



## Topical negative pressure wound therapy (TNPWT): current practice in New Zealand

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### Abstract

**Aim** To survey current opinion, regarding TNPWT, from New Zealand vascular surgeons.

**Method** Registered vascular surgeons currently practicing in New Zealand were identified from the Vascular Society of New Zealand (VSNZ) database. A questionnaire was emailed asking if they used TNP in their vascular surgical practice and whether or not they considered themselves 'up to date' regarding published evidence for TNP. Surgeons were also asked how often and how successful they felt that TNP was in different clinical situations (arterial ulcers [after revascularisation]; venous ulcers; mixed arterial/venous ulcers; following debridement of the 'diabetic (Db) foot'; lower limb (LL) surgical wound infections/dehiscences; and lymphocoeles/seromas/lymph fistulas not treated successfully with conservative management). One email reminder, followed by a hard copy reminder was sent to those who failed to respond to the first email.

**Results** Of 38 vascular surgeons 34 responded (89.5%). Median response time was 3.38 days (range 12 min–11.8 days). 28 (82%) vascular surgeons used TNP in their NZ clinical practice. 17 (50%) considered themselves up to date regarding published evidence, 8 (23.5%) admitted to not being up to date with the evidence and 9 (26%) did not know. TNP appears to be used most frequently and with most success following debridement of diabetic foot wounds and in the management of infected/dehiscenced surgical wounds.

**Conclusion** TNPWT is widely used by NZ vascular surgeons, despite many not considering themselves up to date regarding published evidence. It is most favoured for treating diabetic feet post debridement and for lower limb surgical wounds.

Topical negative pressure (TNP) is also known as vacuum assisted closure (VAC), sub-atmospheric pressure dressing (SPD), vacuum sealing technique (VST), foam suction dressing, sealed surface wound suction (SSS), vacuum pack therapy, and sealing aspirative therapy.<sup>1–3</sup> It is the application of a local sub-atmospheric pressure across a wound.<sup>4</sup>

TNP is used both as primary treatment of chronic and complex wounds; and as an adjunct for temporary closure and wound bed preparation before definitive surgical procedures—e.g. wound bed preparation pre skin grafts.<sup>4,5</sup> TNP has been recommended for a variety of acute and chronic wounds including pressure wounds, diabetic leg ulcers, lower leg wounds, traumatic wounds, burns, infected wounds, necrotizing fasciitis, infected sternal wounds, and after skin grafting.<sup>1,3,6</sup>

TNP therapy does not replace surgical wound debridement, measures to improve blood circulation, or relevant treatment of infection.<sup>6</sup> TNP may also be useful to stabilise wounds in patients not well enough to be considered for surgery.<sup>4,5</sup>

It has been proposed that TNP promotes wound healing through a number of mechanisms. These include oedema reduction, increased wound/dermal perfusion, increased granulation tissue stimulation, decreased bacterial loading and enhanced wound exudate removal.<sup>2-5,7,8</sup>

A recent meta-analysis concluded that only increase in blood flow appears to be proven, whereas the actual mode of action of TNP still remains unclear.<sup>4,5,9</sup> There is still a paucity of data on optimal duration of TNP, however it seems to have its greatest effect in the early stage of wound healing.<sup>5</sup>

Complications associated with TNP include decreased mobility, pain, pressure necrosis, haemorrhage, haematoma, infection, and toxic shock.<sup>1-4,7</sup> Topical negative pressure is contraindicated where there is necrotic tissue or eschar. The therapy should not be placed directly over exposed organs or blood vessels, untreated osteomyelitis, non-enteric or unexplored fistulas or malignancy in the wound.<sup>1-4</sup> TNP should be used with caution in patients with difficult wound haemostasis, with active bleeding or taking anticoagulants.<sup>1-4</sup>

The clinical evidence supporting the use of TNP has been largely based on clinical perception, case series, small cohort studies and weakly powered RCT's, constituting a large amount of low level evidence.<sup>10</sup> Most published studies on TNP are poorly designed and therefore its use in surgical practice remains controversial. In 2006, an updated Health Technology Policy Assessment regarding TNP was published from Canada.<sup>1</sup> The assessment reviewed seven international health technology assessments on TNP and found that TNP was consistently reported as being helpful for healing a variety of wounds. However, the effectiveness of TNP could not be quantified because of the poor methodological quality of studies.<sup>1</sup>

Two recently published systematic reviews concluded that there remains a lack of clinical evidence to support the use of TNP over more conventional treatments.<sup>6,7</sup> Despite this, the use of TNP has increased substantially for treating a variety of clinical scenarios. It has been suggested that because TNP is readily available and easy to administer compared with multiple daily conventional dressing changes, it has the potential to be used inappropriately.<sup>1</sup>

The aim of this audit was to establish current opinion regarding TNP from vascular surgeons practicing in New Zealand.

## Method

Vascular surgeons currently practicing in New Zealand were identified using the Vascular Society of New Zealand (VSNZ) database. A questionnaire was emailed to identified surgeons asking how often and how successful the surgeons felt that TNP was in a variety of common clinical situations (i.e. arterial ulcers (after revascularisation); venous ulcers; mixed arterial/venous ulcers; following debridement of the 'diabetic (Db) foot'; lower limb (LL) surgical wound infections/dehiscences; and lymphocoeles/seromas/lymph fistulas not treated successfully with conservative management).

The responses were graded for use of TNP as always, often, sometimes or never; and success was graded as very good, good, average, poor or none. Surgeons were also asked if they used or recommended TNP in their vascular surgical practice and whether or not they considered themselves 'up to date' regarding published evidence for TNP.

A week later, a second email was sent to non-responders asking them to complete and return the questionnaire. Finally, a week later, a third reminder was sent by post with an enclosed postage paid, self addressed envelope asking surgeons to send their response back.

If email addresses were not available surgeons were sent a hard copy of the questionnaire by post in the first instance.

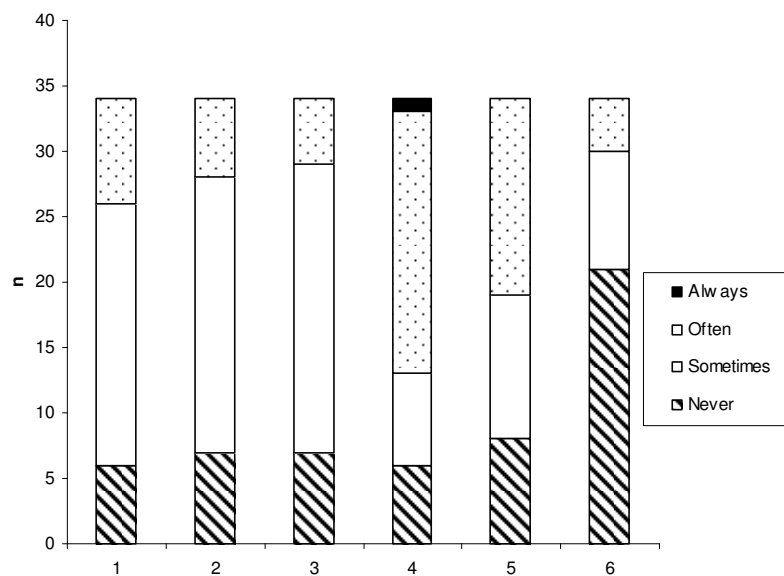
## Results

Thirty-nine vascular surgeons are registered on the VSNZ database, however this included one radiologist who was excluded from the current audit (therefore n=38); 34 surgeons responded (response rate of 89.5%). The median response time was 3.38 days (range 12 min–11.8 days); 16 (47.1%) responded to the initial email, 8 (23.5%) to the second reminder, and 10 (29.4%) to the third. Of those surgeons who responded, 47% replied electronically and 53% replied on paper.

Twenty-eight (82%) vascular surgeons in NZ used TNP in their clinical practice, however only 17 (50%) considered themselves up to date regarding published evidence for TNP. Eight surgeons (23.5%) considered that they were not up to date with the evidence and 9 (26%) were not sure whether or not they were up to date. Six (18%) surgeons did not use TNP in their vascular surgical practice.

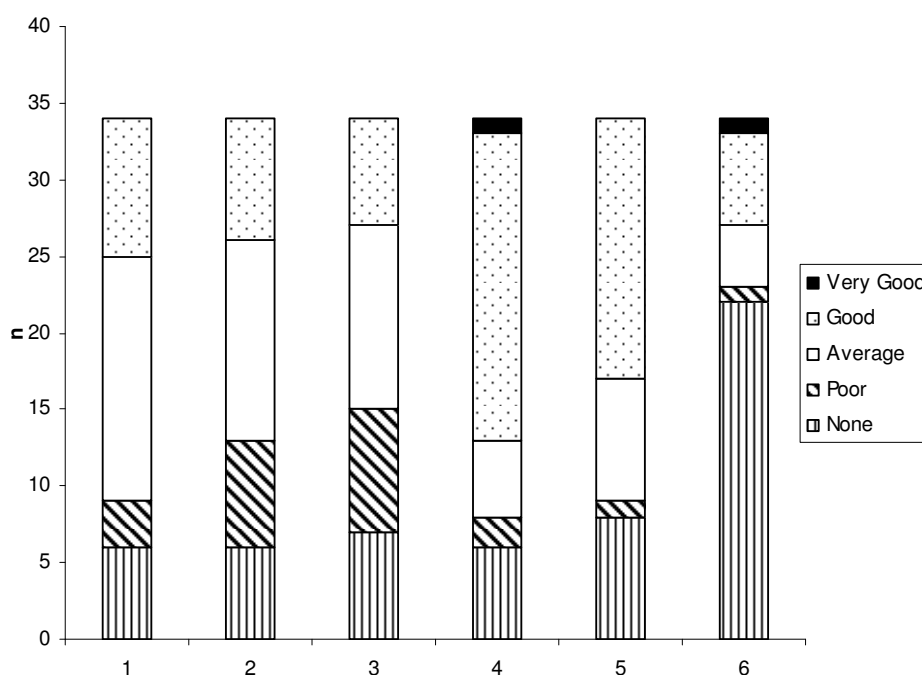
The use of TNPWT for different wounds is presented in Figures 1 and 2, and Table 1.

**Figure 1. How often TNP is used in above clinical situations by New Zealand vascular surgeons**



1=arterial ulcers; 2=venous ulcers; 3=mixed arterial/venous ulcers; 4=following debridement of the diabetic foot; 5=lower limb surgical wound infections/dehiscences; 6=lymphocholes/seromas/lymph fistulas not successfully managed conservatively.

**Figure 2. How successful TNP is considered when used in various clinical situations by New Zealand vascular surgeons**



1=arterial ulcers; 2=venous ulcers; 3=mixed arterial/venous ulcers; 4=following debridement of the diabetic foot; 5=lower limb surgical wound infections/dehiscences; 6=lymphocoeles/seromas/lymph fistulas not successfully managed conservatively.

Surgeons were invited to submit any relevant comments with their responses. Three surgeons not using TNP were limited by its availability in their institutions. One surgeon commented that he sees little point in using TNP, particularly if an ulcer is treated by good compression. Regarding persistent lymphatic leakage, one surgeon thought that there was some logic in using TNP, although in this situation he felt that patients often do not present to a hospital setting.

## Discussion

A chronic wound is defined as a wound that does not heal in an orderly set of stages and in a predictable amount of time the way most wounds do; wounds that do not heal within three months are often considered chronic.<sup>11</sup> The vast majority of chronic wounds can be classified into three categories: venous ulcers, diabetic wounds, and pressure ulcers.<sup>12,13</sup>

Management of chronic wounds remains costly and challenging to health practitioners. They can also impose significant emotional and physical stress to patients. Topical Negative Pressure (TNP) is becoming widely accepted as a first line treatment in the management of a variety of wounds. Negative pressure has been used as part of the treatment of wounds in the form of various drains since the 1940's.<sup>6</sup> Its use in encouraging healing of open surgical wounds, diabetic foot ulcers and chronic

non-healing wounds has been widely studied. Unfortunately most published studies on TNP are poorly designed and therefore recommendations for its use in surgical practice remain controversial—both clinically and economically.

A systematic review of topical negative pressure therapy for acute (split skin grafts, diabetic foot amputation) and chronic (venous, arterial, diabetic or pressure) wounds was recently published.<sup>7</sup> Fifteen relevant publications of thirteen RCT's evaluating effectiveness of TNP for patients with chronic wounds, diabetic wounds, pressure ulcers, skin grafts and acute wounds were included.

The authors concluded that these studies contained no aggregate evidence for more relevant wound healing for any type of wound when using TNP and that TNP should not routinely be promoted for use in local wound care.<sup>7</sup> The authors also emphasised the flaws seen with the study designs including invitations for selection bias, insufficient follow up periods and use of surrogate (yet clinically irrelevant) endpoints, differing endpoints between studies and differing control treatments meaning meta-analysis could not be performed.<sup>7</sup>

Individual trials suggested that chronic and diabetic wounds treated with TNP appeared to be ready for secondary closure surgery between one to ten days earlier, however this came at a cost of increased complications (including two cases of sepsis in the TNP group). The authors of the review also argued that ten days difference is negligible given that the nature of these wounds often means that they take many months to heal.<sup>7</sup>

In another systematic review published the same year the authors considered the effectiveness and safety of negative pressure wound therapy (NPWT) for problematic wounds including pressure wounds, post-traumatic wounds, diabetic foot ulcers and miscellaneous chronic ulcers.<sup>6</sup>

Of the fourteen RCTs reviewed, twelve were included in the systematic review discussed above,<sup>7</sup> plus an additional two part study.<sup>14</sup> The authors reported that the methodological quality was poor in most studies and that only two trials were considered to have good internal validity.<sup>6</sup> Despite the poor methodological quality of most papers the authors suggested that tentative evidence suggests that NPWT appears to be at least as effective, if not more effective, than other available local wound treatments.<sup>6</sup>

The most promising results were obtained in patients with lower leg vascular ulcers, diabetic foot ulcers and split thickness skin grafting.<sup>6</sup> The main adverse events when using TNP appeared to be infection, irritation of the skin and pain when changing the dressing, however these were reported as mild and overall TNP appears to have an acceptable safety profile.<sup>6</sup>

Two studies included in the review attempted to calculate costs between TNPWT and alternative modern wound care products, one of which found no difference between therapies.<sup>15</sup> The other calculated that TNPWT was less costly than that of the reference therapy, US\$3381 compared with \$5452,<sup>15,16</sup> however the extent to which the equipment outlay was taken into consideration was unclear in the cost analysis.<sup>6</sup>

Theoretically TNP may become more cost effective as less expensive newer technology emerges. Faster healing times may result in shorter hospital stays and less

demand on health care systems. As there is a longer time between dressing changes with TNP, there is less demand on nursing staff. Braakenburg (2006) suggested that although overall costs between TNP and traditional wound therapy were similar, TNP resulted in improved patient comfort and decreased time and cost of nursing staff.<sup>15</sup>

The systematic reviews concluded that the lack of well-designed RCT's evaluating the efficacy of TNP, means that no firm findings can be drawn from them.<sup>6-7</sup> Individual papers tended to present more favourable findings.

Armstrong et al investigated TNP for its use in acute wounds following diabetic foot amputation.<sup>10</sup> Ubbink et al. argued that although there was a 17% earlier wound healing time (number needed to treat was six), there was an 11% higher infection rate (number needed to harm was nine) in the TNP group.<sup>7</sup> Armstrong et al reported that none of these infections were treatment related.<sup>6,10</sup>

A large multicentre randomised controlled trial enrolled 342 patients to evaluate the safety and clinical efficacy of negative pressure wound therapy (NPWT), compared with advanced moist wound therapy (AMWT), to treat foot ulcers in diabetic patients.<sup>17</sup> They concluded that a greater percentage of foot ulcers achieved complete wound closure with NPWT (43%) compared with AMWT (29%) within the 112 day active treatment period.<sup>17</sup>

Significantly fewer secondary amputations were required in the NPWT group whilst there was no significant difference observed at 6 months between the two groups in treatment related complications.<sup>17</sup> NPWT appears to be as safe and more efficacious than AMWT for treating diabetic foot ulcers.<sup>17</sup>

It has been documented that TNP leads to a significant improvement in the wound management of recalcitrant chronic lower limb ulcers (venous, mixed and arterial) that require skin graft operations.<sup>16</sup> Despite increased success of skin grafting in patients using TNP, there was no difference in ulcer recurrence rates.<sup>16</sup> The number of patients recruited in this study was too small to enable a sub group analyses for different types of chronic leg ulcer.

McCallon had earlier reported that TNP is useful for large venous ulcers, but arguably had no impact on arterial ulcers and those with persistent arterial deficiency and persistent local ischaemia.<sup>18</sup> Experimentally, TNP results in no improvement in micro-circulation in ischaemic human lower limbs.<sup>19</sup>

In the current audit, vascular surgeons in New Zealand used TNP most often following debridement of the diabetic foot. TNP was used less frequently for treating arterial ulcers (after revascularisation), venous ulcers and finally mixed arterial/venous ulcers. It was used only sometimes or never by 76% (arterial), 82% (venous) and 85% (mixed arterial/venous) of New Zealand vascular surgeons.

The surgeons questioned found that they had the most success when using TNP following debridement of the diabetic foot, with 62% of them saying that they had good or greater success in this scenario. This is in keeping with current literature that suggests that TNP may lead to more rapid wound healing following surgery to the diabetic foot.<sup>10</sup>

Vascular surgeons in New Zealand reported less success when using TNP for arterial, venous and mixed ulcers. Less than 26% of surgeons had anything better than good

success when using TNP for treating ulcers of any aetiology. TNP may accelerate healing in patients with chronic venous ulcers who are also treated with bed rest and punch grafts,<sup>2,16</sup> however there is no evidence to support its use in arterial ulcers.

Despite some evidence to suggest the benefits of TNP for treating venous ulcers, this is not reflected in the experience and opinion of New Zealand vascular surgeons - it is more frequently used in New Zealand to treat arterial ulcers. TNP may not be the favoured method for treating venous ulcers, given that more traditional compression therapy continues to prove beneficial.

One report has been published of TNP successfully managing a MRSA infected/dehiscenced femoro-popliteal bypass surgical wound in a diabetic patient.<sup>20</sup> A larger series reported 33 patients with femoro-popliteal bypass graft post op groin infections and their subsequent treatment with TNP.<sup>21</sup> Although there was no control group, the authors reported significant adverse effects of TNP in this population - including serious TNP associated bleeding and late false aneurysm formation.<sup>21</sup> TNP treated graft infections were associated with a high risk of developing infection-related complications.<sup>21</sup> Non-healing surgical site infections were associated with amputation and death.<sup>21</sup>

No RCTs have reviewed the use of TNP for treating lower limb surgical wound infections/dehiscences. Despite this, this was the second commonest situation that TNP was used for by New Zealand surgeons. 45% of surgeons used TNP often for treating lower limb surgical wound infections/dehiscences, with 50% perceiving success as above average. More RCTs are needed, evaluating the use and safety of TNP for treating these wounds, before its routine use can be justified.

No papers have been published specifically evaluating the effectiveness of TNP for its use in lymphocoeles, seromas or lymph fistulas. The results of this audit suggest that it is rarely used in New Zealand for this—62% questioned had never used TNP in this clinical situation, the most frequent of all responses.

Despite this one surgeon rated that TNP was very good for treating lymphocoeles, seromas or lymph fistulas that were difficult to control with conservative measures and 21% of surgeons rated that they had good success. Its use in this scenario seems to be based entirely on anecdotal favourable clinical experience.

It would seem that use of TNP derives mostly from personal experience. The results of this audit suggest that 50% of surgeons in New Zealand using TNP admit to not being currently up to date with published research. The criticism of the published literature apparent in recent systematic reviews might cast some clinical doubt on the role of TNP. There is however a gradually expanding evidence base allowing clinician's to make informed choices for optimal use of TNP.<sup>4</sup>

Individual trials suggest that TNP may be beneficial in treating diabetic foot ulcers, venous ulcers and arterial ulcers (post revascularisation). Systematic reviews challenge the validity of these results, given the poor methodological quality of many of these RCTs.<sup>6,7</sup> As a consequence, definitive conclusions and clinical guidelines for the use of TNP are difficult to formulate and remain controversial. There still remains a large gap between evidence based data and routine clinical experience.<sup>5</sup> Although TNP appears effective, it still remains unclear as to whether or not it is more effective than other wound closure techniques.<sup>22</sup>

The technology of TNP is continuously advancing, with impregnated foams and gauze containing growth factors or other agents (e.g. silver for altering wound environment) being introduced to the market.<sup>4</sup> This will add to the difficulty of drawing conclusions through systematic reviews and meta-analyses, because to date none of the RCTs have used this technology.

Currently in New Zealand TNP is most commonly used for diabetic foot wounds post debridement, lower limb surgical wounds and arterial followed by venous ulcers, with perceived success correlating with this order of popularity. There is a need for surgeons in New Zealand to understand the controversies regarding TNP.

**Note:** Results of the audit were recently presented at the Vascular Society of New Zealand annual conference in Tauranga, February 2009.

**Competing interests:** None known.

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