RECOMMENDATIONS FOR THE USE OF NEGATIVE PRESSURE WOUND THERAPY

Abstract

Negative pressure wound therapy (NPWT) has become more accessible and is frequently used in the management of a variety of wounds. However, disparity exists in aspects of NPWT, such as the optimal pressure and the best wound filler. Gaps also exist in the evidence base for the use of NPWT in some wound types, for example in leg ulcers. In an attempt to address this, international consensus statements have been developed by an expert panel and are being disseminated in the UK. This article discusses the recommendations and provides an insight into current thinking and practice on the use of NPWT in acute and chronic wounds.

here is a growing body of evidence to support the clinical use of NPWT in the management of acute and chronic wounds. In addition, economic evaluations in the management of diabetic foot ulcers, surgical and traumatic wounds, and burns have shown NPWT to be a cost-effective technique (Armstrong and Lavery, 2005; Blume et al, 2008).

In the past 15 years, more than 1,000 peer review papers have been published

the SIGN (2008) method of classification

Table 1

Recommendation

describing the clinical efficacy and safety of NPWT for all wound types. However, disparities exist in several important areas, such as which wound types benefit most from NPWT, which wound filler to use, and what pressure setting are best for optimal wound healing. In an attempt to respond to these disparities and gaps in knowledge, an international expert panel was set up to review the existing evidence for the use of NPWT and make recommendations for its use, based on the level of evidence and agreement from an international audience.

KEY WORDS

NPWT recommendations Acute and chronic wounds Treatment variables Consensus agreement

recommendation			
Grade	Terminology	Description	
A	MUST	At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results	
В	SHOULD	A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+	
С	MAY	A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++	
D	POSSIBLE	Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+	

Translation of levels of evidence to graded recommendations. Adapted from

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Table 2	
Recommendations for use of NPWT in traumatic soft tissue wounds (K	rug et. 2011)

Treatment goal	Recommendation	Grade	Evidence level
Provide temporary wound cover	NPWT may be used when primary closure is not possible after or in between debridements as a bridge to definitive closure	С	L2 L3
	NPWT may be stopped when delayed surgical closure is possible	С	L2 L3
	NPWT may be used to improve the healing of fasciotomy incisions	С	L2
To reduce complexity of reconstruction	NPWT may be used to downscale the complexity of closure procedures	С	L2 L3

Agreement of 80% had to be achieved for the recommendation to be passed. The consensus statements from the international group were then presented to a UK audience of healthcare professionals, the majority of them nurses, during a series of study days on NPWT. They were invited to agree or disagree with the statements based on their practice and clinical experience with NPWT

METHODS

A panel of clinical experts in NPWT (NPWT-expert panel) was established with representation from a variety of specialities and from countries around the world. The aim of the group was to develop practical recommendations for the use of NPWT in a variety of wounds by integrating the available evidence with clinical experience.

Evidence-based recommendations were obtained by a systematic review of the literature for each indication and all relevant studies were reviewed regardless of the number of patients, type of study or method of delivery of NPWT being reported. The evidence was then graded using a modified version of the Scottish Intercollegiate Guideline Network (SIGN, 2008) guidelines (Table 1). Modification was made using specific terminology to clarify the strength of the evidence-based recommendations. Strong evidence was classified as level 1 and was graded A, with the term 'must' used in the recommendation statement. The term 'should' was used for B level evidence and 'may' for C level evidence.

Consensus on the recommendations was first agreed between the expert panel where 100% agreement had to be achieved and then a formal consultative consensus development programme took place where 422 independent healthcare professionals were able to agree or disagree with the recommendations. At this stage, agreement had to reach an 80% level to pass. Recommendations on the use of NPWT in the following three areas have been published:

- >> Traumatic wounds and reconstructive surgery (Krug et al. 2001)
- >> Treatment variables (Birke-Sorensen et al, 2011)
- >> Chronic wounds (Vig et al, 2011).

TRAUMATIC WOUNDS AND RECONSTRUCTIVE SURGERY

A total of 15 recommendations were developed in this area, including four recommendations for soft tissue trauma. three for fractures, one for burns, three for flaps and four for skin grafts. The evidence is strongest for the use of NPWT in skin grafts and weakest for its use in burns. Its use in softtissue injuries, trauma wounds, open fractures and fasciotomy incisions is widely accepted.

For many of these wounds, primary closure is not possible, initially, due to the general condition of the patient, oedema and contamination of the wound and infection (Wong et al, 2006; Crumbley and Perciballi, 2007). NPWT offers an interim solution to achieve temporary wound closure following

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debridement and before definitive closure. Treatment goals may also include exudate management, pain control and acceleration of patient mobility. It is important to identify treatment goals to ensure NPWT is used appropriately and so that good clinical outcomes can be demonstrated.

TRAUMATIC SOFT TISSUE AND OPEN FRACTURE

A common goal in the use of NPWT in patients with significant soft tissue traumatic wounds is to use NPWT to descend the reconstructive ladder so that a wound requires less complex surgery — for example, a split-thickness skin graft instead of free flap surgery (Parrett et al, 2006; Bollero et al, 2007). NPWT has also been shown to increase the incidence of delayed primary closure in fasciotomy wounds and improve healing times (Yang et al, 2006; Zannis et al, 2009). Treatment goals for traumatic soft tissue wounds and open fracture wounds are similar but the strength of evidence is greater for open fracture wounds and, therefore, 'should' replaces 'may' in the recommending statements, as outlined in Table 2 and Table 3.

FLAPS

The literature pertaining to the use of NPWT in free flaps is weak, with the exception of the use of NPWT as a treatment for flaps that have suffered partial necrosis. It may be possible to salvage a significant portion of the flap with the use of NPWT following debridement and treatment of infection. Due to there being limited available evidence, these recommendations are based on expert opinion and are outlined in Table 4.

SPLIT THICKNESS SKIN GRAFTS

A significant body of literature to support the use of NPWT in split thickness skin grafts (STSG) exists. NPWT has been shown to deliver all the advantages of a 'bolster dressing' — a cotton dressing soaked in saline and secured with sutures — in addition to active fluid removal with the added advantage of allowing the patient to mobilise early. It has also been shown to reduce the number of re-grafting procedures compared with standard bolster dressings (Llanos et al, 2006; Vuerstaek et al, 2006). The literature also suggests that NPWT may be beneficial for use in patients who are susceptible to graft loss, for example elderly patients or those with diabetes

(Körber et al, 2008) or on problematic graft sites, such as irradiated wounds (Senchenkov et al, 2007).

A systematic evaluation of the literature identified that the post-operative time to leave the graft and dressing undisturbed for both conventional dressings and NPWT ranged from 3-7 days, with the most common duration being five days post grafting. With respect to pressure levels, the median pressure setting identified in studies treating STSG with NPWT was 100mmHg and continuous pressure. The recommendations for its use in this area of practice are outlined in (Table 5).

USE OF NPWT TREATMENT VARIABLES:

The evidence-based recommendations for the use of NPWT treatment variables includes pressure levels, wound filler and wound contact layer (WCL). A wide selection of treatment variables exist and it is important to remember that the treatment goals have an impact on choice.

Wound filler

The majority of evidence on wound filler material relates to polyurethane (PU) foam, with a growing body of evidence emerging on the use of antimicrobial gauze. PU foam and gauze have been proven to transmit equal pressure to the wound bed (Malmsjo et al, 2009) and micro-deformation of the wound bed occurs beneath both (Wilkes et al, 2009). Although PU foam has been shown to promote rapid and thick granulation tissue, no differences have been shown in the time to complete healing between foam and gauze fillers (Hu et al, 2009).

The choice of wound filler depends on practical considerations such as wound type, size, ease of application and removal of pain, availability, and cost. In a randomised trial comparing PU foam and gauze-based NPWT, the pain experience on dressing removal was significantly less in the gauzetreated patients (Dorafshar et al, 2011). Polyvinyl alcohol (PVA) foam has also been shown to reduce pain on dressing removal (Timmers et al, 2005). The literature pertaining to the formation of granulation tissue has shown PU foam to promote rapid and thick granulation tissue (Argenta and Morykwas, 1997). Where this is not the desired outcome and in wounds with an irregular shape then gauze-based NPWT may be more beneficial (Jeffery, 2009).

Table 3 Recommendations for use of NPWT in open fractures (Krug et, 2011)				
Treatment goal	Recommendation	Grade	Evidence level	
Provide temporary wound cover following debridement and before definitive closure	NPWT should be used when primary closure is not possible after or in between debridements as a bridge to definitive closure	В	L1+ L3 L4	
	NPWT should be stopped when delayed surgical closure is possible	В	L1+ L3	
To reduce complexity of reconstruction	NPWT may be used to downscale the complexity of closure procedures	С	L2 L3	

Table 4 Recommendations for use of NPWT in flaps (Krug et, 2011) Treatment goal Recommendation Grade Evidence (A-D)level (1-4) Expert opinion recom-DL4Treatment of flaps mends significant caution in applying significant negative pressure to new or compromised flaps *Improve wound management It is possible to use NPWT* DL3of partially necrotic flaps after on partially necotic flaps debridement after debridement Manage flap donor sites which *It is possible to use NPWT* DL3on donor sites which cannot L4 cannot be closed primarily be closed primarily

Table 5 Recommendations for use of NPWT in split skin grafts (Krug et, 2011)			
Treatment goal	Recommendation	Grade (A-D)	Evidence level (1-4)
Improve success rate of grafting procedure	NPWT must be considered to improve the rate of graft sucess	A	L1+ L2+
	NPWT should be considered in wounds/patients with high risk of graft loss	В	L1+ L2+ L3
Treatment variables	As an initial bolster NPWT should be left undisturbed for 3–7 days post grafting	В	L1+ L2 L3
	When NPWT is used as bolster continuous pressure should be used	В	L1+ L2 L3

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Table 6 Recommendations relating to wound filler material and wound contact layer (WCL) (Birke-Sorensen et al, 2011)

Treatment goal/variable	Recommendation	Grade (A-D)	Evidence level (1-4)
Pain on dressing removal	Gauze should be considered to reduce pain on dressing removal.	В	L1 L3
	Possibly consider PVA foam to reduce pain on dressing removal	D	L3 L4
Granulation tissue formation	Use of PU foam wound filler is recommended where a rapid surface granulation response is desired	D	L3 L4
Wound dimensions/shape/ contour	It is possible to use foam for deep uniform contract- ible wounds and gauze for shallow non-contracting wounds ore complex deep cavities	D	L1 L3
STSG (WCL)	Use of a non-adherent WCL is recommended when usign PU foam based NPWT to bolster a skin graft	D	L3

Wound contact layer

The most common wound contact layers are petroleum, paraffin or Vaselineembedded gauze, silicone WCL or lowdensity polyethylene (Birke-Sorensen et al, 2011). The main reason for using these is to minimise tissue in-growth into the wound filler material and protect the wound bed from damage on removal of the dressing. A specific indication for the use of a WCL is when using foam-based NPWT to bolster a graft (llanos et al, 2006; Vuerstaek et al, 2006). A WCL is also used to reduce the pain experience of the patient and if using an active WCL to achieve a specific outcome, for example, the use of an antimicrobial dressing to manage infection. Use of a WCL can be beneficial during application of NPWT on a wound where rapid granulation is expected and a high degree of contraction required (Krasner, 2002).

However using a WCL may reduce the pressure deliver to the wound bed (Jones, 2005) and should only be used where clinically indicated. Recommendations for the use of wound filler material and wound contact layer are outlined in Table 6.

Pressure-related recommendations

There is no evidence to suggest an optimal pressure level when using NPWT. In clinical practice -80mmHg to -125mmHg have become the acceptable norms. Clinicians often find it necessary to vary the pressure setting, for example if the patient has pain or the exudate levels are high. It has become increasingly apparent that there may not be one single optimal pressure level but an effective therapeutic range of negative pressure between -40mmHg and -150mmHg.

This lack of evidence is reflected in the recommendations from the NPWTexpert panel (Table 7).

An additional aspect of the pressure setting is the choice between continuous and intermittent delivery. Where wound stability is important as in the use of NPWT to bolster a graft then continuous pressures are recommended. Much of the evidence is based on expert opinion and further research into this aspect of NPWT is needed to fully understand the impact on wound healing.

'The choice of wound filler will depend on considerations such as wound type and size'

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'Clinicians often find it necessary to vary the NPWT pressure setting, for example if the patient experiences pain'

Table 7 Pressure-related recommendations (Birke-Sorensen et al, 2011)				
Treatment goal/variable	Recommendation	Grade (A-D)	Evidence level (1-4)	
Therapeutic range	It is recommended that NPWT is used within a therapeutic ragne of -50 to -150mmHg	D	L3	
To reduce pain	To reduce pain lower negative pressure may be considered	С	L1 L3	
Caution in ischaemic wounds	Avoidance of higher levels of negative pressure is recommended in wounds with compromised vascularity or otherwise at risk of ischaemia	D	L3	
Fluid management	To manage high levels of wound exudate or wound fluid, higher levels of negative pressure is recommended.	D	L3	

RECOMMENDATIONS FOR THE USE OF NPWT

Chronic wounds

NPWT is commonly used to treat chronic wounds, especially those which have not responded to alternative treatments. NPWT can be used as a bridge to surgical closure

or to progress the wound to healing by secondary intention. For some patients surgery may not be an option due to co-morbidities and some patients refuse to have surgical interventions. A total of 13 recommendations were developed for the use of NPWT in chronic wounds, four for pressure ulcer, four for diabetic foot ulcers,

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Evidence-based recommendations for the use of NPWT in pressure ulcers (Vig et al, 2011)

Treatment goal	Recommendation	Grade (A-D)	Evidence level (1-4)
Primary goal: To achieve wound closure	NPWT may be used until surgical closure is possible/ desirable	С	L1 L3
	Alternatively NPWT should be considered to achieve closure by secondary intention	В	L1 L2 L3
How goal is achieved	NPWT should be used to reduce wound dimensions	В	L1 L3 L3
	NPWT should be used to improve the quality of the wound bed	В	L1 L3

KEY POINTS

- >> NPWT is commonly used to treat chronic wounds, especially those which have not responded to alternative treatments.
- >> NPWT offers an interim solution to achieve temporary wound closure following debridement and before definitive closure.
- >> Use of a WCL is reported to be of benefit during application of NPWT into a wound where rapid granulation tissue formation is expected and a high degree of contraction is required.
- The use of NPWT in ischaemic lower limb wounds should only be carried out by a highly specialised clinicians when every effort has been made to revascularise the patient.

Table 9 Evidence-based recommendations for the use of NPWT in the diabetic foot ulcer (Vig et al, 2011)

Treatment goal	Recommendation	Grade (A-D)	Evidence level (1-4)
Primary goal: to achieve wound closure	NPWT must be considered as an advanced wound care therapy for post-operative Texas Grade 2 and 3 diabetic feet without ischaemia	A	L1 L2 L3
	NPWT must be considered to achieve healing by secondary intention Alternatively NPWT should be stopped when wound has progressed suitably to be closed by surgical means	A B	L1 L3 L4 L1 L3
To prevent wound deterioration	NPWT should be considered in an attempt to prevent amputation or re-amputation	В	L1 L2 L3

three for ishcaemic lower limb wounds and two for venous leg ulcers.

Pressure ulcers

It is generally agreed that NPWT should only be used in grade 3 and 4 pressure ulcers (NPUAP, 2011). It should be used in the context that all underlying problems, such as nutrition, pressure relief and management of co-morbidities, have been identified and treated. The wound bed should also be prepared by removal of necrotic and sloughy tissue and treatment of infection. NPWT has other advantages in pressure ulcers such as improved exudate management, reduced frequency of dressing change and cost reduction associated with dressings and nurses time (Wanner et al. 2003). The recommendations for the use of NPWT in this group of patients is outlined in Table 8

Diabetic foot ulcers

The primary treatment goal in the application of NPWT to diabetic foot ulcers is to progress a wound towards closure either by secondary intention or surgical closure. Secondary goals include reducing the risk of amputation, to achieve faster wound bed preparation and to reduce the frequency of dressing change. NPWT has been shown

in several studies to reduce the time to healing compared with conventional therapy (Armstrong and Lavery, 2005), reduce cost of treatment (Aplelqvist et al, 2008) and lower amputation rates (Blume et al, 2008). In clinical practice NPWT is often used following debridement to reduce the dimensions of the wound before progressing to advanced wound management methods. Recommendations for the use of NPWT in diabetic foot ulcers are outlined in Table 9.

Ischaemic lower limb wounds

The use of NPWT in ischaemic lower limb wounds should only be carried out by specialised clinicians when every effort has been made to revascularise the patient. It should not be used in acute limb ischaemia. Each patient should be assessed individually and carefully monitored during treatment. The recommendations for the use of NPWT in this group of patients is mostly based on expert opinion as outlined in Table 10.

Venous leg ulcers

Compression therapy should be the firstline treatment for patients with venous leg ulcers. NPWT, however can be a useful adjunct to compression therapy (Kieser et al, 2010), particularly in those wounds

Table 10 Evidence-based recommendations for the use of NPWT in ischaemic lower limb wounds (Vig et al, 2011)

Treatment goal	Recommendation	Grade (A-D)	Evidence level (1-4)
Primary goal: to prepare for surgical closure	The cautious use of NPWT in chronic limb ischaemia when all other modalities have failed may be considered in specialist hands and never as an alternative for revascularisation NPWT may be considered as an advanced wound care therapy for lower limb ulceration after revascularisation	C	L1 L3 L3 L4
Caution	The use of NPWT is NOT indicated in acute limb ischaemia	D	Expert opinion

Table 11 Evidence-based recommendations for the use of NPWT in venous leg ulcers (Vig et al, 2011)

Treatment goal	Recommendation	Grade (A-D)	Evidence level (1-4)
Primary goal: to achieve wound closure	If first line therapy (compression) is not efficacious, NPWT should be considered to prepare the wound for surgical closure as part of a clinical pathway	В	L1
Treatment variables	Use of gauze may be considered to reduce pain during dressing changes in susceptible patients	С	L1 L3

that fail to heal in the expected timeframe of 12 weeks. In a randomised controlled trial Vuerstaek et al (2006) demonstrated that NPWT prepared the wound for STSG faster than conventional therapy and the take rate of grafts was higher in patients treated with NPWT following a graft procedure (Korber et al, 2008).

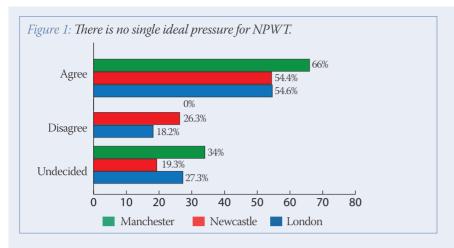
The addition of smaller and more portable devices and single-use NPWT devices offers the opportunity for greater use in this patient group who are usually mobile and less likely to consider using large devices that reduce their mobility and independence. The recommendations for

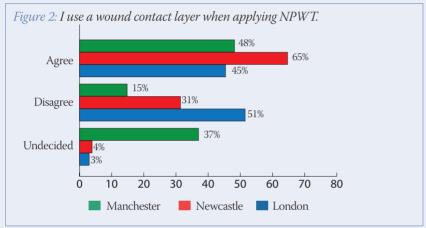
the use of NPWT in venous leg ulcers is outlined in Table 11.

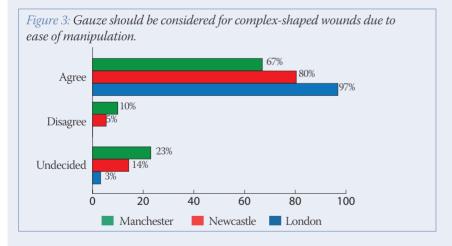
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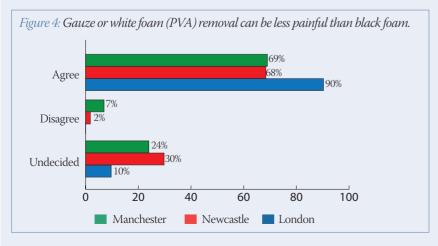
In an attempt to disseminate these international evidence-based recommendations and to explore their relevance to clinicians in the UK, a series of national study days supported by Smith & Nephew, were held on the use of NPWT in clinical practice. Some of the key consensus recommendations were presented to the audience in statement format and they were invited to vote in favour, against or undecided on the recommendations, based on their clinical experience and use of

'NPWT can be used to bridge to surgical closure or to progress the wound to healing by secondary intention'









NPWT. The audiences were made up mostly of nurses with some podiatrists and other allied health professionals. A total of 130 clinicians attended three of these study days across the UK and the results of the voting on the consensus statements are below.

Statement 1 (Figure 1): There is no ideal pressure setting for NPWT

More than 50% of the audience felt that no one pressure level was suitable for all patient and wound types. For some clinicians it was dependent on the type of device they were using where they would use the standard machine setting. The more experience clinicians had with this treatment the more likely they were to vary the pressure setting depending on wound type, level of exudate and the pain experience of the patient. These results are in keeping with the recommendations from the International NPWT-expert panel.

Statement 2 (Figure 2): I use a wound contact layer when applying NPWT

The voting on this question was mixed with some areas almost always using a WCL and other areas never using them. On discussion it was mostly related to the type of wounds that were treated. Clinicians involved in the care of STSG always used a WCL which is in keeping with the international recommendations. Many clinicians treating surgical wounds rarely used a WCL as they felt it reduced the formation of granulation tissue. Clinicians using gauze-based NPWT did not use a WCL.

Statement 3 (Figure 3): Gauze should be considered for complex-shaped wounds used due to ease of manipulation

There was overwhelming agreement here. Between 67–96% of respondents were most likely to use gauze in complexshaped wounds as it was easier and quicker, particularly in undermining or tracking. Clinicians with less experience of using NPWT were undecided and a small number disagreed as they felt they had developed expertise in cutting foam to fill complex cavities. Overall, the response was in keeping with recommendations of the expert panel.

Statement 4 (Figure 4): Gauze or white foam (PVA) removal can be less painful than black foam

Agreement on this statement was 68–90% with most clinicians having found that the patient's pain experience was less at dressing removal with the use of gauze-based NPWT or PVA foam. A number of delegates had not had patients that experience pain when using PU foam and those that had were more likely to use a WCL with the foam filler. The results support the recommendation from the NPWT-expert panel.

Statement 5 (Figure 5): NPWT may be used when primary closure is not possible, after or in between debridements as a bridge to definitive closure

Agreement was between 80-90%, with clinicians understanding the need to ensure the wound is fully debrided and infection controlled for NPWT to be successful.

Statement 6 (Figure 6): NPWT in grade 3 and 4 pressure ulcer should be used to reduce wound dimensions

There was general agreement that treating co-morbidities and off-loading pressure were essential. Some of the audience were undecided about the use of NPWT in pressure ulcer management, but this appeared to be specifically related to the types of patients and wounds they managed. Community nurses shared some very positive experiences of using NPWT in this group of patients and agreement of 60-74% was achieved, below the international consensus statement level for approval.

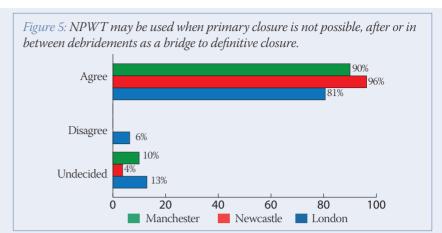
Statement 7 (Figure 7): NPWT should be used to treat venous leg ulcers that fail to heal with compression

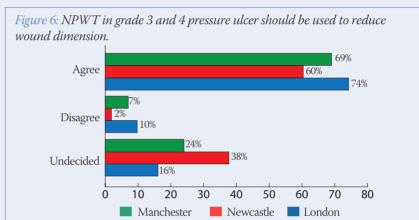
It was agreed that compression therapy was the gold standard in managing venous leg ulcers, and clinicians had limited experience of using NPWT in this group. The voting reflected this, with only 17-36% agreement. Those who had used NPWT with compression to treat non-healing venous leg ulcers had achieved good results with a reduction in the wound size after one week.

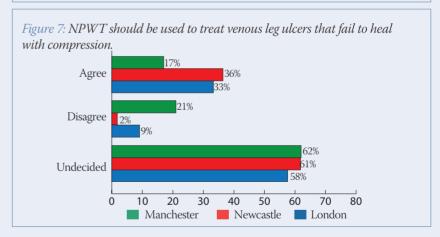
DISCUSSION

The development of international consensus on the use of NPWT in a variety of wound types has been welcomed by clinicians. They bring clarity where lack of agreement often led to inconsistency in the care provided. Additionally the statements are useful to services that have to develop business cases and evidence-based rationale for the use of NPWT in the current financial climate.

It is always important that this type of work is relevant and meaningful to clinicians caring for patients in the 'real







world. The opportunity to benchmark the statements against the clinical practice of UK clinicians involved in using NPWT has been very useful and has demonstrated that current practice is mostly in keeping with the recommendations. The study days in the UK offered a great opportunity for dissemination of the international consensus and for sharing best practice. It is clear that further research evidence and supporting clinical practice experiences are needed for the use of NPWT in chronic wounds in particular pressure ulcers and venous leg ulcers. Wuk

ACKNOWLEDGEMENT

The work of the International NPWT-expert panel and the development of the consensus recommendations have been supported by an educational grant from Smith and Nephew Healthcare.

Smith and Nephew and Wounds UK would also like to acknowledge the work of Elsevier Publications in the production of the Expert Panel work, which forms the basis of this paper.'

Caroline Dowsett has been a key member of the NPWT Expert Panel since its inception in 2009 and she continues to contribute extensively to the work of this group.