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Use of Negative Pressure Wound Therapy on Closed Surgical Incision After Total Ankle Arthroplasty

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Abstract

Background: Wound healing problems of the anterior ankle incision are among the most common complications after total ankle arthroplasty, possibly resulting in exposure of the prostheses and infection. The aim of this study was to investigate the role of negative pressure wound therapy (NPWT) in decreasing the rate of wound healing problems after total ankle arthroplasty.

Methods: This is a retrospective cohort study including consecutive patients who underwent total ankle arthroplasty by a single surgeon at a single institution between 2009 and 2013. The incisional negative pressure dressing was applied to all patients who underwent total ankle arthroplasty between 2012 and 2013 with a continuous application of −80 mm Hg negative pressure for 6 days postoperatively. The control group consisted of patients who underwent total ankle arthroplasty between 2009 and 2012 with a conventional nonadherent gauze dressing. Seventy-four patients were involved in this study: 37 in the control group and 37 in the incisional NPWT group.

Results: All patients tolerated the incisional NPWT to completion without any dressing failures or skin problems. Both groups showed similar distributions in demographics and perioperative risk factors for wound healing. There were 9 (24%) wound healing problems in the control group and 1 (3%) in the incisional NPWT group. Incisional NPWT was found to reduce wound healing problems with an odds ratio of 0.10 (95% CI, 0.01-0.50; $P = .004$).

Conclusions: Our study demonstrated that there was a decreased incidence of wound healing problems following total ankle arthroplasty with incisional NPWT dressings. This is the first study evaluating the efficacy of incisional NPWT as an adjunct treatment for wound healing after total ankle arthroplasty.

Level of Evidence: Level III, retrospective comparative study.

Keywords: dressing, incisional negative pressure wound therapy, surgical complications, total ankle arthroplasty, wound healing problem

Total ankle arthroplasty (TAA) is an alternative to arthrodesis for the treatment of end-stage ankle arthritis. Recently, TAA has become increasingly popular due to good clinical outcomes, largely associated with advanced surgical techniques and improved implant designs.[9] However, there is still a high incidence of complications in TAA. Wound healing problems of the anterior ankle incision are among the most common complications, with a reported incidence as high as 34%.[7,9,25,29,38] Wound problems after TAA not only impair postoperative physical therapy, clinical outcomes, and patient satisfaction but also notably increase the risk for implant infection, which can lead to dire consequences such as amputation.[19]

Negative pressure wound therapy (NPWT) is an important innovation in the field of wound management. NPWT, a dressing technique that uses a vacuum dressing to promote healing, has been used mainly for open wounds. It has been demonstrated that NPWT can accelerate wound healing by advancing angiogenesis, increasing microvascular blood flow, stimulating granulation tissue formation, and reducing edema.[2] Recently, this therapy has been applied to closed incisions following trauma or clean surgery and has demonstrated notable clinical effects.[8,34,37] DeCarbo and Hyer[6] first described the use of incisional NPWT (iNPWT) for TAA as a technical tip; however, the validity of iNPWT

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Table 1. Univariate Comparison of Demographic Data and Known Risk Factors in the Control Group and the Group Receiving Incisional Negative Pressure Wound Therapy (iNPWT)[a].

	Control Group (n = 37)	iNPWT Group (n = 37)	*P*
Age, y	58.0 ± 13.8	58.6 ± 12.3	.845
Sex, n (%)			.486
Male	16 (43)	20 (54)	
Female	21 (57)	17 (46)	
Body mass index, kg/m^2	30.1 ± 6.3	32.2 ± 6.9	.167
Implant, n (%)			.687
Salto	15 (41)	16 (43)	
STAR	16 (43)	13 (35)	
Inbone	6 (16)	8 (22)	
Diagnosis, n (%)			.443
Posttraumatic arthritis	30 (81)	25 (68)	
Primary osteoarthritis	6 (16)	10 (27)	
Rheumatoid arthritis	1 (3)	2 (5)	
Smoking, n (%)	9 (24)	7 (19)	.778
Alcohol use, n (%)	8 (22)	6 (16)	.768
Comorbidity, n (%)			
Hypertension	24 (65)	16 (43)	.102
Diabetes mellitus	5 (14)	7 (19)	.754
Hyperlipidemia	4 (11)	4 (11)	>.999
Malignant tumor	2 (5)	2 (5)	>.999
Chronic kidney disease	1 (3)	0 (0)	>.999
Chronic liver disease	1 (3)	0 (0)	>.999
Corticosteroid use	2 (5)	1 (3)	>.999
Lymphocyte count, ×10^3 cells/μL	2.2 ± 0.8	1.9 ± 0.7	.206
Previous incision, n (%)	24 (65)	24 (65)	>.999
Surgical time, min	141 ± 34	141 ± 24	.963

[a]Values are mean ± SD or numbers (%) of patients.

for TAA was not evaluated. To address the high incidence of wound problems after TAA, we have adopted iNPWT in the closure of surgical wounds for TAA. The purpose of this study was to investigate the utility of iNPWT in decreasing the rate of wound problems in TAA patients.

Methods

Study Design

The institutional review board of Duke University approved this study. All patients who had undergone TAA by a single surgeon (S.G.P.) were managed with an iNPWT between June 2012 and August 2013. These patients were compared with a control group who had undergone TAA between February 2009 and May 2012, before the application of iNPWT to TAA. No patients were excluded from our study besides revision TAA cases. Medical charts were retrospectively reviewed for the patients of 2 groups: the control group (receiving standard dressing with Telfa, gauze, and army battle dressing [ABD] pads) and the intervention group (receiving iNPWT).

The number of patients managed with standard dressings or an iNPWT was 37 and 37, respectively. Table 1 shows the comparison of patient demographics and known risk factors for wound healing between the control and intervention groups. There were no notable differences in the data between the control and intervention groups.

Surgery

All procedures were performed under general anesthesia with a popliteal block and catheter. Patients were positioned supine, and a thigh tourniquet was used. Prophylactic intravenous antibiotics were administered within 1 hour before surgery. The technique of TAA did not differ between the control and intervention groups. All cases were approached by a standard anterior incision, using the interval between the tibialis anterior and extensor hallucis longus tendons. Three different types of implants were used—the Salto Talaris (Tornier U.S., Bloomfield, MN), STAR (Small Bone Innovations, Morristown, NJ), and Inbone (Wright Medical, Arlington, TN)—depending on individual cases and surgeon preference. All patients were treated by the senior

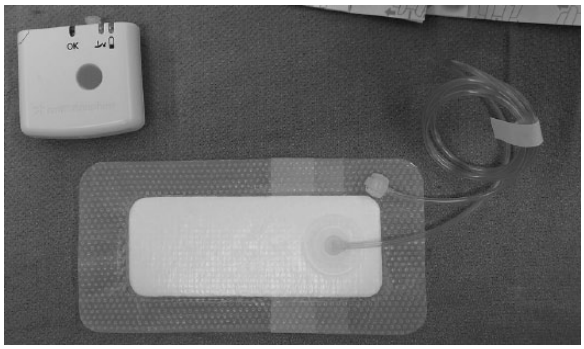

Figure 1. PICO system (Smith & Nephew); dressing and pump allow for a continuous negative pressure of −80 mm Hg for 7 days.

Figure 2. Negative pressure wound dressing system in place over the surgical wound after total ankle arthroplasty.

author (S.G.P.). In both groups, wound closure was done in the same way. The anterior capsule was closed with No. 0 Vicryl (Ethicon, Somerville, NJ), and the tendon sheath and extensor retinaculum were repaired with No. 2-0 Vicryl. The subcutaneous tissues were closed with No. 2-0 Vicryl, and the skin was closed with staples. The intervention group (iNPWT) was treated with a commercially available negative pressure device (PICO, Smith & Nephew Medical, Hull, UK) (Figures 1 and 2).[13] Continuous negative pressure was applied at −80 mm Hg using an accompanying portable pump. The control group received a conventional dressing consisting of Telfa, 4 × 4 gauze, and ABD pads. In both groups, a bulky Jones splint was applied with the ankle joint in neutral position. The patients were usually observed in the hospital for 1 to 3 days until they were determined to be medically stable. They were then evaluated in the outpatient clinic on postoperative day 6 or 7, and the iNPWT dressing was removed. A short leg, non-weight-bearing cast was then applied during the next week or two until the sutures were removed, which occurred 3 weeks after surgery. Then, patients were instructed to be non-weight-bearing in a controlled ankle motion (CAM) boot until 6 weeks postoperatively. This was followed by full weight-bearing as tolerated in a CAM boot and subsequent weaning from the CAM boot at week 10.

Clinical Assessment

The information about patient demographics and risk factors was collected as listed in Table 1. The outcomes evaluated included any wound healing problems and surgical site infections (SSIs). Wound healing problems were defined as the presence of a wound dehiscence, eschar, or drainage over 3 weeks after the index surgery. SSIs were defined according to criteria of the Centers for Disease Control and Prevention.[11] In brief, an infection occurring within 30 days after the surgery must be associated with at least 1 of the following: (1) purulent drainage from the incision; (2) organisms isolated from an aseptically obtained culture from the incisional fluid or tissue; (3) at least 1 of the following signs or symptoms: pain or tenderness, erythema, localized swelling, heat, superficial incision that is deliberately opened by surgeon, *unless* culture of incision is negative; or (4) a diagnosis of SSI by an attending physician.

Statistics

Continuous variables were reported as the mean ± standard deviation (SD) of the mean. Proportions were summarized using counts and percentages. The chi-square test or Fisher exact test was conducted for univariate comparisons of the proportions between groups. When these tests showed significant differences, adjusted residual analysis was performed to identify the categories responsible for it. A P value of less than .05 was considered statistically significant. In multivariate logistic regression analysis, all variables having a P value of less than .05 in univariate analysis were entered into the model. Statistical analyses of the data were performed using the statistical software JMP Pro 11 (SAS Institute, Cary, NC).

Results

All patients tolerated iNPWT well with no dressing failures and no dropouts from the regimen at 1 week post surgery. The results of outcomes are summarized in Table 2. Wound healing problems were found in 9 (24%) of 37 patients in the control group and 1 (3%) of 37 patients in the iNPWT group; the difference was significant (P = .014). An infection was found in 3 (8%) of 37 patients in the control group, including 2 superficial infections and 1 deep infection, and 1 (3%) of 37 patients in the iNPWT group (deep infection); the difference was not significant (P = .615). All 4 cases of infection were accompanied by wound healing problems. Two of the patients with superficial infections in the control group were successfully treated with oral antibiotic therapy alone. One deep infection in the control group occurred in 55-year-old male who had no risk factors other than alcohol

Table 2. Univariate Comparison of the Outcomes Between the Control Group and the Group Receiving Incisional Negative Pressure Wound Therapy (iNPWT).

	Control Group (n = 37)	iNPWT Group (n = 37)	*P*
Wound healing problem, n (%)	9 (24)	1 (3)	***.014***
Surgical site infection, n (%)	3 (8)	1 (3)	.615
Superficial, n (%)	2 (5)	0 (0)	.493
Deep, n (%)	1 (3)	1 (3)	>.999

Note. Boldface italic indicates a *P* value less than .05.

Table 3. Univariate Comparison of Risk Factors and Interventions Between Patients With or Without Wound Healing Problems[a].

	Patients With Successful Wound Healing (n = 64)	Patients With Wound Healing Problem (n = 10)	*P*
Age, y	56.8 ± 12.7	67.8 ± 11.0	***.012***
Body mass index, kg/m^2	31.5 ± 6.9	28.6 ± 3.7	.210
Implant, n (%)			.831
Salto	26 (41)	5 (30)	
STAR	25 (39)	3 (30)	
Inbone	13 (20)	2 (20)	
Diagnosis, n (%)			***.043***
Posttraumatic arthritis	48 (75)	7 (70)	
Primary osteoarthritis	15 (23)	1 (10)	
Rheumatoid arthritis	1 (2)[b]	2 (20)[b]	***<.01***[b]
Smoking, n (%)	14 (22)	2 (20)	>.999
Alcohol use, n (%)	11 (17)	3 (30)	.388
Comorbidity, n (%)			
Hypertension	34 (53)	6 (60)	.745
Diabetes mellitus	10 (16)	2 (20)	.661
Hyperlipidemia	8 (13)	0 (0)	.588
Malignant tumor	3 (5)	1 (10)	.448
Chronic kidney disease	1 (2)	0 (0)	>.999
Chronic liver disease	1 (2)	0 (0)	>.999
Corticosteroid use	1 (2)	2 (20)	***.046***
Lymphocyte count, ×10^3 cells/μL	2.0 ± 0.7	2.1 ± 1.0	.780
Previous incision, n (%)	43 (67)	5 (50)	.307
Surgical time, min	142 ± 29	138 ± 35	.700
Application of iNPWT, n (%)	36 (56)	1 (10)	***.014***

Note. Boldface italic indicates a *P* value less than .05.
[a]Values are mean ± SD or numbers (%) of patients.
[b]Adjusted residual analysis.

use. This patient finally required a below-knee amputation due to persistent infection and poor healing of soft tissue after failures of several interventions including irrigation and debridement, NPWT using the Vacuum Assisted Closure (VAC) system (KCI Medical, San Antonio, TX), and a skin graft and free flap. The 1 deep infection in the iNPWT group occurred in a 72-year-old male who had several risk factors including diabetes mellitus, hypertension, corticosteroid use, rheumatoid arthritis, and low lymphocyte count; the infection was successfully treated with local wound irrigation and debridement.

Patients were subsequently compared based on the presence or absence of a wound healing problem (Table 3). The patient demographic data and known risk factors showed no notable difference between groups with or without wound healing problems besides age and corticosteroid use. Age and corticosteroid use were significantly higher in the group with wound healing problems compared with the group with successful wound healing (age, 57.3 ± 12.8 vs 66.8 ± 10.9, $P = .021$; corticosteroid use, 1 [1%] vs 2 [18%], $P = .042$). The indications for TAA were significantly different between groups with or without wound healing problems ($P = .043$). Adjusted residual analysis showed that this significant difference was attributed to a high prevalence of rheumatoid arthritis in the group with wound healing problems ($P < .01$). The 3 patients in the subgroup of rheumatoid

Table 4. Multivariate Logistic Regression Analyses for Wound Healing Problems.

	Total No. of Patients	Patients With Wound Healing Problem, n (%)	Odds Ratio	95% Confidence Interval	*P*
Age					
<70 y	59	5 (9)	1.00		
≥70 y	15	5 (33)	4.66	0.94-24.2	.060
Corticosteroid use					
No	71	8 (11)	1.00		
Yes	3	2 (67)	9.53	0.64-260	.099
Application of incisional negative pressure wound therapy					
No	37	9 (24)	1.00		
Yes	37	1 (3)	0.10	0.01-0.50	***.004***

Note. Boldface italic indicates a *P* value less than .05.

arthritis were the same 3 patients in the group with corticosteroid use.

A multivariate logistic regression analysis was performed to identify the independent factors associated with the occurrence of wound healing problems (Table 4). Rheumatoid arthritis was not included as a variable because of the complete overlap with corticosteroid use. The results show that the application of iNPWT was an independent predictor of not developing wound healing problem (odds ratio [OR], 0.10; 95% CI, 0.01-0.50; $P = .004$). Age and corticosteroid use were not found to be independent factors for developing wound healing problems (age: OR, 4.66; 95% CI, 0.94-24.2; $P = .060$; corticosteroid use: OR, 9.53; 95% CI, 0.64 to 260; $P = .099$).

Discussion

Despite improvements in operative techniques and implant designs, TAA is still accompanied by a high rate of wound healing problems.[1,4,5,14,20-22,26,32,38] In a matched case-control study including 26 patients with periprosthetic ankle infection, Kessler et al[19] reported that patients with delayed wound healing were at risk for a periprosthetic ankle joint infection with odds ratios as high as 5- to 15-fold. According to the systematic literature review by Zaidi et al,[40] which included 58 papers (7942 TAAs), the infection rate in TAA has been reported to be approximately 2.4% for superficial infections and 1.1% for deep infections. Wound healing problems and subsequent periprosthetic infections can result in devastating consequences for the patients, ranging from multiple surgeries to amputation. Whalen et al[38] reported 57 cases of primary TAA. Two of 4 patients who had wound necrosis were managed with tibiotalocalcaneal fusions after staged procedures, while another required a below-knee amputation. The fourth case was lost to follow-up. Myerson et al[25] reviewed their experience with 19 cases of infected TAA and concluded that only a limited number of patients with infected TAA can expect to undergo successful joint-preserving revision ankle arthroplasty. In this article, the authors reported that 3 of their 19 patients underwent successful revision with replacement, 6 with arthrodesis, and 7 with a permanent antibiotic spacer, and 3 patients required a below-knee amputation.[25] Obtaining primary wound healing in TAA is essential to avoid these types of serious complications.

Many factors have been related to increasing the risks for wound healing in total joint arthroplasty, including previous incisions, lymphedema, poor vascular perfusion, obesity, diabetes mellitus, inflammatory arthropathy, renal or liver disease, immune compromise, corticosteroid therapy, smoking, poor nutrition, and a long operative time.[16,17,19] Specifically, for TAA wounds, Raikin et al[29] identified female sex, a history of corticosteroid use, and underlying inflammatory arthritis as risk factors for major wound complications. In our cohort, we found a similar distribution of these risk factors between the control and intervention groups. Multivariate analysis demonstrated a potentially beneficial effect of iNPWT for preventing wound healing problem after TAA compared with conventional gauze dressings (OR, 0.10; 95% CI, 0.01-0.50; $P = .004$). In our study, metallic staples were used in both groups. Although this recently has been shown to carry a higher risk of infection compared with sutures in skin closure after orthopedic surgery,[33] it has been the standard of care in the senior author's practice. Since the level of evidence is specifically lacking regarding anterior ankle incision, we could not tell how the use of staples contributed to the wound healing problems in our study. Further studies are required to identify the best combination of methods to prevent wound healing problems in the anterior incision over the ankle joint.

The evidence in support of iNPWT has been accumulating since the first peer-reviewed report appeared in 2006.[8] In a study of 235 patients undergoing iNPWT after operative repair of acetabular fracture, Reddix et al[30] showed that the incidence of infection and wound dehiscence was reduced approximately 6-fold from 6% to 1% and from 3% to 0.5%, respectively. Stannard et al[34] showed a notable

reduction in the rate of deep infection (19.0% vs 10.0%) and wound dehiscence (16.5% vs 8.6%) with the use of iNPWT compared with standard dressing in 263 high-energy lower extremity fractures. Three mechanisms of action have been proposed regarding the effects of iNPWT: (1) lateral stress reduction; (2) increased perfusion; (3) and reductions in edema, hematoma, and drainage. Wilkes et al[39] demonstrated in a biomechanical study that iNPWT decreased the lateral stresses by 50% around incisions and normalized the distribution of stresses to preincision levels. Timmers et al[36] showed a greater than 5-fold increase in blood flow by applying NPWT with pressures up to 300 mm Hg to healthy skin. Prolonged wound drainage has been shown to be associated with infection after total joint arthroplasty.[28] Patel et al[28] reported that each day of prolonged wound drainage increased the risk of wound infection by 42% following a total hip arthroplasty and by 29% following a total knee arthroplasty. Hansen et al[10] reported the use of iNPWT at postoperative day 3 or 4 in patients having prolonged drainage after total hip arthroplasty. The investigators reported that more than 76% of 109 patients treated with iNPWT healed successfully with no further problem, which was equivalent to their previous protocol of surgical irrigation and debridement.[15] Finally, Pachowsky et al[27] demonstrated that iNPWT notably reduced the size of seromas after total hip arthroplasty.[27]

Most previous studies used the VAC system, which is the longest established, commercially available device.[24] A high incidence of blisters has been reported when the VAC system is used for closed wounds in total knee arthroplasty and open fractures of lower legs.[12,35] The polyurethane foam, which is used as a wound contact layer or wound filler material in the VAC system, helps promote the formation of granulation tissue on an open wound but can cause maceration to healthy skin. Therefore, when the VAC system is used on a closed wound, it is recommended that an additional nonadhesive wound contact layer be placed between the foam dressing and the skin to avoid direct contact.[3,35] We believe that our lack of local skin complications is due to the PICO system, which is uniquely designed to be a skin-friendly device placed over closed surgical incisions using a multilayer silicone dressing.[13] Hudson et al[13] reported that there was neither skin damage nor maceration to healthy skin by the application of negative pressure in the form of the PICO system and neither pain nor trauma to the wound on dressing removal.

Despite the accumulated evidence about the effect of iNPWT, little information is available about the optimum duration and amount of negative pressure to be applied for clinical use. Most of the literature about iNPWT in orthopedic surgery reports the use of −75 mm Hg or −125 mm Hg with the VAC system. Furthermore, the duration of use varies widely—from 24 hours to 10 days.[18] Although the therapeutic range of negative pressure has been considered to be between −40 mm Hg and −150 mm Hg from several studies of in vivo experimental models,[3] no published studies have investigated the appropriate levels of pressure for clinical outcomes. This lack of data also applies to the duration of use of iNPWT. The PICO system has only 1 fixed continuous pressure setting of −80 mm Hg. In our study, all patients tolerated this setting well with no complaints of pain or discomfort. The PICO system is recommended to be removed by day 7 after surgery.[23] In our study, no patients reported issues such as intolerance, device trouble, or dressing problems before the scheduled visit on postoperative day 6 or 7.

One of the concerns about the routine use of iNPWT is the added cost for the procedure. The equipment cost per PICO unit is $220 (1 pump with batteries and 2 dressings). No additional hospitalization is required by the application of iNPWT, and coordination of dressing changes with a visiting nurse or wound specialist is not needed. Whalen et al[38] reported that the treatment cost for patients who developed wound necrosis after total ankle arthroplasty was 5 times as much as that for patients without a complication. Judging from the high prevalence of wound healing problems and the possible treatment cost resulting from wound problems, the prophylactic use of the PICO system or an incisional iNPWT would be reasonable, especially for patients with a high risk of wound complications.

Some limitations of our study must be acknowledged. Most important, the present study was based on a retrospective survey. To minimize the risk of selection bias, we used consecutive sampling for both the control and intervention groups. Assessment of patient demographics and known risk factors in our study demonstrated similar backgrounds between the control and intervention groups. Surgical experience has been related to postoperative complications after TAA, including wound healing problems. However, we consider this to be limited in our study, as all procedures in this study were performed by 1 surgeon with an experience of more than 100 TAAs prior to the study period. There were not any changes in the practice of the surgeon during the period of this study. Another limitation is the sample size, which may not have been large enough to find important risk factors for wound healing and a notable effect of iNPWT in low-incidence events. Although age and corticosteroid use are well-known risk factors for wound healing,[17,31] we did not see these as independent risk factors in our study; however, we must be careful in drawing any definitive conclusions about this due to the small sample size of our cohorts. Although our study showed a notable reduction in the prevalence of wound healing problems after TAA by the application of iNPWT, we were unable to detect an important reduction in the prevalence of infection with this modality. This may also be due to the small number of the events in both the control and intervention groups. Using data from previous studies,[30,40] power analysis indicated that 434 patients would be

necessary for each group to detect a significant effect of iNPWT on infection after TAA with a significance level of .05 maintaining more than 80% power. Further well-designed studies are required to clearly show the preventive effect of iNPWT on infection after TAA and identify the patients who would most benefit from iNPWT. Despite these limitations, the notable reduction in the prevalence of wound healing problems by iNPWT observed in our study suggests that iNPWT can be an encouraging preventive therapy against TAA wound complications; such complications can lead to devastating consequences, especially in patients who are deemed at high risk according to known risk factors such as diabetes mellitus, corticosteroid use, inflammatory arthropathy, poor vascular perfusion, immune compromise, and smoking.

In summary, this study is the first to demonstrate the effect of iNPWT on the surgical incision of TAA. We believe that the use of iNPWT on the anterior ankle incision in TAA should be considered, especially for those patients with high risks of wound complications.

Declaration of Conflicting Interests

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