Incisional Negative Pressure Wound Therapy: An Effective Tool for Major Limb Amputation and Amputation Revision Site Closure

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Objective: To evaluate our institutional experience of incisional negative pressure wound therapy (iNPWT) applied immediately after major limb amputation closure or amputation revision closure.

Approach: A retrospective review was performed on 25 patients who underwent major limb amputation or amputation revision and had iNPWT placed intraoperatively upon incision closure.

Results: Twenty-one patients underwent lower extremity amputation and four underwent upper extremity amputation. Seventeen were primary amputations and eight were amputation revisions. No patients developed dehiscence, seroma, or hematoma. One patient developed a surgical site infection (4%) that was treated with oral antibiotics. The average time to eligibility for prosthetic fitting for lower extremity amputations was 6.3 weeks.

Innovation: Amputee patients have increased wound healing demands that can impact prosthetic wear and ambulation status. Stump incisions are located at the distal end of their extremities and often are in areas that have had prior surgical procedures performed. Thus, blood supply to the incision site may not be optimal. iNPWT is an effective incision management technique to promote healing and decrease postoperative complications in this patient population, which can lead to increased mortality.

Conclusion: iNPWT is an effective technique of minimizing wound complications in the amputee and should be considered in this high-risk patient population.

Keywords: negative pressure, iNPWT, amputation, surgical site infection

INTRODUCTION

THERE ARE TWO MILLION people living with major limb amputations and an estimated 185,000 new lower extremity amputations performed annually in the United States alone.¹ Wound healing after initial amputation, much like any surgical incision, can be complicated given tissue edema, surgical site infection (SSI), and wound dehiscence.² Amputation incisions have an additional risk for

these complications given the incisions location at the end of the skin flap where tissue perfusion is the lowest. Depending on the reason for the amputation, whether vascular compromise, oncological, infectious, traumatic, or congenital, the residual limb may already have impaired blood flow. Couple that with a history of peripheral vascular disease, prior radiation therapy, diabetes, infection, or traumatic soft tissue injuries

and the setup is a poor wound healing environment, which can lead to increased overall mortality for these patients.

Amputation revision cases also offer unique wound healing challenges. Reasons for amputation revision can include ill-fitting prosthetics or underlying bony pressure points that result in soft tissue breakdown. Other considerations such as existing nonhealing wounds, acute or chronic or chronic infections of soft tissues or bone, or even excess skin from postamputation or other weight loss states can plausibly increase the risk of postoperative complications in amputee patients.

Incisional negative pressure wound therapy (iNPWT) is an adjunct for postoperative closed incision management. It maintains a clean incision line environment and decreases the occurrence of SSIs.³ iNPWT acts as a soft tissue splint to reduce tension on the incision line, decreasing the rate of dehiscence.^{4,5} It reduces the rate of seroma and hematoma formation by decreasing tissue edema and promoting lymphatic outflow.^{6,7} Horch found that iNPWT decreases seroma formation and facilitates earlier drain removal after body contouring procedures.⁸ It has also been demonstrated to improve the rate of healing due to increased blood flow to the wound.⁹ In a randomized control trial of patients undergoing bilateral breast reduction mammoplasty, where one breast was treated with iNPWT and the other with conventional dressings, Galiano *et al.* found fewer wound healing complications (56.8% vs. 61.8%) in the iNPWT-treated breast.¹⁰ These benefits have encouraged the use of iNPWT for complex incision management in high-risk patients. Published international consensus recommendations suggest considering the use of iNPWT for patients at high risk of developing SSI as well as in cases where high morbidity would result from SSI.¹¹ Recent publications in orthopedic surgery and general surgery literature have demonstrated the benefits of iNPWT in a number of areas, including high-risk patients and SSI reduction.^{3,12–14} Another recent review by Kotha *et al.* described the potential for reduction of morbidity and mortality by using iNPWT in amputees.¹⁵

In this series we report our experience utilizing iNPWT in patients who have undergone major limb amputation or amputation revision surgery. We demonstrate that immediate postoperative application of iNPWT results in a low number of SSIs, wound dehiscence, delayed wound healing, and hematoma or seroma formation. Effective healing of the amputation stump allowed patients to focus on rehabilitation and prosthetic fitting in a timely manner.

CLINICAL PROBLEM ADDRESSED

We explore our institution's experience with iNPWT placed immediately after major limb amputation, including revision amputation. We report the incidence of surgical site complications in these patients to evaluate the application of this wound management technique.

MATERIALS AND METHODS

A retrospective cohort study was performed on patients with iNPWT applied to extremity incisions after major limb amputation or amputation revision at our institution. Medical records were evaluated for comorbidities that are known to contribute to poor wound healing, specifically diabetes mellitus, coronary or peripheral vascular disease, a history of radiation to the affected limb, and active smoking status. Drain placement, duration of iNPWT therapy, and complications, including SSI, dehiscence, seroma, and need for reoperation, were noted. Length of stay and time to eligibility for prosthetic fitting was also recorded. All data were collected after institutional review board approval. Descriptive statistics were used to evaluate the demographic characteristics and the incidence of wound complications.

RESULTS

Our cohort consists of 25 patients who had iNPWT applied intraoperatively upon surgical incision closure. Twenty-one patients underwent lower extremity amputations, with 11 above knee amputations (AKAs), 8 below knee amputations (BKAs), 1 hip disarticulation, and 1 partial foot amputation. Four patients underwent upper extremity amputation, one transradial, one forearm, and two transhumeral. Seventeen patients underwent primary amputation, and eight underwent stump revision. Of the primary amputations, two were due to traumatic injury, eight were oncological resections, six were infectious causes, and one was a vascular indication.

Looking at relevant comorbid conditions, 28% ($n = 7$) had diabetes mellitus, 12% ($n = 3$) had coronary artery disease or peripheral vascular disease, 8% ($n = 2$) had a history of radiation to the affected area or limb, and 16% ($n = 4$) were active smokers (Table 1).

Drains were placed intraoperatively at the surgeon's discretion. This occurred in 32% of patients ($n = 8$), 2 at the time of primary amputation and 6 at the time of amputation revision. The average duration of treatment was 9.0 days (95% [confidence interval] CI: 6.7–11.3), including a reapplication of iNPWT before discharge or in the office if >7 days. The average length of stay was 6.1 days (95% CI: 3.8–8.5).

Table 1. Prevalence of medical comorbidities

	Primary Amputation	Amputation Revision	Upper Extremity	Lower Extremity	Overall
DM	41.1% (n=7)	0% (n=0)	25% (n=1)	28.6% (n=6)	28% (n=7)
CAD/PVD	17.6% (n=3)	0% (n=0)	0% (n=0)	14.3% (n=3)	12% (n=3)
Active smoker	23.5% (n=4)	0% (n=0)	25% (n=1)	14.3% (n=3)	16% (n=4)
Radiation	11.8% (n=2)	0% (n=0)	0% (n=0)	9.5% (n=2)	8% (n=2)

CAD, coronary artery disease; DM, diabetes mellitus; PVD, peripheral vascular disease.

The incidence of wound complications is displayed in Table 2. Two patients (8%) developed superficial blistering of the skin, which resolved. No patients developed a seroma or hematoma. No patients had wound dehiscence. One patient (4%) developed an SSI, which was treated successfully with oral antibiotics and did not require reoperation. No patients had serious adverse reactions to iNPWT.

The average time from operation to documented eligibility for prosthetic fitting was 6.3 weeks (95% CI: 5.6–6.9) for both upper and lower extremity patients regardless of whether it was a primary amputation or amputation revision. All patients with follow-up >6 weeks did go on to receive evaluation for a prosthetic with the exception of two upper extremity amputation patients, who were cleared for prosthetic evaluation but declined to pursue it.

Representative cases

Case one (primary amputation). A 42-year-old man with a past medical history, including uncontrolled type 2 diabetes mellitus (hemoglobin A1C of 9.6%), coronary artery disease with a history of stents, and active smoking (two packs per day), presented with days of worsening foot pain and acute wound changes in the setting of a chronic diabetic foot ulcer. He was emergently taken to the operating room for an incision and drainage, which was converted into a guillotine right BKA (Fig. 1). Once the infection was controlled, he returned to the operating room for a repeat incision and drainage, complex closure, and placement of a Prevena Plus Customizable Incisional VAC (KCI; an Acelyty company, San Antonio, TX) (Fig. 2). The iNPWT was left

Figure 1. Intraoperative guillotine BKA. BKA, below knee amputation. **Figure 2.** iNPWT application complete with vacuum machine functioning. iNPWT, incisional negative pressure wound therapy.**Table 2.** Incidence of wound complications

	Primary Amputation	Amputation Revision	Upper Extremity	Lower Extremity	Overall
Blistering of skin	11.8% (n=2)	0% (n=0)	0% (n=0)	0% (n=0)	8% (n=2)
SSI	5.9% (n=1)	0% (n=0)	0% (n=0)	4.8% (n=1)	4% (n=1)
Dehiscence	0% (n=0)	0% (n=0)	0% (n=0)	0% (n=0)	0% (n=0)
Seroma	0% (n=0)	0% (n=0)	0% (n=0)	0% (n=0)	0% (n=0)
Hematoma	0% (n=0)	0% (n=0)	0% (n=0)	0% (n=0)	0% (n=0)

SSI, surgical site infection.

Figure 3. iNPWT application complete with vacuum machine functioning.

in place for 7 days postoperatively and removed. Despite his risk factors, postoperative course was unremarkable without SSI, wound breakdown, hematoma, or seroma formation. Upon iNPWT removal, the patient was then transitioned into a stump shrinker and fit for a prosthetic 6 weeks later.

Case two (amputation revision). A 39-year-old man with a past medical history of Klippel Trenauay syndrome, who had undergone an AKA 4 years prior, presented with significant skin laxity and medial and lateral thigh, which inhibited his prosthetic wear. He underwent revision of his AKA stump as well as a medial and lateral thighplasty, and application of a Prevena Plus Customizable Incisional VAC (KCI; an Acelity company) (Fig. 3). The iNPWT was removed after 7 days, and soft tissue edema was well controlled, and the incision healed well without complication (Fig. 4). He

Figure 4. Intact incision after iNPWT removal on postoperative day 7.

transitioned into a stump shrinker, was fit for a new socket 4 weeks after surgery, and began wearing his prosthetic at the 6-week mark.

DISCUSSION

Major limb amputation changes a patient's life significantly, and dealing with the stress of a non-healing wound in the setting of recent limb loss has lasting effects on the patient's quality of life. In patients with diabetes mellitus undergoing lower extremity amputation, a study by Lopez-Valverde *et al.* described an overall postoperative complication rate of 61%, which was associated with an increased risk of perioperative mortality, as high as 12.3%.¹⁶ Oncological amputees with a nonhealing incision have delays in important postamputation treatment, such as radiation or chemotherapy. Amputations performed for infectious reasons or those undergoing amputation revisions that have a history of infection in that limb are at a much higher risk for delays in wound healing, and special care should be taken to ensure optimal conditions to promote healing. After amputation revision, effective and expeditious healing speeds return to mobility and function. Our data demonstrate that using iNPWT in the immediate postoperative period aids in the management of challenging incisions in this high-risk patient population. We found low rates of wound complications in our amputee cohort (4%), comparable with previous published studies of iNPWT. In a meta-analysis conducted by Semsarzadeh *et al.* in 2015, there was an overall rate of SSI of 6.61% with iNPWT versus 9.39% in controls, and an overall rate of dehiscence of 5.32% versus 10.68%.³

iNPWT is described as a method to provide an ideal wound environment.¹⁷ Analysis has shown that iNPWT decreases lateral stress on the incision line, increases blood flow to the incision, and promotes lymphatic drainage.^{4,6,18–20} The resulting clinical benefits include reduced risk of dehiscence, hematoma, seroma, and improved healing.^{3,5,9,21,22} Minor adverse effects, including superficial skin necrosis and blister formation, have been reported and also seen in our cohort.^{23,24} It is not an institutional standard that all patients undergoing major limb amputation or amputation revision receive iNPWT, and this case series does not represent a single surgeon's experience of iNPWT. To better select patients for iNPWT, we use a Patient Grading System that was proposed by Stannard *et al.*: Grade 1 patients have no wound healing failure risk factors, Grade 2 has some wound healing factors, and Grade 3 has several wound healing risk factors or a complex wound, which the authors define as an

incision that is not linear or curvilinear.²⁵ Based on the complex nature of their wounds, all patients in our cohort, both primary and revision amputation, can be classified as Grade 3, giving them the greatest potential to benefit from iNPWT. A large portion of our cohort also has additional medical comorbidities that put them at increased risk for wound healing complications, and patients in both groups have had previous wound complications, both of which were also taken into account when considering the use of iNPWT. Fewer wound healing delays in these high-risk patients decreases their need for additional procedures and use of medical resources.

Effective wound management for amputees expedites time to rehabilitation and ultimately prosthetic fitting. Delayed wound healing or wound infections may be associated with decreased quality of life; conversely, faster rates of wound healing can accelerate rehabilitation, improve pain control, and allow earlier prosthetic fitting.²⁶ Little is reported in the literature regarding amputation management with iNPWT. One case series demonstrated iNPWT to be effective in BKA closure of patients with chronic venous insufficiency.²⁶ Two cases are described of utilizing iNPWT to allow for early use of prosthetics while the wound is still healing, which later did require refitting.²⁷ iNPWT applied to both acute and chronic amputation wounds (duration less than or greater than 30 days, respectively), has been shown to be effective in managing wound complications.²⁸

There are many factors unrelated to the amputation stump itself that contribute to an amputee going on to successfully don a prosthetic. These include access to prosthetists, insurance approval, and comorbid conditions or medical treatments that delay their ability to pursue this in a timely manner. The avoidance of wound complications allowed our patients to minimize delays in their rehabilitation and ability to obtain prosthetics. Barring aforementioned factors that can delay this, an acceptable time from amputation to prosthetic fitting is typically between 6 and 8 weeks. For our cohort, the time from amputation to eligibility for prosthetic fitting was 6.3 weeks, indicating that iNPWT can minimize delays in prosthetic fitting.

Limitations to this study include the absence of a control group, the relatively small sample size, and the retrospective nature of the study design. Further investigation is needed to determine optimal length of treatment and more specific indications, as well as the cost effectiveness of iNPWT in the amputee. We anticipate that iNPWT will continue

KEY FINDINGS

- Placement of iNPWT at the time of amputation or amputation revision decreases the incidence of postoperative wound dehiscence, seroma, and hematoma formation.
- Effectively managing complex lower extremity incisions after amputation or amputation revision accelerates rehabilitation and time to prosthetic fitting.
- A randomized control trial comparing iNPWT versus standard postoperative dressings applied immediately after major limb amputation or amputation revision is needed to evaluate the efficacy of iNPWT in this patient population.

to be valuable in the management of complex surgical wounds from amputation or amputation revision. Although we did not examine this in our study, limiting perioperative complications in the amputee population may decrease the mortality rate and should be an area of future investigation.

INNOVATION

iNPWT was successfully utilized to manage major limb amputation or amputation revision incisions immediately upon closure to reduce the risk of postoperative complications. Our case series showed no cases of wound dehiscence, seroma, or hematoma, and one SSI was managed outpatient with oral antibiotics. Published literature regarding the amputee population reports that postoperative complications often lead to increased mortality in the long term. Based on our experience, iNPWT is an effective tool for incision management to promote healing and decrease postoperative complications and this series suggests a routine role for iNPWT to manage amputation site incisions.

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Abbreviations and Acronyms

AKA = above knee amputation
 BKA = below knee amputation
 CI = confidence interval
 iNPWT = incisional negative pressure wound therapy
 SSI = surgical site infection