicone adhesive) and Tielle to the forearm of 12 normal volunteers aged 19-53 years. Using a skin staining technique the authors showed that removal of Mepiform Safetac was less damaging to the skin surface than the other products tested.

In the second part of the same study, the authors also recorded the peel force needed to remove adhesive dressings from prestained skin in 20 normal volunteers. The dressings used on this occasion were Allevyn Adhesive, Biatain Adhesive, Duoderm Extra Thin, Mepilex Border Safetac and Tielle. Three consecutive 24-hour applications of each product were made, and peel force readings recorded after each. The amount of dye remaining on the skin at 72 hours was assessed by the surface biopsy method. Statistically significant differences between products were observed in terms of both peak force and steady state force of removal.

This work was repeated in a modified form some years later when the discomfort occasioned by removal of six dressings was investigated in 24 volunteers.[20] Allevyn, Biatain, Duoderm Extra Thin, Mepilex Border (soft-silicone adhesive), Tielle and Versiva were applied to the

lower back according to a randomization schedule and the force required to remove the dressings 24 hours later was recorded using a device which ensured the samples were removed at a constant speed and angle to the skin surface. The degree of discomfort experienced at each removal was assessed by the subjects themselves using an electronic visual analogue scale. Mepilex Border was given a significantly lower discomfort score ($p \leq 0.01$) by the subjects than the other dressings. There were no clear differences between the five other products tested. Tielle and Allevyn Adhesive developed a significantly higher ($p \leq 0.05$) peel force than the other products.

In a final study,[21] the effect of repeated application and removal of samples of the adhesive edges from the same range of dressings on cutaneous irritancy and barrier function in 30 normal volunteer subjects was investigated using a repeat-insult patch test. Samples were applied continuously to the same site (six applications over a 14-day period. The test sites were assessed clinically before product reapplication using established ranking scales for cutaneous erythema. The cumulative irritancy score (CIS) for each test site was determined by adding the erythema scores at days 3, 5, 8, 10, 12 and 15. The barrier function of each test site was assessed at the end of the study by measuring transepidermal water loss (TEWL). The CIS results revealed showed that the products fall into two distinct groups. Allevyn, Mepilex Border and Tielle produced low scores and Biatain, Comfeel and Duoderm higher scores. Statistical analysis confirmed significant differences ($p < 0.05$) between Mepilex and Biatain, Mepilex and Comfeel, Mepilex and Duoderm, Tielle and Biatain, Allevyn and Biatain. The mean TEWL values also indicated that the products fall into two distinct groups: Statistical analysis indicated that Allevyn, Mepilex and Tielle were not significantly different from normal skin ($p < 0.05$), but Biatain, Comfeel and Duoderm were significantly higher than normal skin and the other products tested. These results might perhaps have been predicted as the higher scoring products are hydrocolloid-type dressing which are much more occlusive in their intact state. This would inevitably have the effect of increasing the moisture content of the skin which would then return to normal once the dressings were removed.

Zillmer *et al,*[22] also investigated effect of repeated removal of four different adhesive dressings on peri-ulcer skin using quantitative non-invasive techniques. Forty-five leg ulcers patients were included and peri-ulcer skin was treated for 14 days with patches of two different hydrocolloid-based adhesive dressings, one polyurethane adhesive and one soft-silicone adhesive dressing. Normal skin on the patients' ventral forearm was similarly treated. The patches were replaced every second day and the skin barrier function was assessed by measuring transepidermal water loss and stratum corneum hydration by measuring electrical conductance. Thirty-nine patients completed the study. The hydrocolloid adhesives increased transepidermal water loss and conductance while the polyurethane and soft-silicone adhesives did not influence these parameters significantly compared with adjacent non-treated peri-ulcer skin. For normal forearm skin, similar relative effects among the four adhesives were found. Repetitive treatment with hydrocolloid-based adhesive dressings induced major functional alterations of the stratum corneum. In contrast, a polyurethane adhesive and a soft-silicone adhesive dressing did not alter transepidermal water loss or conductance of peri-ulcer skin. Once again, these results might have been predicted as hydrocolloids have a much lower moisture vapour transmission rate than the foams. This would almost inevitably result in an increase in the moisture content of the skin.

Key points: experimental studies with soft-silicone adhesives

- In controlled studies, products coated with soft-silicone adhesives cause less pain and trauma upon removal than other types of adhesive dressings
- They also appear to have less deleterious effects upon skin barrier functions as measured by TEWL following single and repeated replacement.

1.1.6. Clinical experience with soft-silicone low-adherent dressings

Soft silicone: use in paediatrics

The reduction in pain commonly attributed to the use of silicone dressings suggests that they could play a valuable role in paediatric wound management. Two published studies compared Mepitel with silver sulphadiazine (SSD) in treatment of burns and scalds. Gotschall *et al*.[23] concluded that 'the use of Mepitel represents a significant advance in the treatment of partial-thickness burns in children' and Bugmann *et al*.[24] found removal of Mepitel to be was easy and atraumatic.

Hand injuries are common in children and can represent a source of considerable pain and stress. In a prospective randomized trial, O'Donovan *et al.*[25] compared Mepitel with paraffin gauze in the treatment of 45 children with isolated fingertip injuries. Although no differences were found in healing rates, important statistically significant differences were recorded in both adherence of the dressing and the stress exhibited by the patient over the first three weeks of treatment, leading the authors to conclude that Mepitel dressings offers a less painful and easier alternative to traditional dressings for this indication.

In a second paper involving the management of hand wounds, Mepitel was compared with paraffin gauze and Adaptic.[26] A total of 108 patients undergoing hand surgery were recruited to the study and randomly assigned to treatment with one of the three products under examination. The selected primary dressing was covered with gauze and a crepe bandage together with a plaster of Paris splint as appropriate. The dressing was left intact until the first follow-up appointment. The performance of each dressing was judged in terms of ease of application and removal, amount of blood on secondary dressing, appearance and condition of the wound and pain experienced during dressing removal. Removal of Adaptic and Mepitel was reported to be 'very easy' for 88% and 84% of wounds respectively, compared to 57% of wounds dressed with paraffin gauze. This difference achieved significance for Adaptic but not Mepitel. Pain scores were also lower for Adaptic-treated patients, 75% of whom experienced no pain compared to 56% for Mepitel and 51% for paraffin gauze. All dressings were more difficult to remove from raw tissue and although Mepitel appeared to perform better than the other products in this situation, insufficient numbers of subjects with this type of wound prevented further analysis. The reason for the relatively poor pain scores achieved with Mepitel was discussed by the authors who suggested that this was probably due to the dressing adhering to the intact but bruised or injured skin around the wound. The authors

concluded that of the three dressings, Adaptic had significant advantages over the other products examined in terms of performance and cost, and recommended it as the dressing of choice for this particular application. Mepitel, they suggested, could be used with advantage on wounds such as raw nail beds, as reported some years earlier by Williams,[27] who also described its use following traumatic amputation of the fingers, and in the treatment of a dehisced abdominal wound.

Vloemans and Kreis,[28] in an open prospective study, evaluated Mepitel as an alternative to conventional treatments including paraffin gauze, for the fixation of skin grafts in children. With Mepitel they found that changing the outer absorbent dressing was painless, as was the final removal of the dressing itself, requiring no analgesia or anaesthesia. Graft take rates were good; in 42 out 45 cases the take was almost complete (> 95%). Because the dressing requires a margin of healthy skin, its use was limited to minor skin grafts (maximum 6% of the total body area) and the authors suggested that it could only be used on flat or convex areas; on concave areas firm fixation is either difficult or impossible.

Platt *et al*.[29] also compared Mepitel with paraffin gauze as the first dressing layer applied to 38 newly grafted wounds in a prospective randomized trial. At the first postoperative dressing change all patients in the paraffin gauze group experienced some degree of pain on dressing removal. In contrast, 53% of patients dressed with Mepitel experienced no pain.

Soft-silicone following radiotherapy

Adamietz *et al*.[30] in a prospective study involving 21 patients evaluated Mepitel as a method of protecting skin during radiotherapy for malignant disease. In seven of the patients treated the skin was intact, but five patients had epithiliolysis, and nine patients had ulcers, seven of which were malignant. The silicone-coated net was shown to cause no additional irritation of irradiated skin and it was suitable for the treatment of both dry desquamation and the moist desquamation that occurs with high doses of radiation. This latter condition is particularly difficult to manage with conventional dressings as the skin is very fragile and easily damaged by the removal of dressings that can adhere to the drying serous fluid on the skin surface. When applied over ulcerative wounds, the dressing was easy to remove and did not cause damage to the newly formed epithelium.

Soft-silicone dressings: miscellaneous applications

The use of Mepitel has also been described in wounds resulting from wide local excision of skin tumours[31], severe mycosis fungoides Taylor[32] and a progressive skin tumour, which resulted in the formation of extensive ulceration over her scalp, neck and back. Gates,[33] similarly described how the dressing reduced the pain from an extensive arterial leg ulcer and improved the condition of the surrounding skin.

Mepitel is said to be particularly useful in the management of the genetic skin disorder, epidermolysis bullosa (EB), both for the treatment of intact blisters and areas where the epidermis has been lost. This is because it stays in place and prevents the type of frictional damage that can occur as a result of dressing slippage.

Other reported applications for the use of silicone dressings include urethral erosions in the male patient, a known but poorly documented sequelae of catheter injury,[34] and in skin tears.[35]

Key points: clinical studies on soft-silicone adhesives

- Clinical experience with low-adherent dressings coated with soft-silicone adhesive supports the findings of experimental studies.
- Dressings produce less pain upon removal, and are particularly useful for paediatric patients and those with fragile skin.

4.4. Part 3: Clinical experience with foam/film coated with soft-silicone adhesive dressings

Numerous publications have described the use of foam/film dressings coated with soft-silicone adhesive. Viamontes *et al.* first compared standard Allevyn Adhesive with Mepilex Border in a retrospective review of data collected in 'real time' in a database containing treatment details of nursing homes patients over a one year period in order to determine the incidence of skin stripping of periwound skin, wound healing rates and pain.[37] Data collected from 403 evaluable wounds in 206 patients was analysed. Evidence of skin stripping was detected following the use of both products, in 5% (5/106) patients dressed with Allevyn and 4% (4/100) in patients dressed with Mepilex Border. Closure rates achieved with the two dressings were similar. Independent nurse evaluations highlighted the failure of the self-adherent soft-silicone foam dressing to either initially adhere to the wound area, or to remain in contact for more than a few days, as the dressing frequently needed the application of additional tape to ensure adhesion. They reported that the failure of the self-adhesive soft-silicone foam dressing to adhere effectively to the periwound area was a significant disadvantage and a disincentive to use this type of dressing routinely.

In their second study, [38] using the same methodology they review clinical data, collected over a 5-year period (1997-2002) which identified 1,891 residents with 4,200 wounds who had been treated with the products in question in 30 nursing homes in the state of Florida. The data collection period was chosen to capture a change in wound dressing regimens in these nursing homes which occurred in 2001. Patient demographic and wound assessment variables, including evidence of surrounding skin stripping, were abstracted from the database. Of the 4200 relevant wounds, 3795 (90%) were treated with Allevyn Adhesive, 352 (8%) with Mepilex Border and 53 (1%) were treated with both dressings at some points. Of the 3,795 wound treated with the Allevyn Adhesive, 3,579 (94%) were pressure ulcers (mainly Grade II of Grade III), as were 339 of 352 wounds dressed with Mepilex Border and 51 wounds managed with both dressings. Wounds in the Allevyn group were larger, (7.53 *vs* 5.5 cm^2) and took longer to heal than those in the Mepilex group, (70.1 *vs* 39.2 days) but the proportion of ulcers healed was the same in both groups, (63%). Skin stripping was rare with either dressing occurring in less than 1% of wounds. Problems with infection occurred more frequently in the Mepilex Border group (9%) than in the Allevyn Adhesive group (3%). The authors, whilst acknowledging the limitations of retrospective studies, once again concluded that periwound skin stripping is uncommon and that differences between the two products are minimal. As in the previous study it was reported that the dressings using

soft-silicone technology tended to adhere less well, requiring the use of tape to retain the dressing firmly in place. This failure was considered a significant deterrent to staff to use this type of dressing routinely.

Woo *et al*.[39] compared Mepilex Border with Allevyn Adhesive in a prospective randomized crossover study designed to recorded pain at dressing change. Subjects were randomized to receive one of the two foam dressings for the first two scheduled follow-up visits. On the third visit the local wound treatment was changed to the alternative product for a further two dressing changes. Pain was measured using a visual analogue scale and standard questionnaire. A total of 32 patients entered into the study, and 26 patients completed all 5 follow-up study visits. Results indicated statistically lower levels of pain both before and during at dressing removal. Periwound maceration was also significantly less with the soft-silicone adhesive dressing.

Meaume *et al.* [40] similarly reported a favourable outcome for the use of Mepilex Border when they compared it with Tielle, another widely used foam dressing, in a randomized controlled trial involving 38 patients with Stage II pressure ulcers. Wounds were evaluated at baseline and weekly for 8 weeks or until completely healed for a number of parameters which included wound size, presence of granulation, epithelialization, exudate, signs of inflammation, damage to tissue (bed, edge, surrounding skin), maceration, odour, leakage, number and ease of dressing changes. Damage to tissue was defined as any damage to the wound bed, edge, or surrounding skin caused by the adhesive; maceration was defined as the softening and breaking down of skin resulting from prolonged exposure to moisture. They reported that although they found no significant difference in healing rates, the soft silicone coated product was superior to the control with a conventional adhesive with regard to tissue damage and ease of dressing removal.

MacBride *et al.,*[41] used a silicone dressing, Mepilex Lite, to treat areas of dry and moist desquamation in 16 patients following radiotherapy. Some patients found that the dressing minimised pain during dressing changes and was easily lifted and adjusted without loss of adherent properties. Its use was also reported to produce a soothing or cooling effect in some patients and a number reported a more normal sleep pattern. No negative effect on wound healing were observed leading the authors to conclude that the dressing offers a useful alternative to existing therapies which is worthy of further research.

Cunningham in 2005 [42] presented a case study in which a thin foam dressing coated with soft-silicone adhesive but without an integral backing layer (Mepilex Transfer) was successfully used to treat patient with painful leg ulcers who had experienced significant pain with previous forms of therapy.

Key points: Foam/film dressings with soft-silicone adhesives

- Overall clinical experience with low-adherent dressings coated with soft-silicone adhesive tends to support the findings of experimental studies in that they appear to minimise pain and trauma upon removal, although some authors appear to have experienced less positive outcomes with these materials, recording problems experienced with the retention of the soft-silicone dressings..

5. CONCLUSIONS

The results of this review strongly support the proposition that both adhesive and non-adhesive dressings made from polyurethane foam with a polyurethane film backing have an important role to play in the management of many types of exuding wounds.

The value of these dressings, particularly with regard to patient acceptability, appears to be enhanced when the adhesive system used is based upon soft-silicone technology.

It is the opinion of the author that the evidence available suggests that the new Cilguard range should be broadly equivalent to existing dressings of this type in terms of their physical properties and clinical performance.

Signed _____ 20th December 2010

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