EXPERT PANEL REPORT

An expert panel report: Key considerations when using wound contact layers with negative pressure wound therapy (NPWT)

Wounds UK

PUBLISHED BY:
Wounds UK
1.01 Cargo Works
1–2 Hatfields
London SE1 9PG, UK
Tel: + 44 (0)20 7627 1510
Fax: +44 (0)20 7627 1570
www.wounds-uk.com

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FOREWORD

This document is a practical guide for wound care clinicians using wound contact layers in conjunction with negative pressure wound therapy (NPWT), such as specialist nurses, district nurses, practice nurses, general practitioners, and podiatrists.

A survey and subsequent focus groups were conducted, including specialist wound care clinicians from across the UK, which highlighted the need for increased guidance in this area.

This Expert Panel Report provides an introduction to this issue, summarises the results of the survey and focus groups, and makes practical recommendations for future practice, based on the opinion of an expert working group of key opinion leaders.

EXPERT WORKING GROUP
Emma Bond Vascular Clinical Nurse Specialist, Glan Clwyd Hospital, North Wales
Gemma Davies Tissue Viability Lead Nurse, Shrewsbury and Telford Hospital NHS Trust
Julie Evans Tissue Viability Nurse, Abertawe Bro Morgannwg University Health Board
Joanne McCardle Podiatry Research Fellow, Royal Edinburgh Infirmary
Jane Nicoll Lead Tissue Viability Nurse, NHS Fife
Joy Tickle Tissue Viability Specialist, Shropshire Community NHS Trust

Understanding negative pressure wound therapy

Negative pressure wound therapy (NPWT), also referred to as topical negative pressure therapy, is a useful treatment to aid healing in a variety of acute and chronic wounds.

NPWT can be considered when the wound:

- is not progressing towards healing in the expected time frame (e.g. the wound edges are slow to contract using standard care)
- produces excessive exudate that is difficult to manage
- is in an awkward location, so that achieving an effective seal with traditional dressings is problematic
- requires reduction in size to achieve surgical closure (Henderson et al, 2010).

NPWT involves achieving an airtight vacuum seal, and applying negative pressure (suction) to the wound bed through a foam or gauze contact medium using an electrically, battery or mechanically powered pump.

Negative pressure can be intermittent or constant, using either a portable or stationary pump, exerting a sub-atmospheric pressure that is dependent on the chosen device and clinician's preference (Cutting et al, 2013). The negative pressure is transmitted to the wound surface through tubing that is connected to either a flexible dome or a wound dressing that is either foam sponge or gauze material (Sullivan et al, 2009).

The therapeutic effects of NPWT are based on the premise of two underpinning theories:

1. The vacuum created assists in the removal of excess interstitial fluid, which leads to a decrease in oedema and thus promotes local perfusion (Lee et al, 2009), together with the removal of the exudate, which assists in lowering the concentrations of damaging inhibitory factors (Thompson, 2008).
2. The stretching and deformation of the tissue by the negative pressure may disturb the extracellular matrix, resulting in the release of a variety of intracellular messengers (Saxena et al, 2004; Morris et al, 2007); intracellular messengers regulate protein production and thus influence the formation of granulation tissue.

There is a plethora of clinical evidence supporting the use of NPWT and its benefits, both for patients and the healthcare system. Reported benefits of using NPWT include:

- Increased local blood flow to the wound through increased dilation of arterioles
- Reduced tissue oedema through the removal of excess fluid
- Stimulation of granulation tissue, resulting in progressive wound closure
- Stimulation of cell proliferation
- Removal of free radicals from the wound
- Debridement/removal of slough
- Reduction in wound volume
- Protection from outside contaminants
- Decrease in wound bioburden
- Maintenance of a moist wound healing environment
- Reduced wound bed trauma due to less frequent dressing change (Fletcher et al, 2012).

NPWT USED IN CONJUNCTION WITH WOUND CONTACT LAYERS

In a variety of clinical conditions, wounds treated with NPWT require the use of a wound contact layer. Where necessary, this provides an interface between the cavity and the wound filler (i.e. foam or gauze). NPWT is contraindicated in wounds where the device is positioned directly over exposed organs, large veins and arteries, anastomotic sites, tendons, bone or nerves,

necessitating the use of a wound contact layer in such cases. Although wound contact layers should be used in conjunction with NPWT where required (Barrett, 2012), it is crucial that this is carried out correctly.

Wound contact layers are placed between the wound bed and the wound filler. They serve multiple purposes in supporting the granulation process, protecting the vulnerable area, and helping prevent new tissue from growing into the wound filler as well as protecting new tissue structures (Chadwick et al, 2010). Using a wound contact layer also helps to reduce pain and trauma when the wound filler is changed (Upton et al, 2012).

If a wound contact layer interface is not used, the high suction forces delivered at the wound site (between –80mmHg and –200mmHg) will increase the risk of adhesion between the wound bed and the filler. Adhesion may cause damage to newly formed and delicate tissue, which may in turn lead to delayed wound healing (Mölnlycke Health Care Survey, Wound contact layers with NPWT, Sept–Nov 2015).

However, not all wound contact layers can be safely used with NPWT. In order for it to be used with NPWT, a wound contact layer must meet specific requirements, which are prerequisites for the release of the CE mark (which shows that a medical device is fit for its intended purpose and meets safety legislation [MHRA, 2015]) and the subsequent labelling of the medical device for that specific indication according to the instructions for use. The majority of wound contact layers currently available in the market do not meet the requirements to be labelled for use with NPWT.

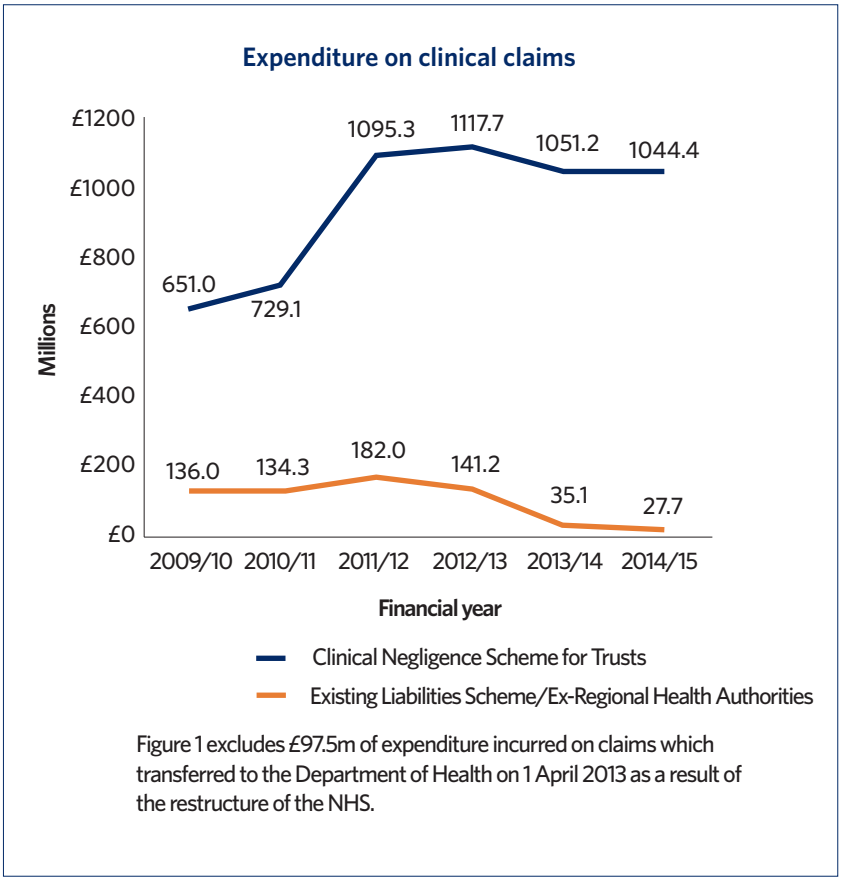
Importantly, this crucial area still requires highlighting in clinical practice. The lack of knowledge in this area opens up potential problems for both practitioner and patient. Incorrect use of wound contact layers in conjunction with NPWT may be associated with impaired delivery of NPWT and delayed healing, resulting in time and cost increases as well as impacting upon the wound healing process.

In addition, using medical devices off-label may result in legal and practical implications. From a legal and regulatory perspective, manufacturers cannot support off-label use, and as a result are legally unable to support practitioners in such cases (e.g. in the case of adverse reactions, incidents or patient issues) – meaning that the responsibility lies solely with the practitioner. Manufacturers explicitly state that if a product is not specifically intended for this use, they cannot guarantee patient safety or protect clinicians from an increased risk of litigation.

During 2014/15, the NHS paid over £1.1 billion in total to patients who suffered harm and to their legal representatives (NHS Litigation Authority, 2015); see Figure 1. This is a figure that has increased substantially over recent years and is set to continue to rise (NHS Litigation Authority, 2015).

Litigation is a significant and growing issue, now more than ever, that all practitioners and institutions need to consider: the NHS has called for 'increased focus on safety and learning, transferring back into the NHS our experience of what has caused harm to patients and what might be done to achieve reductions in harm and the cost of harm' (NHS Litigation Authority, 2015).

Figure 1: NHS expenditure on clinical claims (NHS Litigation Authority, 2015)



Wound contact layers and NPWT: the current state of clinical practice

A survey (supported by Mölnlycke Health Care) was sent to clinicians across the UK during October–November 2015, in order to gauge the current state of clinical practice regarding the use of wound contact layers in conjunction with NPWT. The 120 respondents were from multi-disciplinary teams – primarily tissue viability nurses (TVNs) – and were all experienced users of NPWT.

From the results, it was apparent that this is an area that requires highlighting and may involve serious and growing implications if not addressed appropriately. Subsequently, a series of focus groups was carried out with specialist wound care clinicians to analyse and discuss the results in more detail, and to formulate practical strategies to tackle the problems highlighted by the survey responses.

KEY FINDINGS

To gauge the extent of the problem, clinicians were initially asked what percentage of wounds being treated with NPWT require a wound contact layer to be used. The overall consensus was that approximately 40% of all wounds being treated with NPWT require the use of a wound contact layer. In order to further define this figure, respondents agreed that approximately 71% of foam-treated wounds require a wound contact layer, compared to only 13% of gauze-treated wounds.

The main reasons for using a wound contact layer in conjunction with NPWT, according to clinicians in practice, were:

- To protect tendons, bones or nerves
- To protect exposed organs
- To protect large veins and arteries
- To allow easy removal of the foam
- To prevent adhesion/adherence to the wound bed
- To prevent tissue ingrowth
- To help avoid pain at removal
- To protect sensitive wound bed
- To protect flaps.

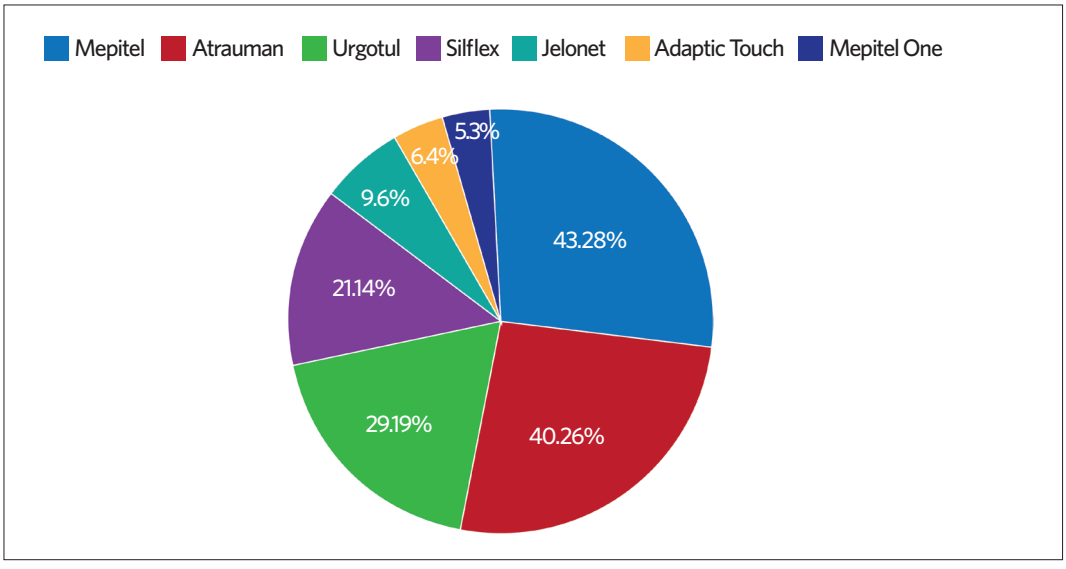
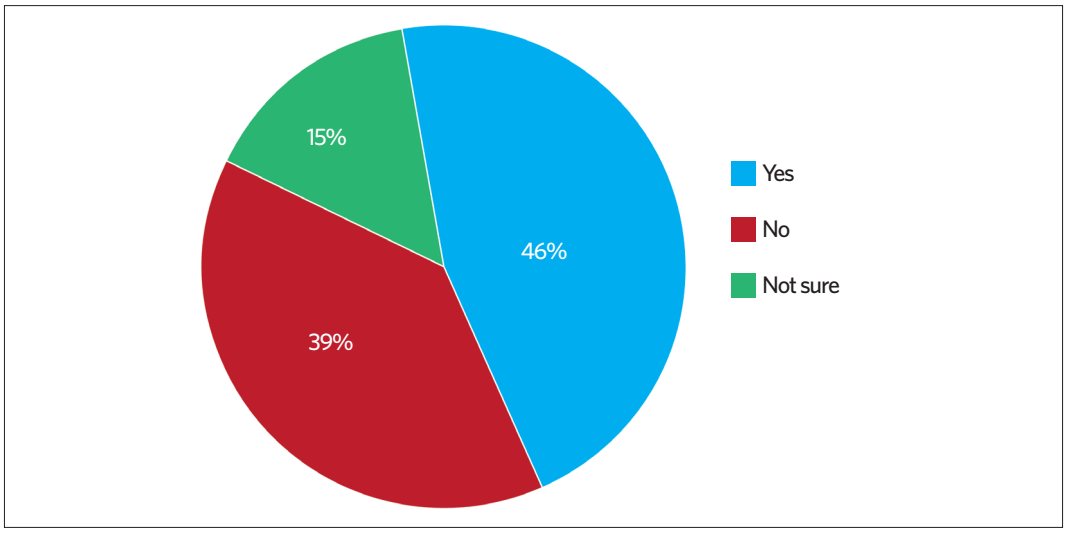


Figure 2: The wound contact layer products used by clinicians in conjunction with negative pressure wound therapy (NPWT)

Figure 3 Are you aware if your wound contact layer is indicated for use with NPWT?



When surveyed about use of wound contact layers in conjunction with NPWT, clinicians reported using a wide range of different products (see Figure 2 for details). As such, clinicians reported the specific problems that they had encountered in using wound contact layers in conjunction with NPWT. The most common problems were:

- Adhesion to the wound bed
- Pooling of exudate at the wound site
- Damage to delicate structures (i.e. organs, blood vessels, tendons, bones and/or nerves)
- Pain.

In turn, the potential clinical implications of these issues were suggested as being:

- Damage to newly formed tissue, leading to delayed wound healing (risk of damage to underlying structures – e.g. potential risk of haemorrhage)
- Impaired delivery of NPWT, leading to less effective treatment and clinical outcomes
- Increased costs
- Reduced patient compliance.

It was also noted that any increased healing times will have a knock-on effect, with consequences such as increased costs and increased need for corrective actions. Additionally, increased complications may have an effect on patients, such as reduced concordance and issues connected to pain on dressing change if the correct product is not used.

Addressing the problem: clinicians' recommendations

The fact that inappropriate usage of wound contact layers with NPWT is clearly a widespread and underreported problem was highlighted for further discussion, both in a practical patient-led sense and in terms of the potential financial and time-associated repercussions.

The specialist clinicians agreed that experienced practitioners should – in an ideal scenario – be able to use their own knowledge and skills to make a judgement about which wound contact layers should be used in the specific clinical situation. However, it must be acknowledged that it is crucial for practising clinicians to realise that this is their sole responsibility – i.e. companies and manufacturers of products cannot take any responsibility for clinicians not using the appropriate wound contact layer correctly.

As such, the issue of litigation was also highlighted as a crucial factor affecting current practice and that it is vital for clinicians to be aware of this and the potential effects and consequences.

The clinicians' recommendations for addressing the problem focussed on education and raising awareness, as well as ensuring that practitioners have access to the correct resources and products.

It is vital that clinicians are aware of the risks and the potential legal implications of incorrect usage, through education and clear guidance. Education is also required regarding the potential knock-on effects of incorrect usage and less effective treatment, resulting in delayed healing and, in turn, increased costs and time-related issues.

Specific strategies suggested to address the problem included:

- Development of clear guidelines for the use of wound contact layers with NPWT
- Formulary decision making – ensuring that a wound contact layer approved/suitable for use with NPWT is included in the formulary
- TVN and specialist podiatry leadership – developing multi-professional and holistic patient pathways
- Inclusion of wound contact layers in the NPWT dressing pack – 90% of clinicians agreed that this would be a useful step in ensuring correct usage in future.

Clinicians acknowledged that choice of wound contact layers appropriate for the clinical scenario can be limited by practical barriers, such as cost and availability on formulary, indicating a need for further action in this area.

The survey highlighted the need for an increased evidence base to support clinical practice, in conjunction with specific education and training on the subject to improve clinicians' knowledge. As well as case studies and practical evidence, formal trials are necessary to improve the state of practice. For existing information and clinical evidence surrounding the issue of NPWT in conjunction with wound contact layers, please see Table 1.

TABLE 1: Evidence for wound contact layers used in conjunction with negative pressure wound therapy (NPWT)	
Publication	**Main findings**
Banwell (1999) Topical negative pressure therapy in wound care (literature review)	■ Results suggest 'dramatic improvements in wound healing rates' when NPWT is used ■ It is vital to develop standardised protocols and ensure cost-effectiveness, using a correct wound contact layer
Dunbar et al (2006) Silicone net dressing as an adjunct with negative pressure wound therapy	■ NPWT is 'invaluable' in treating complex wounds ■ Using a suitable wound contact layer optimises treatment and reduces pain ■ Mepitel was used as wound contact layer and found to effectively handle drainage and allow optimal granulation
Jones et al (2005) Interface dressings influence the delivery of topical negative pressure therapy	■ Commonly used off-label dressings at the foam/wound interface may alter pressure and compromise delivery of therapy
Muller et al (2008) Craniofacial necrotizing fasciitis: reconstruction after radical surgery	■ NPWT with a suitable wound contact layer (Mepitel) was used to create a 'significant and viable' layer of granulation tissue, which could then be covered with split skin grafts
Nordmyr et al (2009) Vacuum assisted wound closure in patients with lower extremity arterial disease	■ NPWT with a suitable wound contact layer (Mepitel) was associated with high healing rates ■ Non-healed wound after NPWT were predictors for amputation and death
Poulakidas (2008) Facilitating residual wound closure after partial graft loss with vacuum assisted closure therapy	■ The combination of NPWT with VAC Granufoam Silver in conjunction with Mepitel was found to promote healing ■ In selected cases, this method may allow for less graft loss and earlier wound closure
Terrazas (2006) Adjuvant dressing for negative pressure wound therapy in burns	■ NPWT is an effective adjunct to burn treatment ■ A suitable wound contact layer is recommended to alleviate pain

Addressing the problem: practical solutions

The issues highlighted by the specialist clinicians require implementation of practical strategies, in order to alleviate the problem of inappropriate wound contact layers being used with NPWT.

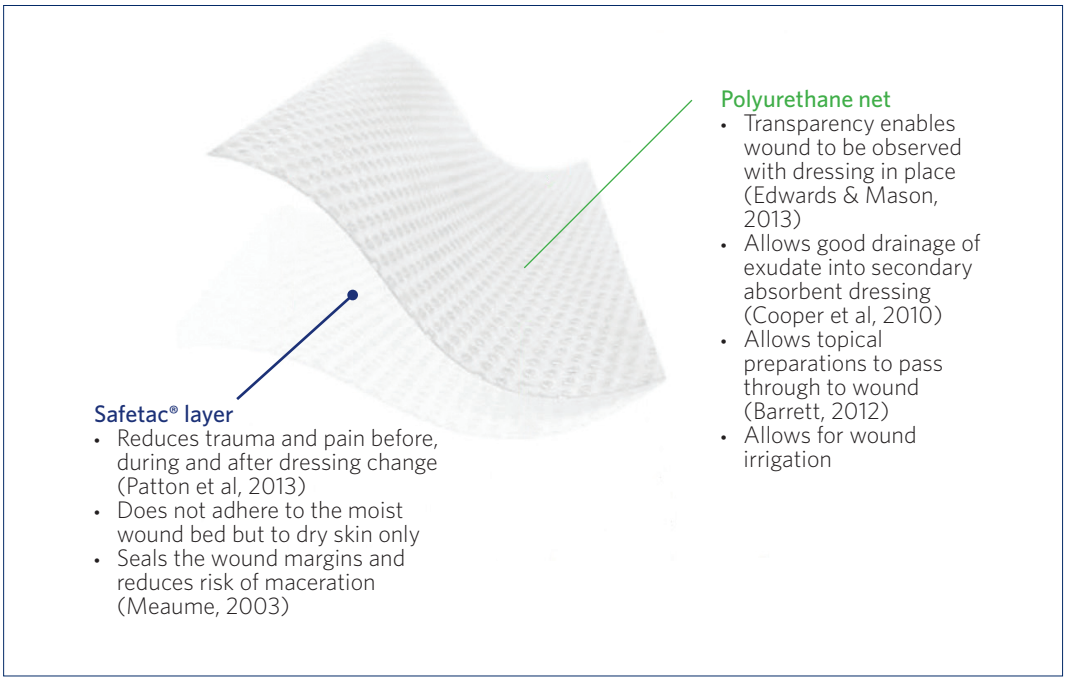
Mepitel® and Mepitel® One (Mölnlycke Health Care) are wound contact layer products that are suitable and intended for safe use in conjunction with NPWT. The safety and suitability of Mepitel and Mepitel One have been tested and validated for use with any NPWT device, resulting in a clear indication in the Instructions for Use (CE marked approved).

MEPITEL ONE

Mepitel One is a one-sided silicone wound contact layer that effectively protects the peri-wound skin and the wound bed (see Figure 4 for the dressing's construction and mode of action).

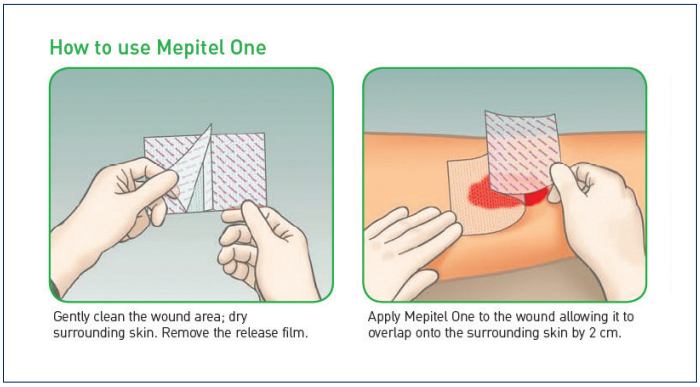
Mepitel One is indicated for use with Avance® (Mölnlycke Health Care) or other NPWT systems. The product can be utilised to protect exposed organs, large veins and arteries, tendons, bones or nerves from the risk of dressing adherence and tissue ingrowth during treatment with NPWT. See Figure 5 for instructions on how to use the product.

Figure 4: Construction and mode of action of Mepitel One



Mepitel One incorporates Safetac® on its wound contact surface. Based on patented soft silicone technology, Safetac confers upon Mepitel One the ability to adhere to intact dry skin but not to a moist wound bed, thereby permitting atraumatic and pain-free removal (Patton et al, 2013). The Safetac layer also seals around the edges of the wound, thus minimising the risk of maceration by preventing exudate from leaking onto the surrounding skin (Meaume et al, 2003). The porous structure of Mepitel One allows exudate to pass through it into an outer absorbent dressing (Cooper et al, 2010).

Figure 5: How to use Mepitel One



When Mepitel One is used in conjunction with the Avance NPWT system, it should be changed every 48 to 72 hours, but no less than three times a week or as instructed by the clinician. When Mepitel One is used in conjunction with other NPWT systems, follow the clinician's recommendation regarding frequency of change.

CLINICIAN PERSPECTIVE

The expert clinicians discussed Mepitel One during the focus groups, and agreed anecdotally that Mepitel One is an ideal choice for use in conjunction with NPWT. The one-sided silicone technology provides superior ease of handling, allowing for ease of application and secure fixation onto the wound bed (Patton et al, 2013). The one-sided mesh also minimises the risk of adherence to the NPWT wound filler (i.e. foam or gauze dressing), thus facilitating dressing changes.

Specific points mentioned included that Mepitel One has 'the correct perforation size', which enables optimum exudate management properties. The open mesh of Mepitel One is designed for optimum fluid drainage and allows the exudate to pass through the dressing (Hulten, 2010; Buggmann, 1998) and be transferred into the canister tubing (Meuleneire, 2012). It was also commented that it is 'less tacky' than other wound contact layer product options in general use, thus resulting in less or no pain on removal. In addition to its mode of action and atraumatic removal, specific factors that were commented upon were the benefits of the dressing's transparency and wear time. The products are also available in 'a good range of sizes'. It was also noted that they provide a cost-effective as well as clinically effective solution. For the key product features and clinical benefits, see Table 2.

TABLE 2. KEY PRODUCT FEATURES AND CLINICAL BENEFITS OF MEPITEL ONE

Product feature	**Clinical benefit**
One-sided silicone mesh	Easy to apply and remove (Patton et al, 2013)
Correct perforation size and open area	Optimum exudate management properties (Hulten, 2010; Buggmann, 1998) Reduced risk of maceration (Meuleneire, 2012)
Thin mesh	High conformability Less risk of impacting the set level of pressure (Jones et al, 2005)
Transparency	Wound inspection with dressing in place (Edwards and Mason, 2013)
Atraumatic at removal	Effective protection of underlying structures (Barrett, 2012) Less disruption to the newly formed tissue and undisturbed wound healing (Rippon et al, 2012) Reduced patient pain (Patton et al, 2013)

Case studies

A case study series (Acton, 2010) investigated the use of Mepitel One in conjunction with NPWT and tracked the progress of four wounds using the dressing, including three abdominal wounds and a foot amputation wound.

In the study, the wounds were dressed with Mepitel One and treated with NPWT. At each visit, the wounds were assessed and the performance of the dressings rated. All the patients were between 50–65 years of age, had underlying diseases including type 2 diabetes and suffering from infected surgical wounds. At each visit, the wounds were assessed and the performance of the dressings rated (on a scale from 'very bad,' 'bad,' to 'good' or 'very good').

In all cases, Mepitel One was rated as 'very good'. Of the four cases, three wounds reduced in size during the study, while the other could not be measured. All the wounds exhibited good healing progression. At the final visit evaluations, the dressing was rated very highly in terms of lack of pain experienced, patient comfort, ease of use, and conformability.

The study found that the one-sided self-adhering wound contact layer Mepitel One, when used in combination with NPWT, improved wound healing compared to previous treatments. The dressing had no adverse effects on the performance of the NPWT system. Mepitel One was found to minimise wound-related pain, especially during dressing changes. The dressing was easy to apply and remove from the wound area, with no sticking to gloves.

The study concluded that Mepitel One used with NPWT showed very good wound healing and excellent overall performance. See Box 1 for further details of the study.

CASE STUDY RESULTS USING MEPITEL ONE IN CONJUNCTION WITH NEGATIVE PRESSURE WOUND THERAPY (ACTON, 2010)

CASE 1

Wound history: Surgical wound of the abdomen (midline). The wound showed infection and dehiscence post operatively
Underlying disease: Type 2 diabetes
Wound size (baseline): 7 x 4 x 5cm
Age of wound: 20 days
The wound was treated for 11 days with two evaluations; after this time, the patient was discharged home. During treatment, the condition of the wound improved, exudate levels decreased and the patient did not experience any sleep disturbance.

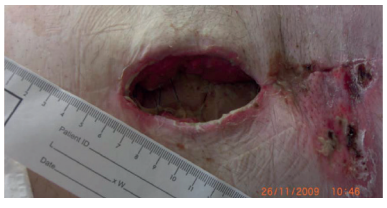


Figure 6: Case 1; wound before treatment

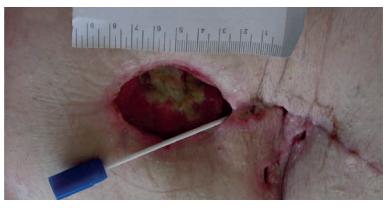


Figure 7: Case 1; after 11 days of treatment

CASE 2

Wound history: Surgical wound of the abdomen (midline). The wound showed dehiscence due to infection
Underlying disease: Type 2 diabetes and bowel cancer
Wound size (baseline): 9 x 5 x 5cm
Age of wound: 10 days
The wound was treated for 14 days with three evaluations. During that time, the wound condition improved, exudate levels decreased and the patient experienced reduced pain. Clinical signs of infection were also resolved.

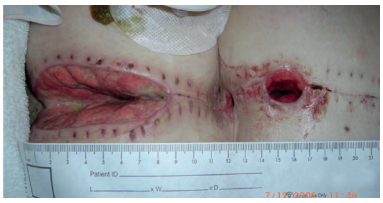


Figure 8: Case 2; wound before treatment

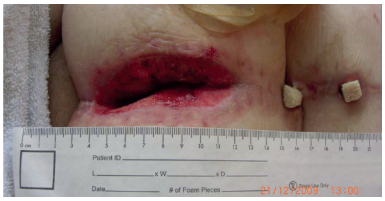


Figure 9: Case 2; after 14 days of treatment

CASE 3

Wound history: Surgical wound of the abdomen (left side). The wound had an abscess
Underlying disease: Type 2 diabetes and bowel cancer
Wound size (baseline): 10 x 4.5 x 6.5cm
Age of wound: 1 day
The wound was treated for 10 days and four evaluations. During that time, the wound condition improved, exudate decreased, wound pain was reduced and there was less pain on dressing removal. The clinical signs of infection were resolved.

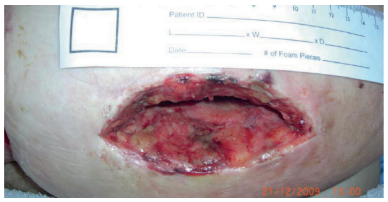


Figure 10: Case 3; wound before treatment

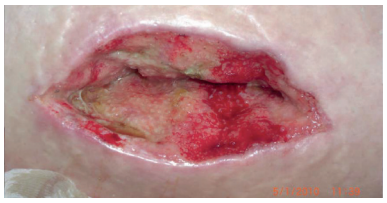


Figure 11: Case 3; after 10 days of treatment

CASE 4

Wound history: Surgical wound of the left forefoot. The wound resulted from a forefoot amputation undertaken due to infection
Underlying disease: Type 2 diabetes and arterial insufficiency
Age of wound: 2 days
The wound was treated for 13 days and three evaluations. During that time, the wound condition improved, wound pain was reduced and there was reduced pain on dressing removal.

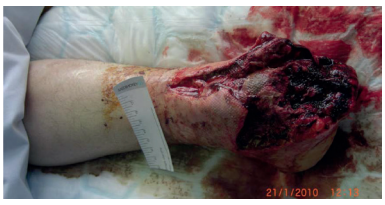


Figure 12: Case 4; wound before treatment

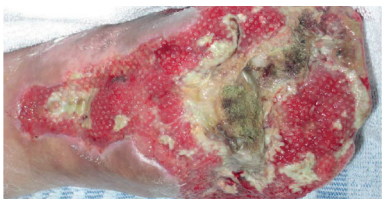


Figure 13: Case 4; after 13 days of treatment

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