

# **Key considerations in choice of wound management therapeutics between an advanced wound care dressing utilising *Hydration Response Technology* or a durable medical device *NPWT*.**

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## Introduction

An innovative wound dressing (sorbion sachet S) utilising Hydration Response® Technology (HRT, sorbion AG) is now available in Europe and USA. It is founded on the interactive response of two components; mechanically modified cellulose fibres and selected gelling agents that in conjunction with the dressing's outer polypropylene cover interact with the wound environment. This advance in dressing design represents a significant development in wound dressing technology. Following a series of clinical observations that focussed on the patient/wound benefits delivered by this technology culminating in a subsequent real life evaluation of sorbion sachet S<sup>1</sup> an expert working group was formed in order to explore at greater depth the clinical benefits and related performance characteristics. The report of this meeting identified interesting similarities in performance characteristics that appear to be shared between this advanced wound management dressing and generic negative pressure wound therapy (NPWT).

A select group of clinicians, all of whom are recognised experts in wound management subsequently met to share their experiences in light of the aforementioned clinical observation report<sup>1</sup> and to draw on their combined knowledge/experience to elucidate the nature of these performance similarities. The experts received an attendance honorarium together with travel expenses and the meeting was funded by an unrestricted educational grant from sorbion Aktiengesellschaft, Senden, Germany. The project was directed and managed by Keith Cutting, Visiting Professor, Buckinghamshire New University and Director of Health Directions, (tissue viability and clinical research consultancy).

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It is envisaged that following the deliberations of the expert group on 24<sup>th</sup> September 2010 in Anaheim, CA, USA, this document will provide direction when a choice of wound management therapeutic options has to be made between a topical advanced wound dressing and negative pressure wound therapy. The primary considerations in any wound management situation

include the patient, the wound and the wider environmental circumstances. Here, the choice of therapeutic intervention between use of a HRT advanced wound dressing (sorbion sachet S) or NPWT is discussed when progress to healing and or the principles of wound care that support best practice, in exudating wounds, will be most appropriately served.

The broad aim of the expert group meeting was to carefully consider the clinical performance attributes of generic NPWT and to critically examine how these properties compare with HRT performance. An additional aim was to identify in which discrete circumstances NPWT or HRT would be recommended.

In order to provide a starting point in this evolutionary treatise background information is provided on chronic wound aetiology, the concept of wound bed preparation and information relating to both generic NPWT and HRT (sorbion sachet S). This preamble is required as both therapeutic options have a role to play in favourably influencing the biological actions/processes that may occur within the wound so that an active contribution to the healing process is made.

## Background

Globally, choice of wound management device 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 technological alternatives to confront the day to day clinical challenges. These materials and techniques offer innovative approaches to wound management that have the potential to provide benefits both in terms of quality of life to the individual and cost efficiency for the healthcare provider/institution.

## The recalcitrant wound

It is generally acknowledged that persistent inflammation is a feature found in chronic wounds and that as a consequence of elevated levels of pro-inflammatory cytokines, proteases and neutrophils, healing is stalled<sup>2</sup>. This state of delayed healing is often accompanied by

an elevated production of exudate. The combined effects of raised exudate output and the pro-inflammatory mediators in this exudate contribute to potential wound enlargement and damage to the peri-wound skin such as maceration and excoriation<sup>3</sup>. These barriers to healing need to be identified and dealt with. Wound bed preparation (WBP) has been suggested as a model that may prevail over these barriers to healing when targeted therapeutic measures are initiated<sup>4</sup>.

## NPWT

Discussion on generic NPWT is justified in this document on the basis of a recent report (Sullivan et al 2009)<sup>5</sup> 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."

Negative pressure wound therapy (NPWT), also known as topical negative pressure therapy (TNP), is a generic topical treatment used to promote healing in acute and chronic wounds<sup>6</sup>.

NPWT comprises: a negative pressure generating device (vacuum pump) often incorporating an alarm warning of loss of negative pressure; tubing and a collecting canister; wound draping 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<sup>5</sup>. The different device types available and their delivery modes are summarised in Table 1:

- 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 (VAC)<sup>®</sup> uses foam dressings as a cavity 'filler' dressing.

Table 1 adapted from Miller & McDaniel<sup>7</sup>

The application of negative (sub-atmospheric) pressure in wound management has led to a raft of publications advocating the application of NPWT in a variety of wounds<sup>7</sup>. It is claimed that the vacuum created by the pump pulls the wound edges towards each other and provides a moist 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 perfusion<sup>8</sup>, together with the removal of the exudate which assists in lowering the concentrations of the inhibitory factors previously mentioned<sup>9</sup>, 2. A proprietary claim made by one manufacturer is that the stretching and deformation of the tissue by the negative pressure is believed to disturb the extracellular matrix resulting in the release of a variety of intracellular messengers<sup>10</sup>.

## Hydration Response Technology

The development of sorbion sachet S (sorbion Aktiengesellschaft, Germany) provides an advance in wound dressing technology that at first glance appears counter intuitive. Simplicity in visual appearance masks an inner sophistication. The technology was created to generate a dressing which is easy to use and which specifically meets the everyday clinical challenges of wounds which produce moderate to high levels of exudate.

The outer covering of the dressing is hypoallergenic polypropylene which interfaces with the wound bed providing low adherent contact. The construction of this outer hull allows passage of wound exudate into the inner core while providing a moist wound interface. The inner core of material, consists of hydrodynamic fibres<sup>®</sup> which comprise specific gelling agents based on high performance polymers embedded in a complex

mixture of selected and mechanically treated cellulose fibres, was created to comply with the specifications of HRT. In essence this provides management of wound fluid volume while at the same time avoiding dehydration of the wound bed or conversely, saturation of the peri-wound skin. sorbion sachet S also demonstrates excellent performance when used in conjunction with external graduated compression<sup>11</sup> ensuring performance in venous leg ulcer management is not compromised. The absorbed exudate is effectively retained within the dressing<sup>12</sup>.

### Wound bed preparation (WBP)

The concept of wound bed preparation (WBP) was first proposed in 2000 with the virtually simultaneous publication of three papers<sup>13-15</sup>. Wound bed preparation is a pre-requisite for a successful outcome because there is a dire need for “optimal basic wound care” due to the fact that in the broader medical community a lack of general knowledge and related experience in the management of chronic wounds exists<sup>14</sup>. Falanga also points out that the reason why advanced and innovative technologies such as topically applied growth factors and bioengineered skin products sometimes fail follows a lack of “proper wound care and wound bed preparation”<sup>14</sup>. The principles of WBP have undergone a number of revisions since 2000 and are now articulated through the adoption of the acronym TIME which represents<sup>16</sup>

- 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

#### Table 2

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 assessment precision and diligent treatment skills in its execution. It demands recognition of patient, wound and environmental complexities and the application of a targeted therapeutic approach.

### Expert panel

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 the nature of the performance overlap for both NPWT and HRT. It also became apparent that each modality had a role to play in preparing the wound bed and, consequently, the components of WBP were applied to NPWT and HRT. In clinical/practical terms WBP targets wound management on three specific areas; managing exudate/oedema, reducing the bacterial burden, debridement and, importantly, correcting the biochemical abnormalities that contribute to impaired healing.

### Management of exudate and interstitial oedema

Oedema is a consequence of a filtration system discrepancy between the capillary and interstitial spaces<sup>17</sup>. Wound exudate (a generic term) found on the wound surface is a consequence of the soft tissue oedema<sup>18</sup>. Efficient management of oedema and the associated exudate is a WBP requirement. Removal of oedema (excessive interstitial fluid) from the deeper tissue may promote perfusion through a reduction in pressure on vessel walls<sup>19 20</sup> and thus promote healing.

HRT utilises high performance polymer gelling agents in its construction. These agents assist in the modulation of matrix metallo proteases (MMPs)<sup>21</sup> and in combination with the cellulose fibres provide hydrodynamic performance that ensures the efficient management of large volume of exudate, high level of fluid retention, modulation of MMPs, management of bio-burden, maintenance debridement<sup>22-24</sup> and extended duration of application<sup>12 23-26</sup>.

NPWT provides continuous removal of wound exudate<sup>5</sup> and thereby retains, via the evacuation tube, the exudate in a canister distal to the wound. Exudate contains MMPs and their proteolytic activity in chronic

wounds is a contributor to chronicity<sup>27</sup>. It is reasonable to assume that through the removal from the wound of exudate that contains harmful MMPs progression to healing will be supported. Provided the negative pressure is adequately maintained and the collecting canister is of adequate size, the need for frequent NPWT dressing changes is avoided.

A reduction in nursing time is claimed with both modalities<sup>28 12 29 30</sup>.

### Bacterial burden

All wounds are considered to be contaminated with microorganisms and the opportunity for an increase in the microbial populations is therefore constantly present. While an increase in numbers is not necessarily indicative of ensuing infection the microbial populations need to be controlled by the host's immune defence systems so that the host maintains a position of control. Removal of the bioburden from the wound surface is therefore an important management consideration since it will reduce the total bacterial load the immune system will have to deal with.

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<sup>31</sup>. 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 would 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<sup>32</sup>. Evans has reported on the control of wound bioburden using sorbion sachet S<sup>26</sup> with similar findings being made elsewhere<sup>33 34</sup>.

Willy<sup>35</sup> lists 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 effect the healing process<sup>36 37</sup>.

Additionally, a reduction in wound bioburden may result from application of NPWT through prevention of proximal spread from the wound surface<sup>38</sup>.

### Debridement

Debridement has a vital role to play in preparation of the wound bed<sup>39</sup>. Slough is now considered by some to be not just an infection risk factor but a manifestation of infection itself<sup>40</sup>. This consideration raises the stakes as regards not only debridement but also management of the wound bioburden when considered as a component of the wound bed preparation process.

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. HRT has been recorded as possessing significant potential to assist autolytic debridement. In a case report series Romanelli and colleagues<sup>23</sup> 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<sup>24</sup> found a reduction in slough together with an increase in the granulation tissue over a 4 week period.

The value of NPWT as a facilitator of debridement is not so positive. Sullivan et al<sup>5</sup> have included discrete contraindications to NPWT for use in chronic wound management and these include necrotic tissue with eschar<sup>5</sup>.

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<sup>41</sup>.

### Correction of wound biochemical abnormalities

Chronic wounds are in a state of chronic inflammation<sup>42</sup>. 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<sup>43-46</sup>. In brief there is a decrease in chronic wound mi-

togenic cellular activity whereas acute wound fluid promotes DNA synthesis.

HRT dressing is able to modulate wound proteases<sup>21</sup> and is categorised within the UK Drug Tariff as a protease modulator<sup>24</sup>.

NPWT removes with the excess wound fluids proteolytic enzymes and cytokines that are directly related to delayed healing<sup>38</sup>.

Both modalities possess the capability to promote granulation tissue<sup>12 24 32 47</sup>.

## Discussion

The expert panel discussion highlighted the interesting clinical performance similarities between negative pressure wound therapy (NPWT) and sorbion's HRT dressing, particularly in terms of wound bed preparation and specifically in relation to exudate management, improved wound conditions, the effect on generation of granulation tissue and associated decrease of wound surface and volume

that can be achieved with each modality. Generally speaking, efficient exudate management is achievable in clinical practice if the most appropriate resources are utilised. Device performance criteria should include functions that are in addition to management of exudate volume; 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 be used so that optimal therapeutic benefit is achieved in conjunction with promoting patient concordance together with any related cost efficacy considerations.

The group discussion led to the construction of Tables 3 and 4 listing the advantages and indications for use together with the disadvantages and contraindications of NPWT and HRT modalities.

## NPWT

Advantages and indications for use	Disadvantages and contra indications for use
Large open wounds where stability of the wound margin may be promoted in conjunction with application of the seal dressing	Change of dressing / canister risk of infection and X-contamination increases
Heavily exudating 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	Foam (dressing) fragmentation and retention
Where there is a perceived convenience for the attending clinician	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
	Risk of overuse and misuse
	Confusion arising from misinformation / poor education
	Reduces patient mobility
	Significant unit cost / consumables implications
	Unsubstantiated claims made that increased perfusion obviates the need for pressure relief in pressure ulcers
	Not indicated for bleeding wounds
	Should not be applied in close proximity to major blood vessels.

Table 3

## Hydration Response Technology

Advantages and indications for use	Disadvantages and contra indications for use
Heavily exudating wounds	Can get heavy when soaked if left for too long
Clinician convenience (reduction in dressing changes)	Difficulty in retaining/securing dressing in situ sometimes
Reduction in material costs	Difficulty experienced when applied to very narrow/deep fistulae/sinuses
Reduction in nursing time	Intimate conformability may be difficult on highly undulating wound bed
Negligible risk of bleeding	Dressing cannot be cut to shape
Low (dressing) adhesion	Not suitable for 'drier' wounds
No fragmentation	
Provides autolytic debridement	
Simple to use	
Promotes granulation	
Provides fluid shift – wound surface to dressing	
Sequesters bacteria	
Reduces bacterial burden	
Modulates MMPs	
Minimises wound inflammation	
Reduces wound pH	
Reduces peri-wound TEWL	

Table 4

Kwon Lee et al<sup>1</sup> stated that their clinical results indicated interesting similarities between NPWT and HRT. The HRT level of performance in managing exudate, the improved wound conditions, the increase in percentage of granulation tissue and decrease of wound surface and volume, demonstrated to these authors a hitherto previously unpublished similarity to what might have been expected if the treatment modality had been NPWT.

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). It is interesting to note that the indications for circumstantial use of NPWT are not as extensive as one may have presumed.

NPWT has been 'traditionally' used to manage wounds with a heavy production of exudate. The expert group discussion and associated clinical experience clear-

ly indicates a performance overlap between NPWT and HRT. Wound care is a dynamic activity where adjustments in practice follow advances in science and technique. The expert group estimated that where in the past NPWT would have been the preferred option, today, the situation is now reversed and they are now using HRT in eight out of ten indications. The reasons for this are not just clinical (risk of x-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.

Table 5 leads us to conclude that NPWT should only be recommended in the three identified circumstances and consequently HRT is the preferred modality in all other situations.



### NPWT preferred indications

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

Large deep wounds that have an irregular geometry (provided an effective seal can be maintained).

When a reduction in interstitial pressure (and subsequent increased capillary perfusion) is required.

### HRT comparative performance

HRT dressing may be retained in place by adhesive tape but would not provide wound margin stabilisation of a comparative level

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

Although HRT dressing would appear to possess a strong osmotic pull this has yet to be quantitatively measured.

Table 5

## Conclusions

The reader will appreciate that 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 Hydration Response Technology. The discussion and supportive literature suggest that each modality possesses the potential to save costs in relation to nursing time. When considering the comparative daily costs of NPWT and HRT the balance would appear to tip heavily in favour of Hydration Response Technology. This fact, together with the advantages in respect of patient mobility from application of HRT dressing and associated potential for increased patient concordance strongly suggests 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. This bold statement will no doubt be a surprise to many, especially those who have placed a heavy reliance on NPWT to manage wounds in the past. However, this is not the first time that scepticism as regards NPWT and perceived advantages over modern wound dressings has been raised<sup>48</sup>. Perhaps it is now time to view with 'new eyes' the precise role of NPWT in modern wound healing and thereby bestow advantages to patient and health care provider alike.

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