AN EXPERT PANEL REPORT

Key considerations in choice of wound management therapeutics between an advanced wound care dressing utilising Hydration Response® Technology and a durable medical device (NPWT) – a USA perspective

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Key considerations in choice of wound management therapeutics – a USA perspective

KEY WORDS
- NPWT
- HRT dressing
- Wound bed preparation
- Exudate management

Wound healing is a dynamic process where the events of each phase occur in a precise and regulated manner. Wound management is also dynamic in nature but here the process is dependent on the clinician's ability to regulate the wound environment. Wound care therapeutics are constantly evolving and with the bewildering array of modalities that are now available it is often difficult to choose between approaches that are of a similar nature. This article focuses on an expert panel meeting that considered the clinical performance attributes of two wound care modalities – generic NPWT and an innovative wound care dressing (sachet S, sorbion GmbH & Co. KG) utilising Hydration Response® Technology (HRT) – in order to provide key considerations for selection.

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The primary considerations in any wound management situation include the patient, the wound and the wider environmental circumstances. Choice of modality must therefore include these considerations and not solely defer to tradition or familiarity of use. This necessitates keeping abreast of developments, including those of a clinical/practical nature and those whose provenance is research/academic in origin.

Globally, the choice of wound management options will vary but in many countries these will include advanced wound dressings together with a range of 'durable medical device' technologies. This vast range of options offers the clinician an array of alternatives and include innovative approaches to wound management that may have the potential to provide benefits both in terms of quality of life to the individual and cost efficiency for the healthcare provider/institution.

BACKGROUND

An initial series of clinical observations by a small number of clinicians who are experienced in the use of negative pressure wound therapy (NPWT) and HRT (sachet S) identified broad similarities in performance between the two modalities and prompted the construction of a 10 patient prospective observational study (Kwon Lee et al, 2009) where patients with a variety of exudative lesions received sachet S as the primary wound dressing. On average, patients were treated for a period of 23.1 days. The authors concluded that the clinical results indicate:

"Interesting similarities between sorbion sachet S and negative pressure wound therapy (NPWT): exudate management and wound bed preparation is the primary goal of NPWT and the way sorbion sachet S was shown to handle exudate, the improved wound conditions, the increase in percentage of granulation tissue and decrease of wound surface and volume, demonstrated in this evaluation, appear to be similar to what might have been expected had NPWT been used for the management of these wounds."

This stimulated the formation of a working group who met on 24th September 2010 in Anaheim, CA, USA. The broad aim of the expert panel meeting was to carefully consider the clinical performance attributes of generic NPWT and to critically examine how these properties compare with HRT (sachet S). An additional aim was to identify in which discrete circumstances NPWT or HRT would be recommended.

Expert panel

The working group consisted of internationally recognised experts (see Box 1) in wound management who met to share their experiences and to draw on their combined knowledge/experience to elucidate the nature of these performance similarities.

Box 1: Expert panel

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As part of their deliberations the expert panel first sought to clarify the competencies and limitations of NPWT and HRT. This process was followed by a discussion on clinicians' experience with each modality and led to the panel identifying not only the similarities in performance but also the nature of the performance overlap for both NPWT and HRT. It became apparent that each modality had a role to play in preparing the wound bed and, consequently, the components of wound bed preparation (WBP) were applied to NPWT and HRT.

In clinical/practical terms WBP in recalcitrant wounds targets wound management on three specific areas:

1. Managing exudate/oedema
2. Reducing the bacterial burden/debridement
3. Correcting the biochemical abnormalities that contribute to impaired healing.

NPWT

NPWT, also known as topical negative pressure therapy (TNP), is a topical treatment used to promote healing in acute and chronic wounds (Beldon, 2005).

Discussion on generic NPWT is justified in this document on the basis of a recent report (Sullivan et al, 2009) prepared for the Agency for Healthcare Research and Quality that stated it was not possible "to identify a significant therapeutic distinction of one NPWT system or component over another through the use of head-to-head comparisons."

Typically NPWT comprises: a negative pressure generating device (vacuum pump), which often incorporates an alarm warning of loss of negative pressure; tubing and a collection canister; a wound drape or film to create a seal and a wound tissue interface dressing. Briefly, negative pressure can be intermittent or constant, using a pump that may be portable or stationary, exerting a sub-atmospheric pressure that is dependent on the chosen device and clinician's preference. 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 different device types available and their delivery modes, not including the disposable/single use devices recently introduced, are summarised in Table 1.

Table 1: Different NPWT devices available (adapted from Miller and McDaniel, 2006)

- The Chariker-Jeter technique uses a silicone drain which lies on the wound bed within a sandwich of gauze
- The Kremlin technique uses rigid domes to protect the wound and to provide a closed, moist wound environment, allowing for the application of negative pressure to the wound surface
- The Miller technique, a modern variation of the Kremlin technique uses a softer, lower profile and a more easily adaptable dome
- Vacuum Assisted Closure (V.A.C.®) uses foam dressings as a cavity 'filler' dressing.

The application of negative (sub-atmospheric) pressure in wound management has led to a number of publications advocating the application of NPWT in a variety of wounds (Miller and McDaniel, 2006). It is claimed that the vacuum created by the pump pulls the wound edges towards each other and provides a moist wound healing environment. 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

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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. It has also been claimed that 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).

Hydration Response Technology (HRT)

Sorbion sachet S is an advanced wound care dressing utilising HRT, which is founded on the interactive response of two components — mechanically modified cellulose fibres and selected gelling agents — combined with an outer polypropylene cover, for the management of moderate to high levels of exudate (Romanelli et al, 2012).

The outer hypoallergenic covering of the dressing offers low adherent contact with the wound interface. The construction of this outer layer allows passage of wound exudate into the inner core while providing a moist wound environment (Treadwell et al, 2010; Romanelli et al, 2012). The inner core of the dressing consists of hydrokinetic fibres, which comprise specific gelling agents based on high performance polymers embedded in a complex mixture of selected and mechanically-treated cellulose fibres. This provides management of wound fluid volume while at the same time avoiding dehydration of the wound bed or conversely, saturation of the periwound skin (Treadwell et al, 2010; Sharp, 2010).

The dressing may also be used in conjunction with external graduated compression (Kwon Lee, 2010; Treadwell et al, 2010) as fluid absorbed into the dressing is effectively retained (Chadwick, 2008; Cutting and Westgate, 2012). Sorbion sachet S is available in Europe and USA and has recently been re-branded as sorbion sachet EXTRA in the UK.

The recalcitrant wound

Chronic inflammation resulting from persistent infection can cause elevated levels of pro-inflammatory cytokines, proteases and neutrophils (Moore, 2010). This state of delayed healing is often accompanied by elevated levels of exudate (Wolcott et al, 2010). The combined effects of raised exudate output and the associated pro-inflammatory mediators contribute to potential wound enlargement and damage to the periwound skin such as maceration and excoriation (Bishop et al, 2003). These barriers to healing need to be identified and managed. WBP has been suggested as a model that may prevail over these barriers to healing when targeted therapeutic measures are initiated (Schultz et al, 2003).

Wound bed preparation (WBP)

The concept of WBP was first proposed in 2000 with virtually simultaneous publication of three papers (Cherry et al, 2000; Falanga, 2000; Sibbald et al, 2000). WBP is a systematic approach to wound management that can be used to identify and remove barriers to healing. This grew out of a need for "optimal basic wound care" in the management of chronic wounds (Falanga, 2000). Falanga also pointed out that the reason why advanced and innovative technologies such as topically applied growth factors and bioengineered skin products sometimes failed was due to a lack of "proper wound care and wound bed preparation" (Falanga, 2000). The principles of WBP have undergone a number of revisions since 2000 and are now articulated through the adoption of the acronym TIME (Table 2, Schultz et al, 2004). This has recently been re-examined in the light of new data and evidence generated over the past decade and it was concluded that the TIME framework remains relevant (Leaper et al, 2012)

Table 2: TIME (adapted from Schultz et al, 2004)

- Tissue: non viable or deficient
- Infection or inflammation: chronic inflammation and/or infection
- Moisture imbalance: too much or too little
- Edge of wound: non-advancing or undermined

It is important to recognise that WBP, rather than just an umbrella term for the components of optimal wound care, is a continuous process that requires precise assessment and diligent treatment skills in its execution. It demands recognition of the

patient, wound and environmental complexities and the application of a targeted therapeutic approach.

COMPARISON OF NPWT AND HRT

Management of exudate and interstitial oedema

Oedema results from an imbalance in the filtration system between the capillary and interstitial spaces (O'Brien et al, 2005). Wound exudate is a consequence of soft tissue oedema (Thomas, 1997) and its efficient management is a WBP requirement. Removal of oedema from the deeper tissues may enhance perfusion through a reduction in pressure on vessel walls (Ichioka et al, 2008; Wackenfors et al, 2004) and thus can promote healing.

NPWT provides continuous removal of wound exudate (Sullivan et al, 2009) and thereby retains, via the evacuation tube, the exudate in a canister distal to the wound. Exudate contains matrix metalloproteases (MMPs) and their proteolytic activity in chronic wounds is a contributor to chronicity (Cutting, 2003). It is reasonable to assume that removal of exudate containing harmful MMPs will support progression to healing. Provided the negative pressure is adequately maintained and the collection canister is of adequate size, the need for frequent NPWT dressing changes is avoided.

HRT comprises high performance polymer gelling agents. These agents have been shown *in vitro* to reduce MMP activity (Wiegand et al, 2011) and, when combined with the cellulose fibres, have been shown to absorb large volumes of exudate, retain high levels of fluid, manage bioburden, assist maintenance debridement (Treadwell et al, 2010; Romanelli et al, 2009a; Cutting, 2009) and have an extended duration of application (Cutting, 2009; Armitage and Macaskill, 2009; Romanelli et al, 2009a; Chadwick, 2008; Evans, 2010).

A reduction in nursing time is claimed with both modalities (Pham et al, 2003; Braakenburg et al, 2006; Chadwick, 2008; Romanelli et al, 2012).

Bacterial burden

All wounds are considered contaminated with microorganisms and the opportunity for an increase in the microbial populations is therefore constantly present (Percival and Dowd, 2010). While an increase in numbers of microorganisms is not necessarily indicative of infection (Pruitt et al, 1998), microbial populations none the less need to be controlled by the host's immune defence systems (Percival and Dowd, 2010). Reduction of the wound bioburden is therefore an important management consideration (Percival and Dowd, 2010).

Exudate that emanates from the wound bed provides not only an ideal medium for bacterial proliferation but has the potential to provide a source of sustained nutrition to the microbial populations residing on the wound bed (Wolcott et al, 2010). Thus the swift removal of this fluid provides not only a cleansing action of the wound bed but deprives the microbial populations of a potential fluid and nutrient source which could support their survival and proliferation. It is reasonable to assume that a process of continuously cleansing a wound through the sluicing action of the wound bed with endogenously produced exudate may have a role to play in reduction of the wound bioburden (Morykwas et al, 1997).

Willy and Anagnostakos (2006) identified continuous wound cleansing after adequate primary surgical debridement as a mechanism by which NPWT may support wound healing. Conversely, some studies have noted no change or an increase in the bioburden during the use of NPWT although this did not appear to affect the healing process (Weed et al, 2004; Moues et al, 2004). Additionally, a reduction in wound bioburden may result from application of NPWT through prevention of proximal spread from the wound surface (Gustafsson et al, 2007). Other workers (Deva et al, 2000; Wu et al, 2000; Pinocy et al, 2003) have reported a reduction in bacteria under NPWT but these findings cannot be conclusively attributed to the direct effect of NPWT. Assadian et al (2010), using an *in vitro* model, found that under a NPWT dressing there was no significant reduction in level of *Staphylococcus aureus* and considered that immune-modulating factors rather than the direct effects of suction were responsible for the clinical findings of Morykwas et al (1997) and Moues et al (2004). The combined use of NPWT with instillation therapy (NPWTi) using a variety of topical antimicrobials has shown promising results (Lehner et al, 2011), although further research is required to understand the mechanism of action.

"It is reasonable to assume that removal of exudate containing harmful MMPs will support progression to healing."

More recently Dezfuli et al (2013) demonstrated in a retrospective study that NPWT is a successful therapy for local superficial sternal wound infections. However, an expert working group (2008) did not recommend NPWT as a stand-alone treatment for wound infection or in the presence of persistent infection or deterioration in the wound.

Evans (2010) has reported in a case study on the control of wound bioburden using HRT dressings with similar findings from Sharp (2010). *In vitro* studies have shown that HRT dressings have lower levels of pathogens on the dressing surface in comparison with another absorbent dressing following exposure to a solution containing 104 CFU/ml *Staphylococcus aureus* (ATCC 35556 and ATCC 33592) (Kramer and Maassen, 2009), indicating bacterial sequestration. Additional work (Cutting and Westgate, 2013) has shown that the HRT dressing exhibits bacterial sequestration and retention capabilities of *Pseudomonas aeruginosa* superior to knitted viscose and a non-medicated fibrous dressing. Sequestration and retention equivalence was found between the HRT (non-medicated) dressing and a fibrous dressing containing ionic silver.

Biofilms

Wound biofilm is extremely difficult to treat and its presence in chronic wounds may help to explain why achieving progression towards healing can be challenging (Cutting et al, 2010). Its ability to endure onslaught from antimicrobials that would normally be effective against planktonic bacteria and to rebut cellular immune defense mechanisms suggests biofilm capability to deliver robust, complex and dynamic strategies that ensures survival (Wolcott et al, 2010).

Using an *in vitro* model Ngo et al (2012) found a modest reduction in colony count over a 2-week period and image analysis confirmed reduction in biofilm viability with altered physical dimensions when applying NPWT in conjunction with black foam and white foam cavity wound fillers.

In an *in vitro* investigation of the bacterial sequestration and retention capability of a HRT dressing (Westgate and Cutting, 2012) the dressing sample was immersed in a broth inoculated with *P. aeruginosa*. Following incubation sections of the dressings were sampled at 48 hours. These sections, the outer polypropylene (PP) layer that was in contact with the inoculated broth and the inner gel layer were visualised using a scanning electron microscope (SEM). Bacteria were not visualised on the contact PP layer. The inner gel layer appeared to be covered by a thick, irregular substance (suggestive of biofilm presence) that was suspected to be of bacterial origin. Thus, it would appear that the bacteria suspended in the broth had been drawn into the inner core of the dressing.

Debridement

Debridement has a vital role to play in preparation of the wound bed (Falabella, 2006). Slough is now considered by some to be not just an infection risk factor but a possible manifestation of infection itself (Cutting et al, 2010). As both NPWT and HRT are positioned as having the capacity to contribute to the WBP process, efficacy in debridement performance is an important consideration.

The value of NPWT as a facilitator of debridement is somewhat mixed. Sullivan et al (2009) have included discrete contraindications to NPWT for use in chronic wound management and these include necrotic tissue with eschar. Similarly, Bollero et al (2010) have clearly indicated "inadequate debridement" as a contraindication for NPWT. In a retrospective study of NPWT use in a vascular surgery unit (74 patients with 77 wounds) it was found that the appearance of wound slough was a reason for discontinuation of NPWT in nine cases, exceeding the six cases when NPWT was discontinued due to poor healing (Ha and Phillips, 2008). However, Riley et al (2009) have found positive results in a small case series suggesting that NPWT may aid the debridement of wounds when gauze is used to fill the defect.

HRT has been recorded as possessing significant potential to assist autolytic debridement. In a case report series Romanelli et al (2009a) found significant wound debriding capability when using HRT and stated: "In 10 out of 10 cases a significant change in tissue types was observed so that a stark reduction in presence of slough was seen." In a 53 patient HRT clinical evaluation (Cutting, 2009) found a reduction in slough together with an increase in the granulation tissue over a 4-week period.

Correction of wound biochemical abnormalities

Chronic wounds are in a state of chronic inflammation (Wolcott et al, 2008). This statement is supported by studies that have reported on the analysis of the comparative differences in the components of chronic and acute wound fluid (Katz et al, 1991; Bucalo et al, 1993; Harris et al, 1995; Baker and Leaper, 2000). In brief there is a decrease in chronic wound mitogenic cellular activity whereas acute wound fluid promotes DNA synthesis.

NPWT removes the excess wound fluid containing proteolytic enzymes and cytokines that are directly related to delayed healing (Gustafsson et al, 2007). In a pilot study set in the community, Kilpadi et al (2006) has shown a decrease in pressure ulcer protease levels when using NPWT from baseline use to the initial week of treatment.

A polymer-containing dressing has also been shown *in vitro* to inhibit MMP activity and bind to elastase, reducing enzyme activity significantly (Wiegand et al, 2008); the HRT polymer dressing is categorised within the UK Drug Tariff as a protease modulator (Cutting, 2009), although it is important to note that not all dressings in this category will work in the same way.

Both modalities, following their application, claim the capability to promote granulation tissue (Morykwas et al, 1997; Morykwas et al, 2001; Chadwick, 2008; Cutting, 2009). This may suggest protease modulation thereby avoiding the denaturing of collagen laid down during the reparative process.

Economic evaluation

Economic evaluations in wound care are important as they assist healthcare professionals to identify cost-effective strategies that may improve patients' health-related quality of life together with the potential to save costs (Guest, 2013).

Using an economic model populated with French-specific data, Whitehead et al (2011) followed the progression of 1000 hypothetical patients with diabetic foot ulcers over a 1-year period. The analysis found that patients treated with NPWT experienced more Quality Adjusted Life Years (QALYs) (0.787 v. 784) and improved healing rates (50.2% v. 48.5%) at a lower cost of care per patient per year (€24,881 v. €28,855) when compared to advanced wound care dressings.

From the case records of patients registered with general practitioners (GPs) drawn from The Health Improvement Network (THIN) database a decision model was constructed that depicted the patient pathways and management of 439 patients with highly exuding chronic venous leg ulcers (VLUs) of greater than 3-months duration (Panca et al, 2013). The model estimated the costs and outcomes of patient management over 6 months and the related cost-effectiveness of each dressing used in the model. As a result of the aberrant response of a number of wounds that received one particular dressing (fibrous CMC) this dressing had to be removed from the cost-effectiveness analysis. The 6-monthly cost of managing a VLU with the HRT dressing was £370 per patient, which was 15–28% lower than the three other absorbent dressings. Patients who received the HRT dressing benefited from an improvement in health status and accrued 0.3–3% more QALYs.

EXPERT PANEL DISCUSSION

The expert panel discussion highlighted the interesting clinical performance similarities between NPWT and the HRT dressing, particularly in terms of WBP and specifically in relation to exudate management, improved wound conditions, the effect on generation of granulation tissue and associated quality of wound tissue together with a decrease in wound surface area and volume that can be achieved with each modality.

Efficient exudate management is achievable in clinical practice if those resources that are most appropriate to the given situation are utilised. Device performance criteria that include functions in addition to that of management of exudate volume have the potential to deliver 'added value' in terms of patient outcomes and include: ability to manage a large volume of exudate; fluid retention; modulation of MMPs; management of bioburden; continuing debridement; and extended duration of application.

The question of which modality is the most beneficial in broad wound healing terms is not the main focus of this report but rather an exploration of the circumstances in which either modality may be used so that optimal therapeutic benefit is achieved in conjunction with promoting patient concordance together with any related health economic considerations.

"The expert panel highlighted clinical performance similarities between NPWT and HRT dressing."

Tables 3 and 4 provide an overview of the advantages and indications together with the disadvantages and contraindications of NPWT and HRT modalities resulting from expert panel discussion based on the evidence base for each intervention. NPWT has been 'traditionally' used to manage wounds with high exudate production. The expert group discussion and associated clinical experience indicated a performance overlap between NPWT and HRT.

Wound care is a dynamic activity where adjustments to practice follow advances in science and technique. The expert group estimated that where in the past NPWT would have been the preferred clinical option, today, the HRT dressing could be used in approximately eight out of ten indications. The reasons for this are not just clinical (risk of cross-contamination, difficulty in maintaining an effective seal, dressing fragmentation/retention, lack of debriding capability, pain from vacuum and dressing change, propensity to cause bleeding), but include risks from overuse/misuse, confusion from misinformation/poor education, high cost of units/consumables, and restrictions on patient mobility. The disadvantage of restricted patient mobility with NPWT has recently been addressed, to some degree, in patients who have smaller sized wounds with the development of disposable, portable NPWT devices.

The deliberations of the expert group led to the generation of a recommended set of circumstances for NPWT use when the same performance advantages could not be better achieved when using HRT (Table 5).

From this discussion, the expert group concluded that NPWT should be recommended in the three identified circumstances cited in Table 5 only and HRT be considered as the preferred modality in all other situations.

CONCLUSIONS

Adequate wound bed preparation is a necessary prequel to healing. What emerged from the discussion of the expert group was that similar performance attributes exist between NPWT and a dressing that utilises HRT. The discussion and supportive literature suggest that each modality possesses the potential to provide a cost-effective approach to care. When considering the comparative daily costs of NPWT and HRT, the balance would appear to tip in favour of HRT. This fact, together

Table 3: NPWT

Advantages and indications for use	Disadvantages and contraindications for use
Large open wounds where stability of the wound margin may be promoted in conjunction with application of the dressing seal	Change of dressing/canister risk of infection and cross-contamination increases
Heavily exuding wounds with a concurrent reduction in soft tissue oedema	Difficulty in maintaining an effective vacuum seal
Where the reduction in soft tissue oedema will allow for an increase in tissue perfusion	Fragmentation and retention of foam dressing
Where there is a perceived convenience for the attending clinician (e.g. reduction in dressing change frequency)	Lacks debriding capability
Where rapid closure of large wounds is desired	May cause pain from effects of the vacuum and at dressing change
Primary closed wounds	May promote bleeding
	Not indicated for bleeding wounds
	Should not be applied in close proximity to major blood vessels
	Significant unit cost/consumables implications
	Confusion arising from misinformation/poor education/training with risk of overuse/misuse
	Reduces patient mobility

Table 4: Hydration Response Therapy	
Advantages and indications for use	**Disadvantages and contraindications for use**
Heavily exuding wounds	Can get heavy when saturation and left *in situ* for too long
Clinician convenience (e.g. reduction in dressing change frequency)	Difficulty in retaining/securing dressing *in situ*
Reduction in material costs/nursing time	Difficulty when applying to very narrow/deep fistulae/sinuses
Simple to use	Intimate conformability may be difficult on highly undulating wound bed
Provides autolytic debridement	Dressing cannot be cut to shape
Negligible risk of bleeding	Not suitable for 'drier' wounds
Low (dressing) adhesion	
No fragmentation of dressing material	
Promotes granulation	
Provides osmotic effect – wound surface to dressing	
Sequesters bacteria/reduces bacterial burden	
Reduces MMP activity	
Minimises wound inflammation (Romanelli et al, 2012)	
Reduces wound pH (Romanelli et al, 2009b)	
Reduces periwound trans-epidermal water loss (TEWL) (Romanelli et al, 2009b)	

Table 5: Recommended indications for NPWT	
NPWT preferred indications	**HRT comparative performance**
Large open wounds that benefit from stabilisation of the wound margin as provided by the dressing seal in conjunction with the negative pressure (e.g. intra-abdominal compression syndrome)	HRT dressing may be retained in place by adhesive tape but would not provide wound margin stabilisation of a comparable level
Large deep wounds that have an irregular geometry (provided an effective seal can be maintained)	HRT dressing is suitable for large wounds but would struggle to obliterate all areas of dead space in a wound that possesses multiple wound bed topographical irregularities
When a reduction in interstitial pressure (and subsequent increased capillary perfusion) is required	Although HRT dressing would appear to have an impact on interstitial pressure there is no data on increased capillary perfusion

"Each modality possesses the potential to provide a cost-effective approach to care."

with the advantages in respect of patient mobility from application of HRT dressing and associated potential for increased patient concordance may suggest that HRT is the dressing of choice in the management of moderate to highly exuding wounds.

It is the view of the expert panel that only in the set of circumstances outlined in Table 5 preference of modality should be ascribed to NPWT and reflects the belief that further research is needed to confirm the perceived advantages of NPWT over modern wound dressings (Greenhalgh, 2007). Perhaps it is now time to review the precise role of NPWT in modern wound healing and to recognise and accept advances in wound dressing technology in order to bestow advantages to patient and healthcare provider alike.

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