Evidence-based recommendations for the use of Negative Pressure Wound Therapy in traumatic wounds and reconstructive surgery: Steps towards an international consensus

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ABSTRACT

Negative pressure wound therapy (NPWT) has become widely adopted over the last 15 years and over 1000 peer reviewed publications are available describing its use. Despite this, there remains uncertainty regarding several aspects of usage. In order to respond to this gap a global expert panel was convened to develop evidence-based recommendations describing the use of NPWT. In this paper the results of the study of evidence in traumatic wounds (including soft tissue defects, open fractures and burns) and reconstructive procedures (including flaps and grafts) are reported.

Evidence-based recommendations were obtained by a systematic review of the literature, grading of evidence, drafting of the recommendations by a global expert panel, followed by a formal consultative consensus development program in which 422 independent healthcare professionals were able to agree or disagree with the recommendations. The criteria for agreement were set at 80% approval. Evidence and recommendations were graded according to the SIGN (Scottish Intercollegiate Guidelines Network) classification system.

Twelve recommendations were developed in total; 4 for soft tissue trauma and open fracture injuries, 1 for burn injuries, 3 for flaps and 4 for skin grafts. The present evidence base is strongest for the use of NPWT on skin grafts and weakest as a primary treatment for burns. In the consultative process, 11/12 of the proposed recommendations reached the 80% agreement threshold.

The development of evidence-based recommendations for NPWT with direct validation from a large group of practicing clinicians offers a broader basis for consensus than work by an expert panel alone.

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Abbreviations

FTSG: full-thickness skin grafts
NPWT: negative pressure wound therapy
NPWT-EP: International Expert Panel on Negative Pressure
            Wound Therapy
RFF: radial forearm flap
SIGN: Scottish Intercollegiate Guidelines Network
STSG: split-thickness skin graft

Introduction

Negative Pressure Wound Therapy (NPWT) is a treatment modality that has become widely adopted for a broad range of wound indications since its advent over 15 years ago. NPWT is a generic technology, which can be delivered to a wound using a range of variables (including source and level of negative pressure, wound filler and wound contact layer). Over 1000 peer-reviewed publications describing the clinical efficacy and safety of NPWT for all wound types have been published over this period. The aim of the present project was to condense the existing body of literature into evidence-based clinical recommendations, which reflect the strength of evidence in support of each statement. The present paper covers the use of NPWT in the treatment of traumatic injuries and resulting reconstructions. Further communications covering the full range of wound types treated with NPWT will appear elsewhere.

In order to develop good-quality and robust recommendations it is important that the recommendations are developed by, and in consultation with, experts who are vigorously active in the practice of medicine. The development of recommendations from a purely academic perspective would lead to 'gold standard' recommendations, which may represent theoretical clinical practice but may be difficult to apply to real-life clinical settings[76]. The intention of these recommendations is that they avoid bias from any particular manufacturer of NPWT. In order to achieve this goal, generic terminology has been used throughout without reference or limitation to any specific manufacturer of NPWT products. A panel of clinical experts in NPWT (NPWT-EP) was established with representation from a variety of disciplines and from many countries around the world. The panel also sought validation of the principal recommendations during a formal consultative phase with 422 independent healthcare professionals during a global symposium to further dilute any potential source of bias.

In addition to developing recommendations, the panel sought to clarify treatment goals that can be achieved using NPWT. It is increasingly recognized that NPWT can be used to achieve a variety of treatment goals, which will vary according to the patient and wound characteristics. Currently, there is a propensity to believe that the only valuable end-point with regards to wound management is complete wound closure. However, the advent of NPWT has introduced the concept that other treatment goals may act as staging posts along the path towards complete closure, which are in themselves useful end-points in any clinical trial. In addition to developing evidence-based recommendations, the intention of this project was to clarify the appropriate goals for different wound types.

Methods

This study adopted a novel approach by combining a formal consensus development program involving consultation with 422 independent healthcare professionals with a formal evidence-based medicine activity (i.e., a full systematic review of the literature). The recommendations presented here have undergone extensive consultation with healthcare professionals and have been peer reviewed as a requirement of publication.

Systematic literature review

A series of systematic searches (PubMed, EMBASE, British Nursing Index) were carried out by one of the authors (JS) using the following search terms: (NPWT OR "negative pressure" OR VAC OR "vacuum-assisted" OR TNP) AND [one of the following] burn; ("skin graft" OR STSG OR "split-thickness"); flap; (orthopedic OR "open fracture"); ((Trauma AND "soft tissue") NOT (orthopedic OR "open fracture" OR burn OR chronic)). The use of NPWT in trauma resulting in an open abdomen will not be covered in this publication. Searches were limited to studies published after 1996 (when modern formats of NPWT became commercially available). Results are shown in Table 1. One search was obtained for each indication and reviewed separately. Titles and abstracts of all studies were reviewed for relevance and cross-referenced where necessary into the other sections. The main searches were supplemented where appropriate by literature identified by other means.

All selected papers were assessed against the following criteria before being identified for further review:
– Duplicates were removed.
– Studies where end-points relevant to NPWT were not reported or where the use of NPWT was incidental to other therapies/ techniques under investigation and papers reporting irrelevant clinical indications (i.e., where <80% of patients described were the required indication) were excluded.
– Only studies/abstracts in English were reviewed (for relevant papers in languages other than English only information contained in the abstract was reviewed).
– All relevant studies were reviewed regardless of the number of patients, type of study or method of delivery of NPWT being reported.

Table 1
Results of the systematic searches[a]

	Open fractures	Soft tissue	Burns	Grafts	Flaps
Papers identified	150	78	129	212	325
Reasons for exclusion					
Duplications	11	9	10	62	90
Not on NPWT	57	7	8	2	19
Out of scope	31	7	62	67	164
Reviewed in another section	4	19	16	27	49
Non-human[b]	3	2	7	3	2
Papers reviewed	**44**	**34**	**26**	**51**	**37**

[a] This list was supplemented by relevant studies from other sources. In total 208 references were reviewed for relevant information (see supplemental material).

[b] *In vivo* and *in vitro* studies were reviewed where they were of particular relevance.

Table 2A
Translation of Evidence levels to graded Recommendations[a]

Recommendation		Description
Grade	Terminology	
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
B	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+
C	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+

[a] Adapted from the SIGN method of classification[76]. Modification was made by using specific terminology to clarify the strength of each evidence-based recommendation ('Must' for grade A, 'Should' for grade B, 'May' for Grade C).

Table 2B
Evidence levels[a]

Evidence level	Description
1++	High-quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias
1+	Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias
1−	Meta-analyses, systematic reviews, or RCTs with a high risk of bias
2++	High-quality systematic reviews of case–control or cohort studies. High-quality case–control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal
2+	Well-conducted case–control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal
2−	Case–control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal
3	Non-analytic studies, e.g. case reports, case series, *in vivo* or *in vitro* studies
4	Expert opinion

[a] Adapted from the SIGN method of classification.

A total of 208 papers met the inclusion/exclusion criteria identified through the systematic review and supplemented from other sources (full list available as supplemental material).

Development of recommendations

The recommendations described in this report were determined during a series of meetings between the members of the NPWT-EP over 6 months. Recommendations were developed according to a modification of the SIGN (Scottish Intercollegiate Guidelines Network) classification system[76]. This classification system is designed to reduce variation in practice and outcome through the development and dissemination of clinical guidelines containing recommendations for effective practice based on current evidence. Tables 2A and 2B describe the classification of the levels of evidence used and the corresponding strength of recommendation that can be made from each evidence level. Evidence levels were identified in the text as outlined in Table 2B and referred to as Level (L) 1–4 as appropriate. Modification to the SIGN guidelines was made by using specific terminology to clarify the strength of each evidence-based recommendation ('Must' for grade A, 'Should' for grade B, 'May' for Grade C).

A separate series of recommendations was developed for each specific clinical indication as outlined in the recommendations section below. A series of treatment goals was defined for each indication consistent with the recommendations. The treatment goals are shown in Table 3.

Formal consensus development

Formal consensus techniques were then used to gain consensus of the recommendations in a two-stage process. In both stages of consensus development, consensus was defined as >80% agreement with the recommendation. Firstly during the development phase, consensus was obtained between the members of the expert panel. At this stage, the recommendations were modified until 100% agreement among the panel members was obtained. The second phase of consensus development was consultative; the principal recommendations were presented at an international NPWT meeting (Hamburg, February 2010) to an invited audience of 422 healthcare professionals from 29 countries (comprising 69% surgeons and 31% other clinicians; see Appendix 1 for further details below). Finally, the entire audience voted using interactive handsets (manufactured by Turning Point, UK) on whether they agreed or disagreed with the proposed recommendations. The strength of the consensus was indicated as the percentage of participants who agreed with the recommendation. Lack of consensus (<80% agreement) was generally considered an indicator of varying clinical practice along with insufficient published clinical evidence, and signified a potential evidence gap. In some parallel sessions smaller specialist break-out groups of 100–150 clinicians considered certain recommendations and voted by show of hands.

Use of NPWT in traumatic wounds

NPWT has become widely accepted in the treatment of extensive soft-tissue injuries, high-energy penetrating trauma, open fractures and fasciotomy incisions. The available evidence falls into two groups: use of NPWT for soft tissue traumatic wounds (including soft tissue defects with exposed tendon, non-fractured bone and orthopaedic implants, not complicated by fracture) and use of NPWT for open fracture wounds. There is considerable overlap between these two groups in terms of the treatment goals for applying NPWT (Table 3). This leads to similar recommendations.

Table 3
Treatment goals for application of NPWT[a]

Goal	Indication				
	Soft tissue trauma	Open fractures	Flaps[b]	Grafts	Burns
To provide temporary wound cover	●	●	–	–	–
To reduce complexity of reconstruction	○	○	○	–	–
To improve wound management of failed or partially failed flaps following debridement	–	–	●	–	–
To improve success rate of procedure	–	–	–	●	–
To manage wound fluid and oedema	○	○	○	○	○
To accelerate patient mobility	–	–	–	○	–
To improve pain management	○	○	–	–	○
To prevent wound progression	–	–	–	–	●

[a] Although NPWT is a treatment that operates simultaneously through multiple actions, in order that specific recommendations could be made and voted on, a single overarching treatment goal was selected as part of the consensus process. Solid circles indicate the primary goal and open circles indicate secondary goals within each indication. The clinical benefit clearly derives from the combination of all of the treatment goals.

[b] Significant caution is recommended when applying NPWT to a flap. The goals described here relate to very specific circumstances – please refer to later sections and Table 6 for more details.

Table 4
Evidence-based recommendations for the use of NPWT in soft tissue traumatic wounds

Treatment goal	Recommendation	Grade	Evidence level (1–4) and supporting reference(s)
Primary Goal: To provide temporary wound cover following debridement and before definitive closure	NPWT **may** be used when primary closure is not possible after or in between debridements as a bridge to definitive closure	C	L2–[87,88] L3[17,38,43,47,86]
	NPWT **may** be stopped when delayed surgical closure is possible	C	L2–[87,88] L3[17,33,38,43,45,47]
	NPWT **may** be used to improve the healing of fasciotomy incisions	C	L2–[33,69]
To reduce complexity of reconstruction	NPWT **may** be used to downscale the complexity of closure procedures	C	L2–[87,88] L3[14,33,45,55]

However, distinct bodies of literature can be identified describing the use of NPWT in soft tissue trauma and in open fracture, which leads to different strength recommendations. Soft tissue trauma and open fracture will therefore be discussed separately.

Recommendations for soft tissue trauma

Recommendation: NPWT **may** be used when primary closure is not possible after or in between debridements as a bridge to definitive closure (**Grade C**)
Agreement in consultative phase = 98%; Table 4.
The principal goal of using NPWT in surgical repair of soft tissue traumatic wounds is to provide temporary wound cover following thorough debridement and before definitive closure (Table 3). Many clinical circumstances result in the inability or reluctance to close a trauma wound in the first operative procedure, including the critical condition of the patient, significant wound contamination, the requirement for further debridement procedures, the need to reduce oedema, availability of expertise, and so on. In the interim, NPWT can be applied to achieve temporary wound closure between surgical debridements (L3 studies[17,86]), or to temporise the wound while the patient stabilizes (L3 studies[38,43,87,88]).

Other treatment goals to be achieved through application of NPWT include prevention of desiccation and bacterial contamination (L3[38,47]), reduction of oedema (L3[3,17,38]) and facilitation of wound drainage (L3[70]) thus enhancing the chance of success of future definitive closure procedures.

NPWT is not a substitute for thorough or repeated surgical debridement. It is recommended, where clinically appropriate, to perform thorough debridement prior to placement of the NPWT dressing. Application of NPWT to wounds containing necrotic tissue is contraindicated[85].

Recommendation: NPWT **may** be used as a method to downscale the complexity of reconstruction (descend the reconstructive ladder) (**Grade C**)
Agreement in consultative phase >80%; Table 4.
A common goal in the use of NPWT, especially in patients with significant soft tissue traumatic defects, is to use NPWT to descend the reconstructive ladder, that is, to progress a wound from a complex wound which may require complex surgical closure (such as a microsurgical free flap) to a smaller and simpler wound which may be adequately managed with a simpler procedure (such as a split-thickness skin graft [STSG]). This progression can have considerable impact on morbidity for the patient as well as significantly reduce hospital costs (L3[33]). In some extreme circumstances, for example in the absence of suitable local flap options, previous flap failure or where co-morbidities make a patient a poor candidate for free flap reconstruction, early closure is not an option and in these cases NPWT may provide an ideal temporary solution (L3[69]).

This shift down the reconstructive ladder has been reported in two comparative studies (L2[87,88]) and several non-comparative studies in the field of soft-tissue trauma wounds (L3[14,33,45,55]). Stronger evidence which supports this concept exists in the related area of open fracture wounds which is described in the next section.

Recommendation: NWPT **may** be stopped when delayed surgical closure is possible (**Grade C**)
Agreement in consultative phase >80%; Table 4.
Just as important as understanding when the clinical indications are correct to start NPWT is the decision on when to stop NPWT. The vast majority of clinical protocols found in the literature (L3[14,33,45,55]; L2[87,88]) and in widespread clinical practice would support the

Table 5
Evidence-based recommendations for the use of NPWT in open fracture wounds

Treatment goal	Recommendation	Grade	Evidence level (1–4) and supporting reference(s)
Primary Goal: To provide temporary wound cover following debridement and before definitive closure	NPWT **should** be considered when primary closure is not possible after or in between debridements as a bridge to definitive closure	B	L1+[79] L3[20,24,65,80] L4[59]
	NWPT **should** be stopped when delayed surgical closure is possible	B	L1+[79] L3[2,20,21,65,80]
To reduce complexity of reconstruction	NPWT **may** be used to downscale the complexity of closure procedures	C	L2−[11,63,75] L3[20,30]

closure of soft tissue traumatic wounds by surgical methods, rather than to progress to healing by secondary intention.

One reason for delayed surgical closure is unsuitability of the wound bed. Often in traumatic soft tissue wounds, exposed bone, tendon or orthopaedic implants are visible. These surfaces make poor recipient beds and often result in poor outcomes following definitive closure. One distinct advantage of NPWT, especially where a delay in reconstruction is inevitable for the reasons discussed above, is that it encourages the formation of granulation tissue over these exposed surfaces (L3[45,64]), suggesting improved success of subsequent definitive closure. An important goal therefore in the application of NPWT is to achieve a good granulating wound bed in preparation for delayed surgical closure but then to stop NPWT, potentially saving costs and minimising inconvenience for the patient.

However, in well selected cases wound closure by secondary intention may be a viable option. The use of NPWT to progress soft tissue traumatic wounds to healing by secondary intention has been reported to good effect in a subset of patients with smaller, non-complicated wounds (L3[14,33]).

Recommendation: NPWT **may** be used to improve the healing of fasciotomy incisions (**Grade C**)
Agreement in consultative phase >80%; Table 4.
Fasciotomy incisions are created surgically to relieve the increased pressures associated with compartment syndrome in upper or lower extremity injury, which commonly occurs as a consequence of blunt trauma. Fasciotomy incisions are characterised by tissue oedema which causes the incisional wound to gape. Because fasciotomies are created by surgical incision, there is great potential to achieve closure by delayed primary suture, once compartment pressures have been normalised. Delayed primary suture of the incision leads to an acceptable cosmetic outcome and reduced need for donor tissue for wound closure. However, this is compromised by the presence of oedema, skin retraction and skin edge necrosis (L2−[88]) resulting in a wound suitable only for closure by other methods, commonly STSG or secondary intention. These alternative methods may lead to cosmetically and functionally inferior results and in the case of STSG, donor site morbidity. Application of NPWT in fasciotomy wounds has been shown to increase the incidence of delayed primary closure (L2−[87,88]) when compared to conventional wet-to-dry dressings. The larger of the two studies[88] reported a significant increase in the percentage of patients able to be closed by suture following treatment with NPWT compared with conventional therapy (79% vs 50%). These reports suggest that the ability of NPWT to reduce oedema and splint the wound edges allows greater success in mobilising the wound edges together to achieve delayed primary suture. In addition, the time taken to achieve closure was significantly shorter when NPWT was applied, regardless of closure method (delayed suture or graft), compared with conventional wet-to-dry gauze dressings (L2−[87,88]).

Recommendations for the use of NPWT in open fracture

Recommendation: NPWT **should** be considered when primary closure is not possible after or in between debridements as a bridge to definitive closure (**Grade B**)
Agreement in consultative phase 99%; Table 5.
The principal goal of using NPWT in surgical repair of open fractures is to provide temporary wound cover following thorough debridement and before definitive closure (Table 4). The many reasons for the need to delay closure are outlined in the soft tissue trauma section above and are equally true for open fracture wounds. NPWT is not a substitute for thorough or repeated surgical debridement. It is recommended, where clinically appropriate, to perform thorough debridement prior to placement of the NPWT dressing. Application of NPWT to wounds containing necrotic tissue is contraindicated.

There is a relatively sophisticated understanding of the impact of delayed surgical closure on open fracture outcomes. The risk of developing infection or bony non-union is increased with the extent of tissue loss[27] and with delays in surgical debridement and in coverage by vascularised tissue[25]. This knowledge has led to the 'fix and flap' approach, which recommends immediate or early wound debridement (within 6 hours) and surgical closure (often defined as within 3 days) and is acknowledged to provide the best protection against development of infection and non-union in open fractures[25]. However, this understanding has not been thoroughly reassessed since the widespread adoption of NPWT in this wound type and does not take into account any additional effect that may be conferred by NPWT. Stannard et al. (2009) (L1+[79]) reported the effect of applying NPWT between serial debridement procedures in open fracture wounds in a randomised controlled trial as a bridge to definitive closure. Wounds were ready for closure within a mean of 3.7 days; however, wounds treated with NPWT were approximately 1/5 as likely as non-NPWT treated wounds to develop an infection, indicating that NPWT may confer a distinct advantage to open fracture wounds capable of being closed relatively early post injury. NPWT was used between serial debridements in a number of Level 3 studies[20,24,65,80].

Some open fracture wounds cannot be closed within this early window. The impact of applying NPWT between debridements, as a bridge to definitive closure when lengthy delays between injury and closure are expected, is currently under debate. The phrase "Damage Control Orthopaedics" has been used to describe the approach to address the most severe injuries early, whilst returning to close the wound after the patient has stabilised[80]. It may be that the need for immediate or early closure is reduced if NPWT is used. Some studies report that delayed closure procedures using NPWT between debridement and closure have no discernible impact on outcome compared with early closure. Dedmond et al. (2007) (L3[20]) reported the infection, amputation and non-union rates in a series of 50 Gustilo grade 3 fractures treated with NPWT. Despite definitive closure at an average of 12.7 days post injury, infection rates were deemed to be similar to those published elsewhere. Steiert et al. (2009) (L3[80]) reported the flap failure and

infection rates of a cohort of 42 open fractures (mostly Gustilo grade 3b) closed at a mean of 28 days and concluded that failure rates were similar to wounds closed within 72 hours as reported in the literature. However, this is not supported by Battacharrya et al. (2008) (L2[9]) who reported that NPWT did not protect late closure wounds (>7 days) from an increased incidence of infection compared with those closed before 7 days. As long as infection can be avoided then it may be possible that longer delays between injury and closure may not be as detrimental to outcomes as originally believed. It is possible that NPWT may be used to protect the wound from infection as it is a closed system which, due to the presence of the drape, can help to prevent bacterial ingress into the wound and therefore may help to prevent development of nosocomial infection. Reduction in tissue oedema might also lead to improvements in resisting infection. NPWT may therefore be able to provide a delay in wound coverage with no negative impact on incidence of infection.

Recommendation: NPWT **may** be used to downscale the complexity of closure procedures (**Grade C**)
Agreement in consultative phase 94%; Table 5.
The shift down the reconstructive ladder facilitated by adoption of NPWT in comparison with other treatment protocols has perhaps been shown best in open fracture wounds (L2[11,63,75]). Parrett et al. (2006)[63] reported that the adoption of NPWT led to a significant decrease in the number of free flaps required, from 20% to 5%, and a concurrent increase in the number of STSGs from 28% to 38%, compared with a similar patient population treated prior to adoption of NPWT. In this study there was no difference in infection, amputation, non-union or re-operation rates between groups, indicating that no detrimental effect of NPWT on outcomes was observed[63]. Bollero et al. (2007)[11], in a retrospective comparative review, reported an increase in closure by STSG from 40% to 65% and a decrease in flaps from 46% to 13.5% in open-fracture patients following their adoption of NPWT. Schilt et al. (2004)[75] also reported significantly fewer flap procedures to close paediatric lower limb traumatic injuries in NPWT-treated patients compared to those who received conventional therapy.

In light of these results it may be tempting to question the need for tissue transfer. The alternative and somewhat controversial approach would be to use NPWT with the primary goal of reducing the complexity of reconstructive procedures. The logical extension of this goal would be to choose to treat a wound with NPWT, which would otherwise have been suitable for immediate or early closure by a complex flap procedure, with the aim of delaying the reconstruction until a simpler procedure could be carried out. However it is important not to forget the fundamental benefits provided by a flap in terms of provision of specialised tissue (e.g. muscle, bone, nerves) to aid the functionality and durability of the reconstructed wound. These features can not be underestimated, particularly in regions where a high degree of functionality is required such as the hand or head and neck regions. Truly differentiated three-dimensional tissue cannot be provided by filling a defect with granulation tissue followed by placement of a skin graft. Other body locations less sensitive to a high degree of functionality such as the lower extremity, or wounds where specialised tissues are not required, can tolerate less specialised tissue and may be better candidates to be encouraged down the reconstructive ladder through NPWT-mediated formation of granulation tissue. In summary, NPWT can not be recommended as a *substitute* for flap reconstruction in wounds which are good candidates for immediate or early reconstruction. This is in accordance with other commentators (L4[59]). In wounds where immediate or early reconstruction is not possible, more prolonged application of NPWT may have the result of reducing the complexity of reconstruction as the wound cavity fills in with granulation tissue leaving a smaller defect to repair.

Recommendation: NWPT **should** be stopped when delayed surgical closure is possible (**Grade B**)
Agreement in consultative phase >80%; Table 5.
The vast majority of published clinical protocols identified in this systematic review[2,9,20,21,65,79,80] and widespread clinical practice would support the closure of open fractures by surgical closure methods, rather than progression to healing by secondary intention. Closure by secondary intention fundamentally results in a longer delay in wound closure. This may be of particular detriment to the outcomes of open fracture wounds where, as described above, evidence suggests that delayed closure leads to greater infection rates with significant impact on fracture healing[25,27]. It is therefore recommended that surgical closure be performed in open fracture wounds at the earliest possible, clinically appropriate point.

Use of NPWT in partial-thickness burns

The most common use of NPWT in burns is following an excision and grafting procedure (L1+[48]; L2+[72]; L3[15,49,66,73]). The ability of NPWT to bolster STSG or artificial dermal substitutes is described in a following section. The present section is limited to the application of NPWT *directly* onto a partial-thickness burn wound. The use of NPWT directly on a full-thickness burn is contra-indicated since this represents necrotic tissue with eschar present[3].

A burn is characterised by three concentric zones that illustrate three grades of dermal damage: the zones of hyperemia, stasis and coagulation[36]. The zone of hyperemia, which heals spontaneously, is separated from the zone of coagulation, which is irreversibly damaged, by the zone of stasis. The zone of stasis is characterised by changes in vascular permeability producing progressive oedema and increased blood viscosity to the point where flow decreases and may stop[61]. This vascular compromise often worsens up to 48 hours after injury[7]. If this burn progression is not halted, this leads to an expansion of the zone of coagulation, and a partial-thickness injury may progress to a deeper partial-thickness or full-thickness injury. The zone of stasis has been described as a reversible situation[89] with the potential to be converted into zone of hyperemia with a good chance of spontaneous healing. The optimal wound management to bring about this reversal is currently uncertain although suggestions include NPWT.

Goals and proposed recommendations

Recommendation: NPWT **may** be beneficial at preventing burn wound progression (**Grade C**)
Agreement during consultative phase 66%; Recommendation rejected; Table 6.
A small number of studies have reported a positive impact of early application of NPWT to a partial-thickness burn wound. The progression of the burn wound usually proceeds for up to 48 hours after injury. Microcirculation seems to become maximally compromised at 12–48 hours post-burn as a result of interstitial oedema and coagulation. After the third day, the necrotic border has usually stabilised. This provides a hypothetical timeline within which NPWT may be applied.

An early porcine study (L3[58]) investigated the impact of application of NPWT following a varying delay from the time of wounding and demonstrated that application of NPWT to a partial-thickness burn wound within 12 hours of injury significantly reduced the depth of tissue necrosis compared to wounds not treated with NPWT. This benefit was not apparent if NPWT was delayed up to 18 hours post-injury, suggesting a therapeutic

Table 6
Evidence-based recommendations for the use of NPWT in partial-thickness burns

Treatment goal	Recommendation	Grade	Evidence level (1–4) and supporting reference(s)
To prevent wound progression in partial-thickness burns	NPWT **may** be beneficial in preventing burn wound progression	C	L2[–39] L3[19,31,54,58]

window within which to apply NPWT of up to 12 hours post-injury. Treatment with NPWT for as little as 12 hours following the initial application was observed to provide optimal benefits in terms of prevention of burn progression. Furthermore, faster rates of re-epithelialisation were observed in wounds treated with NPWT compared with wound not treated with NPWT.

Clinical corroboration of these results was reported by Kamolz et al. (2004) (L2[–39]). In this study, bilateral partial-thickness hand burns were treated with either conservative therapy (SSD) or NPWT within 6 hours of injury. In all cases the worst affected hand was treated with NPWT for at least 48 hours. Burn depth increased in the conventionally treated hand (measured as depth of inadequate tissue perfusion) up to day 3 post injury, however no such progression was observed with NPWT-treated burns, suggesting that NPWT had prevented burn progression. In addition, less oedema (with removal of up to 500 ml of fluid) and a reduced incidence of grafting was observed in the NPWT-treated hand compared to the conventionally treated hand. These studies suggest that the principal potential use of NPWT in partial-thickness burns is its use in preventing burn progression. However, realisation of this goal would involve the early application of NPWT as a first-line therapy in burns presenting less than 12 hours from injury. In order to justify this shift in treatment strategy much more robust and convincing evidence is required. Several Level 3 studies have also reported outcomes in individual cases treated with NPWT (L3[19,31,54]) although these cases are not able to confirm the benefit of NPWT in preventing burn progression but merely demonstrate good outcomes. In the case of partial-thickness burns the recommendation of the expert panel was not approved by the audience in the consultative phase, indicating perhaps that this is not yet an accepted NPWT practice and clinicians are yet to be convinced by the evidence base. Other publications report the application of NPWT several days after the injury by which point the burn wound has stabilised (L3[34,41,62]). In these reports, NPWT was applied to achieve different goals (including maintenance of a sterile wound and coverage of exposed structures with granulation tissue) than those outlined in Table 6 and not to prevent burn progression.

Use of NPWT in surgical wound closure

Once a viable wound bed has been achieved, a decision is made either to allow the wound to progress by secondary intention, or to close by surgical closure, commonly by suture, flap, graft or a dermal replacement product alone or in combination. The goals and recommendations of NPWT usage differ depending on which route is most appropriate.

Goals and recommendations for flaps

Recommendation: It is **possible** to use NPWT as a treatment for flaps, which have suffered partial necrosis after debridement of necrotic tissue (**Grade D**)
Agreement in consultative phase 88%; Table 7.
Although there are several ways in which NPWT may be of use in improving the success rate of flaps, most of these are only weakly supported in the literature. One exception may be the potential use of NPWT as a treatment for flaps which have suffered

partial necrosis, when applied after debridement of necrotic tissue. Following flap placement a degree of tissue necrosis may be observed due to partial loss of the flap. The best course of action is to debride this necrotic tissue by thorough debridement resulting in an open wound which can then be treated with NPWT. These wounds are essentially identical to any other open wound and can be treated the same. Small wounds may be allowed to close by secondary intention while larger wounds may need a period of wound-bed preparation which may involve NPWT followed by grafting.

In flaps with extensive superficial tissue necrosis, it may be possible to salvage a significant portion of the flap through the modified crane principle[50]. The original crane principle described the use of local flaps placed in the recipient defect for 1 week, then partially removed, returning the superficial portion of the flap to its original donor site, leaving the wound, with newly vascularised tissue from the deep side of the flap, to be skin grafted[50]. This principle can potentially be translated to clinical scenarios where a significant area of the flap develops necrosis – the necrotic portion of a flap can be debrided, and the remaining viable portion salvaged. The remaining defect can be treated as a soft tissue wound and treated with NPWT in preparation for STSG. This scenario is entirely dependent on sufficient time elapsing for the deeper portions of the flap to establish some vascularity from the recipient wound bed. In wounds that do not require the additional advantages of a flap (such as those with nerve, bone, tendon, etc.), this technique can salvage a limb that could otherwise not tolerate another flap procedure. In some cases removal of the entire failed flap may be followed by NPWT of the resulting tissue defect (L3[30]) and may be salvaged with granulation tissue and skin graft.

Recommendation: Expert opinion **recommends significant caution** in applying NPWT to newly planted or compromised flaps (**Grade D**)
Agreement in consultative phase >80%; Table 7.
The role of NPWT in the treatment of transferred flaps is currently controversial, with two main conflicting schools of thought. On one hand, application of NPWT is hypothesised to improve flap success. Extrapolation from data generated in other parallel applications of NPWT suggests that NPWT may reduce flap oedema, increase flap blood flow and bolster placed flaps onto the recipient wound bed. These hypotheses remain to be rigorously evaluated clinically in flap procedures. On the other hand, a more conservative school of thought is wary of applying NPWT to the flap; the NPWT dressing obscures the flap, making visual monitoring difficult, and application of negative pressure has unknown consequences on venous congestion, development of flap necrosis and anastomotic failure in free flaps.

Some early experimental work in an animal model suggested that NPWT may be of benefit in enhancing viability of random pattern flaps (L3[57]). Raised flaps that were too long to support the full length of tissue were treated with continuous negative pressure (−125 mmHg) and had a significantly greater viable percentage area compared to flaps which were not treated with NPWT (67% vs 51%). This was postulated to be due to greater nutrient delivery to the flap. However, the clinical equivalence of this early success has yet to be clearly demonstrated. A number of Level 3 studies have described positive results following application of NPWT of transferred flaps resulting in reduced oedema[6,10,13,29,60,82], successful

Table 7
Evidence-based recommendations for the use of NPWT in flap procedures

Treatment goal or variable	Recommendation	Grade	Evidence level (1–4) and supporting reference(s)
Primary Goal: To improve wound management of failed or partially failed flaps following debridement	It is **possible** to use NPWT as a treatment for flaps which have suffered partial necrosis after debridement of necrotic tissue	D	L3[30] L4 (Expert opinion)
Associated Goal: To manage flap donor sites which cannot be closed primarily	It is **possible** in flap surgery to use NPWT to manage secondary defects (donor sites) which cannot be closed primarily	D	L3[26,71]
Treatment variable	Expert opinion **recommends significant caution** in applying significant negative pressure to newly planted or compromised flaps	D	L4 (Expert opinion)

flap take[6,29,60], reversal of venous congestion[82] and good contouring of the flap[6,10,60].

The most wide-ranging variable in these studies is the level of negative pressure applied. Pressures ranging from −75 mmHg to −125 mmHg have been reported, all of which where specified, used continuous application of negative pressure (L3[6,10,13,23,29,56,60,82]) with several studies (L3[10,13,29,60]) reporting the use of lower negative pressures (−75/80 mmHg). In particular, Morgan et al. (2006)[56] ascribed the failure of 2 flaps to the relatively high pressure of −125 mmHg used in these early cases and demonstrated no such issues when the pressure was reduced to −100 mmHg in subsequent cases. However, several other case series (Level 3) used higher pressures and reported good outcomes[6,23,82]. It appears prudent to exercise caution when placing NPWT on top of flaps and to select lower levels of negative pressure. It is feasible that placement of NPWT over a flap can cause either compression over the vascular pedicle of rotational flaps or failure of the delicate vascular anastomoses of free flaps which are highly intolerant of external manipulation. Although NPWT has been demonstrated as a successful bolster over STSG (see below), it is not appropriate to extrapolate this directly to the potential use of NPWT as a bolster for flaps, given the fragility and sensitivity of the blood supply below.

The inability to monitor the flap underneath the NPWT dressing may be overcome by the use of either hand-held (L3[29]) or implanted (L3[6,29,60]) Doppler probes. However, there is no information regarding the success of these techniques in the early identification of graft failure. In addition, placement of an implantable or external Doppler may not always be feasible. A considerable body of evidence is required before further recommendations can be made with respect to the use of NPWT on top of flaps. Ultimately, caution should be used in applying NPWT to flaps.

Recommendation: It is possible in flap surgery to use NPWT to manage secondary (donor site) defects which cannot be closed primarily (**Grade D**)
Agreement in consultative phase >80%; Table 7.
A number of studies have described the successful use of NPWT in the preparation of flap donor sites prior to grafting (L3[26,71]). The most commonly described is the radial forearm free flap donor site. This site is commonly closed by STSG, which often fails in the areas containing exposed tendons. NPWT is used at these donor sites to generate granulation tissue coverage over the exposed tendons prior to STSG placement. The impact of preparing difficult flap donor sites on success rates following subsequent primary closure has not been reported. Application of NPWT on top of the STSG is an additional application for NPWT which is described in more detail below.

Goals and recommendations for skin grafts

Successful skin grafting of full-thickness skin grafts (FTSG), split-thickness skin grafts (STSG) and more recently artificial dermal replacement products, is known to rely upon the ability of the graft to integrate with the recipient wound bed. This is improved by bolstering the graft to the wound bed by applying a dressing along with positive pressure (standard bolster dressing) and is a first principle in performing skin grafting in plastic surgery. This provides a close contact between the graft and the wound bed and minimises seroma formation. However a precaution against graft loss when using the standard bolster technique in many centers includes the need for immobilisation of the grafted area for up to 5 days post graft, sometimes requiring complete bed rest. Other issues with the conventional bolster technique include the inability to maintain even pressure distribution across a large wound bed, especially one with contoured or uneven surfaces.

NPWT was identified as a suitable dressing to bolster STSG very early in the life of the commercially available products (L3[10]). A significant body of evidence is developing that NPWT can deliver all the advantages of a bolster dressing in addition to other advantages such as active fluid removal, which further contributes to reduced seroma formation[40,78], allows earlier patient mobilisation[10,42] and earlier hospital discharge[46,48,67,72]. It is important to note that fenestrated or meshed grafts are likely to have the best outcomes as this maximizes the potential for fluid removal and prevention of seroma[5,35].

Recommendation: NPWT **must** be considered to improve the rate of graft success (**Grade A**)
Agreement in consultative phase >80%; Table 8.
The primary goal in applying NPWT to STSG is often to improve graft success. Graft success can be measured in many ways including the percentage area of successful graft take and the percentage of patients requiring a repeat graft procedure. Several comparative studies have demonstrated benefits of NPWT compared to standard tie-over bolster dressing (L1[48,53,84]; L2[42,72,83]). The majority of these comparative studies measured the mean/median percentage area of the graft with successful graft take, although only one[48] of the six studies reported a significant difference in this outcome measure. However, in studies where the number of re-graft procedures was reported, there was a consistent statistical advantage following use of NPWT on top of STSGs compared with standard bolster dressings. Llanos et al. (2006)[48], Scherer et al. (2002)[72] and Vuerstaek et al. (2006)[84] all reported significantly lower rates of re-graft in NPWT-treated STSGs, and Vidrine et al. (2005)[83] reported a difference approaching significance (p = 0.06). Korber et al. (2008)[42] reported an analogous measure (the number of grafts with greater than 50% take) and reported a significant advantage following use of NPWT compared with conventional bolster dressings. This amounts to a sizable body of evidence supporting the adoption of NPWT to enhance clinical outcomes by reducing the number of re-graft procedures required. One exception to this consistent series of studies reported no significant differences in wound complications or percentage of graft loss following STSG of a radial forearm free flap donor site whether treated with conventional tie over bolster or NPWT (L1−[16]). One reason for the inconsistency of these data in comparison with the main body of data may be the lack of wound-bed preparation prior to grafting reported in this

Table 8
Evidence-based recommendations for the use of NPWT in graft procedures

Treatment goal or variable	Recommendation	Grade	Evidence level (1–4) and supporting reference(s)
Primary goal: To improve success rate of graft procedure	NPWT **must** be considered to improve the rate of graft success	A	L1+[48,53,84] L2+[42,72,83]
	NPWT **should** be considered in wounds/patients with high risk of graft loss	B	L1+[48] L2+[42] L3[4,5,12,32,71,74]
Treatment variables	As an initial bolster NPWT **should** be left undisturbed for 3–7 days post-grafting STSG	B	L1+[16,48,53,84] L2[42,72,83] L3[4,5,10,15,32,35,54,66,74,78]
	When NPWT is used as bolster continuous pressure level **should** be used	B	L1+[53,84] L2[40,72] L3[5,10,12,15,52,66,67,74]

study. The radial forearm flap (RFF) donor site is known to be a difficult area to graft due to the presence of exposed tendons in the wound bed. A common use of NPWT discussed in the previous section is to encourage the formation of granulation tissue over exposed structure such as tendons to promote subsequent graft take. In the absence of this step, it may be that the advantage of having a well-prepared wound bed may outweigh any advantage incurred by using NPWT following graft placement. This study also acknowledged that it was only powered to see differences of 30% in outcomes, which may have been optimistic.

It is important to note that in all of these studies, NPWT was compared with conventional bolster dressings. It is possible that the use of alternative advanced fixation techniques may also yield better results than conventional bolster and performs equally well as NPWT. In the absence of studies comparing advanced fixation techniques with conventional bolster and/or NPWT it is not possible to state that NPWT is the only graft fixation method that encourages optimal graft take.

Recommendation: NPWT **should** be considered in wounds/patients with high risk of graft loss (**Grade B**)
Agreement in consultative phase >80%; Table 8.
Some evidence is available to suggest that NPWT may have an additional benefit in patients susceptible to graft loss. Korber et al. (2008) (L2+[42]) reported improved graft take in sub-analyses of both diabetic and elderly patients treated with NPWT compared with the conventional bolster dressings, albeit with low numbers in each sub-analysis. In a second study, grafts treated with standard tie-over bolster dressings showed a positive correlation between graft size and percentage area of graft loss (L1+[48]). It was reported that treatment of wounds with NPWT obviated this correlation, meaning that both small and large wounds treated with NPWT had the same chance of graft success. Some non-comparative case series have also reported better than expected outcomes in patients exhibiting certain co-morbidities, for example arterial disease, when treated with NPWT (L3[12,71]). One hypothesis suggests that placement of NPWT as the post-graft bolster improves the distal circulation of the involved extremity compared with conventional splinting/bolstering (L3[71]). This remains to be rigorously evaluated but is an interesting hypothesis.

Other case series and case studies have reported excellent outcomes when using NPWT to bolster STSG onto problematic graft sites such as irradiated wounds (L3[74]) and those with exposed bone and tendon (L3[4,5,32]). However, in a randomised controlled trial, Chio et al. (2010)[16] found no difference in outcomes when NPWT was used to bolster STSG onto a RFF donor site compared with standard therapy, although this study was not powered to detect differences smaller than 30%.

Recommendation: As an initial bolster NPWT **should** be left undisturbed for 3–7 days post-grafting STSG (**Grade B**)
Agreement in consultative phase 94%; Table 8.
It is widely accepted that, in the absence of clinical complications, a newly placed graft must be left undisturbed for a few days. This remains true for conventional bolster techniques as well as NPWT. The optimal duration of this post-operative period has not been rigorously studied and significant variation in reported clinical practice exists. A systematic evaluation of the literature identified that the post-operative time to leave the graft and dressing undisturbed ranged from 3 to 7 days. The most commonly reported duration was 5 days post grafting. It is therefore recommended that the first post-operative NPWT dressing remain undisturbed on the wound for a minimum of 3 days and up to 7 days of therapy.

Recommendation: When NPWT is used as bolster continuous pressure level **should** be used (**Grade B**)
Agreement in consultative phase 84%; Table 8.
As a logical extension of the importance of bolstering grafts, it follows that continuous pressure level over grafts would be advisable. Use of intermittent pressure, which involves a cyclical release and reapplication of pressure, is counter-intuitive. Data explicitly exploring this hypothesis have not been published. Of those STSG studies identified during the systematic review where the pressure setting was specified, all but one (L3[18]) used continuous pressure. The median pressure setting for all identified studies treating STSG with NPWT was −100 mmHg. No obvious trend was observed since early publications to suggest that a particular consensus was emerging.

A strong trend was identified in the reported studies (where details were specified) to include a wound contact layer (WCL) between the surface of the STSG and the NPWT wound filler (both foam and gauze) to avoid disruption of the STSG on removal of the NPWT dressing. The more commonly used WCL included petroleum/paraffin/vaseline gauze. Blackburn et al. (1998) (L3[10]) suggested that WCLs which allow fluid transit are preferred. It is known that the presence of some WCLs can reduce the level of negative pressure transmitted to a wound bed[37]. Whether application of the typical choice of WCL reduces the level of pressure transmitted to the wound bed in STSG has not been explored.

Another goal which may be of key importance to healthcare provision is the use of NPWT to allow earlier patient mobilisation, possibly leading to hospital discharge of patients undergoing STSG, thus resulting in significant cost savings. It is hypothesised that because NPWT provides a more stable bolstering of the wound compared to standard tie-over type dressings, the graft site can tolerate more movement from the patient without compromising graft outcomes. Use of NPWT over STSGs has been widely observed to allow earlier mobilisation of patients who

may otherwise be confined to bed rest for the standard 4–7 days normally recommended for conventional bolster dressings, especially required in the immobilisation of lower limb grafts (L2[42]; L3[10,35,46,51,78]). Discharge as early as day 1 post-grafting has been observed (L3[67]). This supports the opinion of the panel, that some patients can be discharged the day following STSG application, if a portable NPWT device is attached, to be managed on an outpatient basis, without compromising clinical outcomes. Earlier mobilisation of the graft site has also been observed in many studies (L2[40]; L3[5,35]) with no reported detriment to graft outcomes.

In addition to the use of NPWT with meshed STSG, there are several potential parallel applications with a small but growing evidence base. To begin with, NPWT has been reported to enhance the success of artificial dermal replacement materials. Several Level 3 studies have reported the successful application of artificial dermal substitutes, including Integra™[1,8,32,46,52,67,77,81], Alloderm™[40] and GraftJacket™[68], to a recipient wound bed in conjunction with NPWT. Some procedural differences are observed between the use of NPWT over an artificial dermal substitute and STSG. Firstly, the use of a WCL was not considered relevant in a large majority of studies due to the presence of the uppermost silicon layer in the Integra dressing. Secondly, the duration of NPWT following placement of dermal substitute was considerably longer than the 3–5 days required for STSG, with durations between 10 days[8] and 84 days[1] and dressing changes taking place at the usual frequency of every 2–3 days. The application of NPWT to a single-stage application of artificial dermis replacement products and skin grafts has also been described (L2[40]; L3[8]). Application of NPWT to this multi-layered reconstruction significantly improved graft take compared with conventional tie-over dressings alone[40].

Another parallel application of NPWT is its use to enhance the success of full-thickness skin grafts (FTSG). The level of evidence for the use of NPWT with FTSG is low, although good outcomes have been reported (L3[22,28,44]). If NPWT is used on top of a full-thickness graft, it may be prudent to fenestrate the graft to allow egress of fluid and prevent seroma formation.

Conclusion

There is wide anecdotal acceptance of NPWT as a successful therapy in a large range of different wound indications. Despite an enormous number of Level 3 studies describing the safety and efficacy of the technology there is a relative paucity of comparative studies including randomised clinical trials. The resulting evidence base is therefore weaker than the wide-spread adoption of NPWT would suggest. In light of this, consensus becomes an important part of recommendation generation. The recommendations proposed here have been restricted by the extent of the evidence base. Further Level 1 and 2 comparative studies are required, in particular in the areas of soft tissue trauma, open fracture, flap reconstruction and partial-thickness burns, in order to enhance the strength of the recommendations.

Competing interests

Funding

Appendix 1. Clinical disciplines and nationalities attending NPWT meeting, Hamburg, February 2010

Discipline	%	Country of origin	%
Burns surgeons	1%	Australia	1%
Cardiac surgeons	2%	Austria	2%
Clinical nurse specialists	15%	Belgium	2%
Diabetologists	3%	Croatia	2%
General surgeons	21%	Germany	40%
Geriatric specialists	2%	Denmark	1%
Orthopaedic surgeons	3%	Finland	1%
Other clinical specialities	10%	France	1%
Paediatric surgeons	1%	Greece	1%
Pharmacists	1%	Hungary	1%
Plastic surgeons	17%	Ireland	1%
Thoracic surgeons	2%	Italy	14%
Trauma surgeons	5%	Kuwait	1%
Vascular surgeons	10%	Lebanon	1%
Visceral surgeons	5%	Netherlands	3%
Wound care physicians	3%	Norway	1%
		New Zealand	1%
		Poland	3%
		Portugal	1%
		Quatar	1%
		Kingdom of Saudi Arabia	1%
		South Africa	2%
		Spain	4%
		Sweden	1%
		Switzerland	4%
		Turkey	1%
		Uganda	1%
		UK	7%
		USA	1%

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