Incisional Application of Negative Pressure for Nontraumatic Lower Extremity Amputations: A Review

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ABSTRACT

In the environment of diabetes and peripheral vascular disease (PVD), there is a high risk of incisional complications following amputation, including seroma, hematoma, infection, and dehiscence. Incisional negative-pressure wound therapy (iNPWT) is a novel application of negative-pressure wound therapy (NPWT) that may be able to mitigate these complications and reduce the need for revisional surgery (including higher-level major lower-extremity amputations). It may also facilitate an increased rate of healing and earlier return to function. iNPWT has been used successfully in high-risk patients to decrease complications. In highly comorbid patients receiving NPWT for primary closure of abdominal wall reconstruction, incisional infection rates were reduced from 48% to 7% (p=0.029). Furthermore, the need for revisional surgery was significantly decreased in those treated with iNPWT (48% vs.7%, p<0.001), as was the rate of dehiscence (10.68% vs. 5.32%, p<0.001). Major lower-extremity amputations in the multi-comorbid patient have a 16% incidence of incisional dehiscence. Additionally, the rate of infection has been reported to be as high as 22%. Five-year mortality following major lower-extremity amputation is reported to be 50% or higher. This high mortality rate is due, in part, to wound-healing complications. iNPWT can potentially reduce these healing complications and mortality. As of yet, no prospective, randomized trial has shown reduced morbidity, earlier return to function, or reduced mortality with the use of iNPWT after a lower-extremity amputation. This review presents recent findings regarding the use of iNPWT. Further studies on this topic are needed.
In patients who require atraumatic lower-extremity amputations, woundhealing is often compromised by diabetes and/or peripheral vascular disease (PVD). In the dysvascular population, healing problems occur in nearly half of all patients following lower-limb amputation. The 5-year mortality following major lower-extremity amputation secondary to diabetes is reported to be 50% or higher. This high mortality rate is due, in part, to wound-healing complications. Because of the sobering outcomes associated with complications of atraumatic amputations, it is important to consider practical options that minimize perioperative wound complications.

To date, no consensus guidelines that optimize healing outcomes of postoperative incisions have been established. Early post-amputation prosthesis-fitting has been shown to yield better outcomes and has driven stump-healing complications. Immediate post-surgical plaster-fitting is now joined by the use of various dressings and applications as options for the amputation patient. Soft dressings and elastic wrapping are commonly used, as are semi-rigid, rigid, and carboxymethylcellulose dressings impregnated with or without silver. Traditional care with gauze pads and dry dressings is still reliable, but often insufficient in patients with compromised healing mechanisms. Hydrocolloids, gels, alginates, and other advanced dressings have improved therapy by aiming to reduce the frequency of wound care.

Negative-pressure wound therapy (NPWT) is the dressing of choice for many wounds, pressure ulcers, and diabetic foot ulcers, as well as skin grafts and flap surgeries. NPWT offers several benefits, including increased perfusion and oxygen saturation, post-capillary venous return, and decreased lateral tension on the wound edges. Negative-pressure wound therapy is now being investigated as an adjunct to primary closure, i.e., incisional negative-pressure wound therapy (iNPWT). If the surgical incision has been primarily closed via sutures and/or staples, the cleaned and dried skin surrounding the incision is covered with a semipermeable occlusive membrane directly over the incision with a slit over the incision line. Typically, a polyurethane foam (a gauze material can also be used) is cut and shaped to approximate the length of the incision as well as spanning across the incision itself. It is generally accepted that wider overlap of the foam correlates to less surface tension, although this must be balanced with the available skin surface area. Next, another occlusive dressing is placed over the foam, and a small hole (quarter-sized) is created through the dressing and foam. The iNPWT apparatus’ egress tube is attached to this hole with the other end connected to a device that imparts negative pressure (Fig. 1). A reservoir/canister is used to collect the exudate. However, since closed incisions typically are not heavily exudative, the lack of exudate is not an indicator of device failure. Further, in cases where exudate is expected, a drain can be used along with iNPWT, as long as the drain exit does not compromise the dressing or the foam and is placed away from the incision line. Other options exist, including a pre-made construct that simplifies application by containing all of the above components in a simple disposable apparatus.

Incisional negative-pressure wound therapy has been used in several surgical disciplines and positive outcomes have been reported. Patients with major lower-extremity amputations are often readmitted for care of amputation-stump complications, including infection, dehiscence, and hematoma/seroma. However, there have been few randomized controlled trials on the use of iNPWT to aid incisional closure in patients with atraumatic lower-extremity amputations. iNPWT may provide added benefit for primary closure in patients following lower-extremity amputations. In this review, we examine the current uses and efficacy of iNPWT and explore its potential benefits for patients with atraumatic lower-extremity amputation.

### Review of Literature

Many studies have demonstrated that iNPWT is beneficial for mitigating postoperative infection regardless of comorbidity, wound classification, or operation. In patients classified as ASA ≥3 and with stomas postoperatively, Bonds et al. reported decreased infection rates with iNPWT following open colon or rectal resection (Table I). Vargo and de Vries et al. reported decreased infection rates with iNPWT in contaminated, dirty, and infected incisions following abdominal reconstruction. In the latter study, almost half of the patients were dependent on parental nutrition. Furthermore, Blackham et al. showed that, in patients with high-risk surgical incisions following abdominal oncologic resection (many of which involved colonic amputations), iNPWT provided a significant decrease in postoperative infection. Incisional negative-pressure wound therapy has been used in several surgical disciplines and positive outcomes have been reported. Patients with major lower-extremity amputations are often readmitted for care of amputation-stump complications, including infection, dehiscence, and hematoma/seroma. However, there have been few randomized controlled trials on the use of iNPWT to aid incisional closure in patients with atraumatic lower-extremity amputations. iNPWT may provide added benefit for primary closure in patients following lower-extremity amputations. In this review, we examine the current uses and efficacy of iNPWT and explore its potential benefits for patients with atraumatic lower-extremity amputation.

**Figure 1. Theoretical benefits of iNPWT.**

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1. Barrier to infection
2. Removal of incisional drainage
3. Reduced surface tension
4. Improved perfusion
resection), fewer surgical-site infections (SSIs) were noted with iNPWT than with standard dressings (6.7% vs. 19.5%, \(p=0.015\)). This trial was particularly interesting because of the high-risk nature of these surgical sites. While patients with iNPWT were more likely to have clean-contaminated wounds, significantly more blood loss during the procedure, and significantly more transfusions, they also showed fewer SSIs. Thus, the higher risk in these patients was mitigated through the use of iNPWT.

Reddy, Grauhan et al. and Atkins et al. all reported positive outcomes following the application of iNPWT to sternotomy incisions in highly-comorbid patients. More than 90% of patients in Reddy’s 30-day case series were diabetic and the average BMI was 38. Grauhan et al.’s prospective study of 150 consecutive patients (with BMI ≥ 30) reported decreased 90-day overall infections compared to a non-iNPWT group (4% vs. 16%, \(p=0.0266\)). A sub-analysis also showed fewer Gram-positive skin-flora-specific infections compared to controls (OR 11.39; 95% CI, 1.42–91.36, \(p=0.0090\)) (Table I). In 57 high-risk cardiac operations, Atkins et al. reported that no sternal wound infections occurred after iNPWT. On the contrary, infection was noted in patients who received dry dressings. In patients who underwent abdominoperineal resection, iNPWT was identified as an independent predictor of avoiding infection (OR 0.11; 95% CI, 0.04–0.66, \(p=0.01\)) after an analysis concluded that control patients experienced a higher incidence of SSI than iNPWT-treated patients (41% vs. 15%, \(p=0.02\)).

These patients closely approximate the atraumatic lower-extremity amputee population in terms of BMI, age, and comorbidity profile. Additionally, in this obese population, as noted by Grauhan et al., surface tension on the incision becomes a significant concern. However, truncal wounds, and more specifically chest wounds, are unlikely to experience perfusion or lymphatic drainage issues that are common among lower-extremity amputations.

Of equal interest to providers considering iNPWT is its effect on postoperative seroma and hematoma development. Stannard et al. reported that iNPWT was associated with fewer days of incision drainage than standard dry dressing (1.8 days vs. 4.8 days, \(p=0.02\)). In a randomized controlled trial by Pachowsky et al., osteoarthritis patients undergoing hip arthroplasty developed fewer and smaller seromas when dressed with iNPWT (44%, 1.97 mL) compared to standard care (90%, 5.08 mL, \(p=0.02\)). In this study, as well as the other orthopedic studies discussed here, incisions were located over joint-articular surfaces, making them more prone to lateral tension. Tauber et

### Table I

**Reported outcomes after iNPWT**

<table>
<thead>
<tr>
<th>Study</th>
<th>No. of Incisions</th>
<th>Type of Surgery</th>
<th>Outcome measures</th>
<th>Results</th>
<th>Follow-up (months)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bonds et al.</td>
<td>254</td>
<td>Open colon or rectal resection</td>
<td>SSI</td>
<td>12.5% SSI in iNPWT group; 29.3% SSI in standard-closure group; DM increased chances of SSI (OR, 1.98; (p&lt;0.05)); iNPWT decreased chances of SSI (OR, 0.32; (p&lt;0.05))</td>
<td>N/A</td>
</tr>
<tr>
<td>Condé-Green et al.</td>
<td>56</td>
<td>Abdominal wall reconstruction</td>
<td>Dehiscence; Skin/fat necrosis; Infection; Hernia recurrence; Sero- ma; Hematoma</td>
<td>22% overall wound complications and 9% skin dehiscence in iNPWT group, 63.6% overall wound complications and 39% skin dehiscence conventional dressing group (overall wound complications-p=0.020; skin dehiscence-p=0.014).</td>
<td>15 (average)</td>
</tr>
<tr>
<td>Grauhan et al.</td>
<td>150</td>
<td>Cardiothoracic</td>
<td>Infection; Dehiscence</td>
<td>4% with iNPWT had wound infections vs 16% with conventional sterile dressings ((p=0.0266)); Gram-positive skin-flora infections were less in iNPWT group ((p=0.0090))</td>
<td>3 (maximum)</td>
</tr>
<tr>
<td>Stannard et al.</td>
<td>263</td>
<td>Stabilization for LE trauma</td>
<td>Infection; Dehiscence</td>
<td>iNPWT patients had less infections than controls ((p=0.049)); Relative risk for infection is 1.9x higher in controls than iNPWT patients (95% CI, 1.03-3.55)</td>
<td>N/A</td>
</tr>
<tr>
<td>Galiano et al.</td>
<td>200</td>
<td>Reduction mammoplasty</td>
<td>Delayed healing; Dehiscence; Infection within 21 days</td>
<td>Fewer healing complications in iNPWT-breasts (56.8%) vs standard care (61.8%) ((p=0.004)); Lower dehiscence in iNPWT-breasts (16.2%) vs standard care (26.4%) ((p&lt;0.001))</td>
<td>0.75 (maximum)</td>
</tr>
<tr>
<td>Masden et al.</td>
<td>81</td>
<td>LE, back, groin, abdomen</td>
<td>Infection; Dehiscence; Reoperation</td>
<td>Insignificant difference in infection, dehiscence, and mean time to dehiscence between iNPWT and control group (Infection 6.8% vs 13.5%, (p=0.46); Dehiscence 36.4% vs 29.7%, (p=0.54) (Mean time to dehiscence between the 2 groups, (p=0.45))</td>
<td>3.5 (average)</td>
</tr>
</tbody>
</table>
al. looked at 24 patients undergoing inguinal lymphadenectomy for penile and urethral malignancies. The incidences of lymphocele (20% vs. 62%), lymphorrhoea (7% vs. 45%), and edema (0% vs. 46%) were lower in iNPWT-treated patients than controls (p=0.032). When complications were grouped together, there were fewer overall lymphatic complications in iNPWT-treated patients (p=0.032).35

Stannard et al. randomized 262 patients following lower-extremity fractures to receive either standard dressings or iNPWT. Patients receiving iNPWT had a lower incidence of SSIs than standard-care patients (9.9% vs. 18.9%, p=0.049).36 Redfern et al. conducted a nonrandomized prospective study after total knee and hip arthroplasty, and concluded that the overall infection rate with iNPWT was lower than that with standard care.17

Patients who received iNPWT were significantly more likely to be smokers, have coronary artery disease, and have a history of malignancy. In that study, iNPWT-treated patients were approximately 4 times less likely to develop incisional complications like hematoma, seroma, dehiscence, or SSI, compared to controls (OR 4.25; 95% CI 1.17–15.41). Matsumoto and Parekh also concluded that iNPWT was an independent predictor of uncomplicated incision-healing after orthopedic procedures (total ankle arthroplasty) (OR 0.10; 95% CI 0.01–0.50, p=0.04).38

Galiano et al., Stannard et al., and Condé-Green et al. all reported a significant improvement in the incidence of dehiscence following iNPWT use.23,36,39 In their lower-extremity fracture cohort, Stannard et al. documented an 8.6% dehiscence rate in iNPWT patients vs. 16.5% in controls (p=0.04).36 Condé-Green et al. reported similar outcomes following abdominal wall reconstruction (8.7% vs. 39%, p=0.014) in patients with an average BMI of 36.4 (Table I).39 In their study, patients who did not receive iNPWT were almost seven times more likely to experience dehiscence (OR 6.83; 95% CI, 1.37–34.14). In Galiano et al.’s study of a large cohort of mammoplasty patients, the dehiscence rate was lower in iNPWT-breasts than controls (16.2% vs. 26.4%, p<0.001) (Table I).3

Stannard and co-workers36 demonstrated that iNPWT after surgery for high-risk lower-extremity fractures, usually over articular surfaces, results in fewer infections, less dehiscence, and fewer hospital days, which are major concerns in the atraumatic lower-extremity amputee. The incidence of infection for lower-extremity amputation has been reported to be between 13% and 40%, and 30–45% of lower extremities already harbor pathogenic bacteria prior to amputation.40 Furthermore, the incidence of dehiscence may be as high as 16%, an alarming figure considering that it has been shown to quadruple the perioperative cost of care.41,42 These benefits, as described by Stannard et al.,36 would likely lead to a lower overall cost of care and improved patient outcomes. However, this conclusion must be viewed carefully, since this study was industry-funded. Additionally, those patients were younger and healthier than the typical atraumatic lower-extremity amputee population, which may augment the perfusion advantages identified.

Other authors have also reported equivocal relationships between iNPWT and outcomes. Blackham et al. noticed increased dehiscence in iNPWT-dressed incisions, but a statistical analysis was precluded by the low incidence.38 After patients underwent open-reduction-internal-fixation for
acetabular fracture, Crist et al. reported increased deep infection under treatment with iNPWT compared to dry dressings, although the differences were not significant (15.2% iNPWT vs.10.6% dry dressing, p=0.25). Randomized controlled trials by Stannard et al. and Howell et al. did not find a difference in healing time between negative-pressure and control incisions. In a pilot randomized trial of 75 patients undergoing elective total hip arthroplasty, Gillespie et al. reported an increased risk of any complication (SSI, dehiscence, seroma, hematoma, bleeding) for iNPWT-dressed incisions vs. dry-dressing incisions (68.5% iNPWT vs.42.8% standard dressing, p=0.04). Although an intention-to-treat analysis concluded that a 3% reduction in isolated SSI was seen with iNPWT compared to a dry dressing, 900 patients per group would be needed for a definitive trial investigating SSI after iNPWT application (RR=0.67; 95% CI=0.11-3.4), which calls into question the cost-benefit of this intervention, since the number needed to treat would likely be prohibitively high.

To date, the only published study on the application of iNPWT after closure of lower-extremity amputation incisions was conducted by Masden et al. in 2012 (Table 1). This was a prospective, randomized, controlled trial in a high-risk heterogeneous population that included diabetes and PVD, among other comorbidities. Seventy-four of the 81 total patients underwent closure of lower-extremity amputation incisions (above-knee amputation, below-knee amputation, knee disarticulation, Chopart’s amputation, transmetatarsal amputation), while the remaining 7 underwent closure of back, groin, and abdominal incisions. There was no statistically significant difference in primary outcomes between the types of care: infections (6.8% NPWT vs.13.5% standard dressing, p=0.46), dehiscence (36.4% NPWT vs.29.7% standard dressing, p=0.53), any event (40.9% NPWT vs.35.1% standard dressing, p=0.59), and reoperation (20.9% NPWT vs.22.2% standard dressing, p=0.89). They concluded that, with at-risk surgical closures, iNPWT may not give different results than standard dry dressings. However, this study is difficult to interpret. First, an appropriate a priori power analysis was not performed and thus this study may have been underpowered to detect a difference. Furthermore, the technique of application was not standardized, including the dimensions of the foam dressing. The foam was typically cut into thin strips that were often limited to the width of the incision. At the time of this publication, the mechanism of action of iNPWT was not well understood. Thus, the critical importance of the width of the foam and the need to substantively span the incision line was not respected. The authors are repeating this study to address these design issues.

Due to the paucity of literature on dressings for lower-extremity amputations, this review attempts to extrapolate from the primary literature for multiple surgical disciplines to define the role of iNPWT. However, certain limitations are inherent to this approach. The most obvious limitation is the lack of high-powered studies specific to patients with lower-extremity amputations. Only one study has investigated the use of iNPWT in lower-extremity amputations, and it showed equivocal results. Furthermore, extrapolation from the available non-amputee data is difficult, since cohorts with similar demographic and comorbidity profiles are often excluded from studies investigating lower-extremity surgical-site management. Alternatively, the studies that do include a multi-comorbidity host are mainly limited to truncal surgical interventions where superficial tissue perfusion is rarely an issue. We have attempted to bridge this gap, but further in-depth investigation is warranted. Selection bias and publication bias further limit our conclusions, since negative or equivocal data regarding iNPWT are unlikely to be published. Particular care was taken to highlight patients with medical comorbidities similar to those seen in patients with atraumatic amputations. Furthermore, not all of the studies employed randomization and the duration of follow-up was inconsistent. The variability regarding both device-type and setting should also be noted. Constant vs. oscillating cycles, subatmospheric pressure values, and length of treatment were inconsistent across studies. While most studies used common devices such as Prevena™ and YAC™ (Acelity Inc., San Antonio, TX, USA), and PICOT™ (Smith and Nephew Inc., London, UK), some investigators created their own negative-pressure devices.

The existing body of literature regarding negative-pressure therapy in both open and closed incisions suggests that there are no differences in the benefits of therapy by wound location, index-operation, or patient demographic. In non-lower-extremity studies, NPWT and iNPWT are consistently associated with decreased rates of common infectious and wound-healing complications. This is true for various wound classifications and is independent of the presence of diabetes and/or PVD.

It is well understood that patients who require atraumatic lower-extremity amputations are at high-risk for wound-healing complications (Fig 2). The current body of literature shows that many disciplines regularly use negative-pressure strategy after incisions are closed, with most authors reporting positive outcomes. For surgeons, there is value in the prophylactic use of wound-healing technologies like iNPWT to minimize the morbidity associated with incisional healing in high-risk patients (Fig 3). Further, the costs incurred for post-operative complication care can perhaps be avoided by the use of devices that reduce these events. While further investigations are needed on this topic, the available data appear to be promising.

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