

# Can negative pressure wound therapy over closed surgical wounds prevent complications?

## KEY WORDS

- ▶ Acute wounds
- ▶ Negative pressure wound therapy
- ▶ Patient recovery
- ▶ Prevention of wound complications

This literature review evaluates the evidence for use of negative pressure wound therapy (NPWT) over closed surgical incisions to reduce wound complications. Wounds that fail to heal post-operatively due to infection, haematoma, seroma or dehiscence can delay a patient's recovery and in the most serious cases, lead to mortality. Patients with comorbidities such as obesity, diabetes or peripheral vascular disease are at an increased risk of wound breakdown post-operatively, with wound management presenting a major challenge. The results of this review indicate that NPWT, when placed at the point of surgical wound closure, has the potential to reduce surgical wound complications in individuals at high risk of impaired healing.

Wound complications following cardiothoracic, abdominal, vascular and orthopaedic surgery are well documented (Matatov et al, 2013; Stannard et al, 2012a; Atkins et al, 2009; Chadi et al, 2015), with additional cardiothoracic-specific risk factors for the delayed healing of sternotomy incisions identified as: re-exploration for bleeding, transfusion, prolonged operating time and the dissection of the internal mammary arteries (Careaga et al, 2006). Risk factors for abdominal wound complications include prolonged operating time and emergency procedures (Sandy-Hodgetts et al, 2013). In addition, comorbidities such as obesity, diabetes, smoking, peripheral vascular disease and chronic obstructive pulmonary disease present challenges in preventing wound complications post-operatively (Wilkes et al, 2011). Delayed wound healing in obesity has been associated with elevated traction forces on skin sutures, leading to skin separation, and colonisation of skin folds with skin flora, causing infection (Grauhan et al, 2013).

Specific complications include infection, haematoma or seroma formation, and wound dehiscence, which can lead to a significant delay in patient recovery and rehabilitation (Stannard et al, 2012a; Sandy-Hodgetts et al, 2013). Wound management interventions to prevent these post-operative complications are therefore crucial.

Negative pressure wound therapy (NPWT) has emerged as an effective therapy for the healing of a range of acute and chronic wounds (Stansby et al, 2010), and recent studies suggest that NPWT may be beneficial when applied over closed surgical incisions (Pauser et al, 2014; Witt-Majchrzak et al, 2014; Nordmeyer et al, 2015).

The proposed functions of NPWT include increased tissue perfusion, reduction in oedema and interstitial tissue fluid and reduced bacterial colonisation (Bovill et al, 2008). More recently, incisional negative pressure wound therapy (INPWT) has been shown to reduce lateral stress on surgical closures by 50%, keeping the superficial and deep tissue layers in contact while avoiding shearing, reducing the risk of dehiscence (Wilkes et al, 2011). In addition, a reduction in incisional stress is thought to decrease tissue myofibroblast numbers, potentially reducing scarring (Timmenga et al, 1991). One adverse effect of the use of INPWT that has been reported is skin blistering (Howell et al, 2011).

There are different INPWT devices available, but the peel and place Prevena™ (Acelity), which delivers a pressure of -125 mmHg, was the first product designed specifically for application at the point of surgical wound closure (Wilkes et al, 2011). A recent Cochrane review (Webster et al, 2014) concluded that the evidence supporting

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the use of INPWT for the reduction of surgical wound complications was unclear, and the authors recommended further research focused on the effectiveness of newer INPWT products. Since the review, other studies have investigated the use of INPWT products designed specifically for closed incisions, with the evidence suggesting INPWT as an effective therapy to prevent wound complications after surgery (Grauhan et al, 2013; Matatov et al, 2013; Pauser et al, 2014).

INPWT as a management option for the prevention of surgical wound complications across a range of surgical wound types will be critically analysed in this review. This will include discussion about the potential benefits of this therapy: infection prevention, seroma reduction and wound dehiscence prevention; and a discussion of the potential harm of blistering.

#### SEARCH TOOLS

Relevant studies for inclusion were identified using the electronic databases MEDLINE (Ovid), PubMed and the Cochrane database of systemic reviews. Google Scholar was also used as a search engine to ensure the literature for this review was as current as possible. Search terms included ‘INPWT’ ‘NPWT over closed surgical incisions’, ‘VAC therapy over closed incisions’ and ‘topical negative pressure.’ Since the purpose of this literature review is to evaluate a treatment effect, all studies included are randomised controlled trials, with the exception of the Cochrane collaboration systemic review. The Critical Appraisal Skills Programme (CASP) tool was used to assess the risk of bias and methodological rigour of studies, culminating in the inclusion of nine randomised controlled trials (CASP, 2013).

#### PREVENTION OF INFECTION

Stannard et al (2012b) published a randomised multicentre study of 249 patients, comparing INPWT with postoperative dressings following high-risk lower-extremity fractures. The authors used the sponge dressing supplied with VAC® (vacuum-assisted closure) device (KCI) and placed this over the closed incision immediately following surgical closure in the treatment group. A total of 263 fractures were randomised to the control

( $n=122$ ) and the INPWT ( $n=141$ ) groups. There was a total of 23 (19%) surgical site infections (SSIs) identified in the control group compared with 14 (10%) in the INPWT group, representing a statistically significant result in favour of INPWT ( $p=0.049$ ). The randomisation of participants and the strict inclusion and exclusion criteria increase the reliability of the study (Moher et al, 2010). The amount of pressure applied by the device was  $-125$  mmHg, which also increases study reliability as this has been shown to be the optimal pressure to increase blood flow to the wound site (Morykwas et al, 1997).

The authors recognise the multicentre nature of the study, which includes four institutions, and different surgeons, as potential weaknesses. This is because different surgical and wound management practices may have had an impact on the treatment effect (Glidden and Vittinghoff, 2004). Additionally, the authors declare that the study was funded by KCI, which is a potential source of bias (Greenhalgh, 2006). While limitations are reported, it appears that a standardised protocol was not followed, and the duration of INPWT differed between participants without explanation by the authors, therefore institutional bias cannot be eliminated (Reeves, 2003). The measurement of infection also appears to have been subjective, with no validated criteria mentioned for the diagnosis of SSI. Furthermore, the length of the follow-up period is not stated. Overall, insufficient reporting of the design methodology reduces the reliability of results. Standard operating procedures and a trial protocol would have helped to reduce the limitations of the study and improve internal validity. However, despite the limitations identified, Stannard et al (2012b) set the scene for future research on INPWT and the prevention of SSI.

Grauhan et al (2013) carried out a prospective, comparative study of 150 obese patients undergoing cardiac surgery via sternotomy, to investigate the effect of the Prevena Incision Management System (KCI) on the prevention of wound infection. Of the 75 patients assigned to the INPWT group, three (4%) developed wound infections in comparison to 12 (16%) of patients in the conventional wound dressing group, which

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was a statistically significant difference ( $p=.0266$ ; odds ratio 4.57). Gram-positive organisms, such as *Staphylococcus aureus*, commonly associated with sternotomy SSIs (Michalopoulos et al, 2005; Kühme et al, 2007) were found in only one of three patients in the INPWT group with an infection, compared with ten patients in the control group.

The authors used the criteria for superficial and deep wound infection, as proposed by the US Centre for Disease Control and Prevention (Mangram et al, 1999). These are the most widely recognised criteria for SSI (Leaper et al, 2013), and have been shown to have a positive predictive value (Huotari et al, 2007), which increases the reliability of the results. The authors also provide a clear description of the standardised method of skin preparation and skin closure used in both groups prior to dressing application, which increases the internal validity of the study (Farrokhyar et al, 2010).

One limitation of the study is that it is not specified whether the investigator was blinded to control and treatment group allocation, which may have allowed investigator bias (Meadows, 2003). Although patient follow-up of 90 days adds rigour to the study, the presence of SSI post-discharge was identified by a patient telephone call, rather than the more sensitive method of direct observation (Petherick et al, 2006). The accuracy of this method is debatable, since patient self-diagnosis of wound infection has been shown to be variable (Seaman and Lammers, 1991; Whitby et al, 2002).

More recently, Grauhan et al (2014) carried out a retrospective secondary analysis of their 2013 study, comparing 238 patients receiving INPWT with 3,508 patients receiving standard dressings. Follow-up at 30 days showed that the INPWT (Prevena) group had a statistically significantly lower rate of infection, compared with the control group ( $n=3$  versus  $n=119$  respectively,  $p<0.05$ ). It is possible that frequent dressing changes in the control group (every 1–2 days) may have increased exposure to environmental contamination and elevated infection risk, since phagocytosing neutrophils during the initial inflammatory stage of wound healing can take up to 48 hours to reach maximum levels at the wound site post-surgery (Enoch and Leaper, 2005). However, the larger

sample size adds power to the study, and builds upon their previous study. The authors concluded that a clean protected environment provided by the Prevena for an application period of 6–7 days may account for the reduced likelihood of infection, which seems a reasonable conclusion.

Matatov et al (2013) also investigated the effect of the Prevena on the prevention of groin wound infection in their retrospective study of 90 patients who underwent longitudinal or transverse cutdown for vascular procedures. Wounds in the control and treatment (Prevena) groups were evaluated at 7 and 30 days postoperatively, with infections classified as superficial to deep (grade I–III), according to the Szilagyi grading system, which is commonly used in vascular studies (Mayer et al, 2011; Hasse et al, 2013). Of 63 groin incisions in 49 patients in the control group, 19 (30%) presented with Szilagyi-graded wound infections I–III, in comparison to three (6%) grade I infections out of 52 incisions in 41 patients in the Prevena group, making the overall incidence of infection statistically significantly lower in the Prevena group ( $p=.0011$ ). A limitation of the study is the small sample size, which may have introduced the risk of sampling error (Coughlan, 2007). Furthermore, the authors do not explain why the control group was followed up for a longer period than the Prevena group, which potentially introduces systematic bias. However, the well-defined methodology, which describes standardised pre-operative skin preparation and surgical procedure prior to dressing application, increases the reliability of the study. Overall, the results appear positive, and the study suggests that INPWT with the Prevena system for 5–7 days may significantly decrease groin SSIs following vascular procedures. The authors hypothesise that following the transection of lymphatics, INPWT may decrease lymphocele formation, reducing skin maceration. This concept has been explored in studies investigating the effects of INPWT on seroma reduction post-operatively.

#### **SEROMA REDUCTION**

In a comparative study, Pauser et al (2014) reported a reduction in seroma formation in older patients receiving INPWT following hemiarthroplasty.

Patients in the control group ( $n=10$ ) developed a seroma of  $3.995 \pm 5.01 \text{ cm}^3$  after 5 days of standard post-operative dressings, and had a secretion volume of  $4.30 \pm 2.45$  days, in comparison to patients receiving the Prevena dressings for 5 days ( $n=11$ ), who developed a seroma of  $0.257 \pm 0.750 \text{ cm}^3$  and had a secretion volume of  $0.9 \pm 1.0$  days. Overall, the authors reported that 80% of the control group developed post-operative seromas, in comparison to 18% in the Prevena group on day 5, and 36% on day 10. Seroma was identified through the use of ultrasonography on days 5 and 10 post-operatively. Ultrasonography is a highly sensitive, valid tool for the diagnosis of early post-operative seroma formation (Susmallian et al, 2001), therefore increasing the reliability of results. The authors also identified no significant differences between group wound sizes ( $p>0.05$ ), which is important since larger wounds may be expected to produce a greater amount of drainage (Patel et al, 2007). While this is encouraging, a significance level is not provided in relation to a reduction in seroma volumes, and the percentage of seroma volumes in the control group on days 5 and 10 is not reported, with the authors stating only an overall percentage. This introduces the possibility of detection bias, where knowledge of patient assignment can influence patient outcome (Jüni et al, 2001). However, inadequate reporting does not necessarily indicate that the conduct of the trial was inappropriate (Hill et al, 2002).

In a more recent study, Nordmeyer et al (2015) investigated the effects of 5 days of INPWT over closed incisions following spinal fracture stabilisation using the PICO™ system (Smith and Nephew plc). Ultrasonography at days 5 and 10 post-operatively indicated a marked difference in seroma volume in the INPWT group (0ml and 0.5ml, respectively), in comparison to the control group (1.9ml and 1.6ml, respectively), which reached statistical significance ( $p=0.0007$  at day 5, and  $p<0.024$  at day 10).

The authors do not comment on the level of pressure delivered by the PICO system, which is  $-80 \text{ mmHg}$  according to the manufacturers. This is lower than the  $-125 \text{ mmHg}$  pressure used in previous studies, making comparisons difficult. However, surgical technique and post-

operative care was standardised in both groups, strengthening the study's internal validity.

The findings of Pauser et al (2014) and Nordmeyer et al (2015) differ from that of an earlier study by Condé-Green et al (2013), in which no significant difference was identified in seroma rates between the control and INPWT groups. While this may appear contradictory, it is not stated by Condé-Green et al how seroma was measured, making a true comparison with other studies difficult.

#### WOUND DEHISCENCE AND SKIN NECROSIS

Condé-Green et al (2013) investigated the effect of 5 days of INPWT on wound dehiscence by applying standard VAC® (Acelity) over closed surgical incisions following abdominal wall construction. Of the INPWT group ( $n=23$ ), two participants (9%) developed wound dehiscence, in comparison to 13 (39%) in the control group ( $n=33$ ), ( $p=0.014$ ). All patients were operated on by the same surgeon, which reduces the likelihood of confounding variables, such as surgical closure technique, impacting on the treatment effect (Meadows, 2003). Patient comorbidities known to have an adverse effect on wound healing, such as obesity, smoking and diabetes (Fowler et al, 2005; Broughton and Janis, 2006) were also equally weighted in both groups, increasing the reliability of results. One limitation is that patients were not randomised into groups, but instead purposely selected into the INPWT group, with a historical control group used to compare outcomes. Therefore, over-inflation of the treatment effect is a possibility and selection bias cannot be completely eliminated (Kunz and Oxman, 1998). However, the results are in agreement with an earlier study by Stannard et al (2012b), which demonstrated an 8.6% wound dehiscence rate in the INPWT group in comparison to 16.5% in the study control ( $p=0.044$ ). Condé-Green et al (2013) are the only authors to mention haematoma rates in each group (0%), therefore further investigation is required to evaluate this treatment effect.

Although Condé-Green et al (2013) report no significant difference in skin necrosis between groups, in a more recent study of sternotomy

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wounds by Witt-Majchrzak et al (2014) the INPWT group ( $n=40$ ) showed no skin necrosis following 6 days of PICO application in comparison to 30% of patients ( $n=12$ ) in the control group ( $n=40$ ). These are the only existing studies found that investigate the effect of INPWT on skin necrosis, and the conflicting results indicate a requirement for further research in this area.

#### HARMS/ADVERSE EFFECTS

Although traditional NPWT as used for patients with open wounds has been associated with increased pain (Braakenburg et al, 2006), no studies to date have reported this as an effect of INPWT over closed surgical incisions.

Howell et al (2011) found an increased rate of skin blistering associated with INPWT in obese patients following knee arthroplasty. The trial was stopped prematurely when 15 of 24 patients (63%) developed skin blisters between the VAC sponge and adhesive tape, in comparison to 12% of patients in the control group. The cause of the blisters was stated as being most likely due to friction. The authors do not state which type of therapy was used, therefore it is difficult to compare it with other systems used. Wittmajchrzak et al (2013) also found that serous vesicles were more common in the INPWT group using the PICO system (12.5%) in comparison to the control group (0%) ( $p=0.0209$ ). However, these vesicles were found to spontaneously absorb following discontinuation of INPWT, with no detriment to wound healing.

There is limited evidence reported in the literature with regard to the potential harms of INPWT, and it is therefore recommended that harms are monitored in subsequent studies investigating the effects of this relatively new wound management intervention.

#### DISCUSSION AND CONCLUSION

Evidence suggests that INPWT is an effective treatment for the prevention of SSI, wound dehiscence and seroma, with minimal adverse effects or harm to the patient (Grauhan et al, 2013; Matatov et al, 2013; Condé-Green et al, 2013; Pauser et al, 2014; Nordmeyer et al, 2015). Further research is required to establish the effects of INPWT on skin necrosis and

haematoma formation. Despite the mechanisms of action of INPWT not being fully understood, it is likely that the benefits include reduced post-operative oedema through improved lymphatic clearance (Bovill et al, 2008), reduced lateral stresses on surgical closures, and the provision of a clean, protected environment to minimise risk of external bacterial contamination (Wilkes et al, 2011).

There is insufficient evidence to support favouring one INPWT system over another, or the desired duration of therapy, since studies have reported positive results with different systems that provide differing levels of topical negative pressure over a varied number of days (Stannard et al, 2012b; Condé-Green et al, 2013; Grauhan et al, 2013; Matatov et al, 2013; Nordmeyer et al, 2015). There is also a marked variation in patient follow-up times between studies, with the potential to impact on trial outcomes. However, the evidence appears robust enough to suggest the use of INPWT as a safe, effective management option for patients with comorbidities, such as obesity, or increased risk factors for surgical site complications. **WUK**

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