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Closed Incision Negative Pressure Therapy Effects on Postoperative Infection and Surgical Site Complication After Total Hip and Knee Arthroplasty

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ABSTRACT

Background: The aim of this study is to determine whether negative pressure wound therapy, used prophylactically in clean surgical incisions, reduces surgical site infection, hematoma, and seroma after total joint replacement.
Methods: A single center, open-label study with a prospective cohort of patients undergoing primary total knee arthroplasty or total hip arthroplasty treated with closed incision negative pressure therapy (ciNPT) of clean surgical wounds was conducted. One hundred ninety-six incisions treated with ciNPT in 192 patients were compared with a historical control group of 400 patients treated with traditional gauze dressing. The rates of clinically significant hematoma, seroma, dehiscence, surgical site infection, and complication were compared using univariate analyses and multiple logistic regression.
Results: The rate of deep infection was unchanged in the ciNPT group compared with control (1.0% vs 1.25%); however, the overall rate of infection (including superficial wound infection) decreased significantly (3.5% vs 1.0%, $P = .04$). Overall complication rate was lower in the ciNPT group than controls (1.5% vs 5.5%, $P = .02$). Upon logistic regression, only treatment group was associated with complication; patients treated with ciNPT were about 4 times less likely to experience a surgical site complication compared with control ($P = .0277$, odds ratio 4.251, 95% confidence interval 1.172-15.414).
Conclusion: ciNPT for total knee arthroplasty and total hip arthroplasty in a comprehensive patient population reduced overall incidence of complication, but did not significantly impact the rate of deep infection. Further research to determine clinical and economic advantages of routine use of ciNPT in total joint arthroplasty is warranted.

Total knee arthroplasty (TKA) and total hip arthroplasty (THA) are 2 of the most common orthopedic procedures currently performed in the United States and the incidence continues to increase annually. This aging population is likely to have chronic diseases such as diabetes, cardiovascular disease, or rheumatoid arthritis which increase the risk of surgical wound complications [1–3].

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Importantly, the rate of revision surgeries has increased the economic burden substantially [4–6]. These revision surgeries are often due to wound healing complications such as seroma, hematoma, and surgical incision infection. Patients requiring early surgical treatment for wound healing problems after TKA are 7.5 times more likely to develop further complications, such as deep infection and major subsequent surgery [7].

Traditionally, complicated and nonhealing wounds have been treated with negative pressure wound therapy (NPWT) [8,9]. This technology has often been used as a tool in the bridge between debridement and surgical closure and is thought to assist in the healing process through a number of mechanisms, including increasing blood flow, decreasing edema, stimulation of angiogenesis, and induction of collagen transcription [10–12]. It has also been suggested that NPWT draws interstitial fluid from the wound, which may contain inflammatory or infectious exudate hypothesized to impair healing [13].

More recently, NPWT has been used in the context of closed incision management, applied prophylactically to clean surgical wounds. Research has focused on high risk patients and susceptible incision types, such as those in vascular surgeries, traumatic orthopedic procedures, abdominal incisions, and sternotomies [14,15]. Initial evidence suggests that closed incision negative pressure therapy (ciNPT) in these populations significantly reduced the incidence of infection as well as the incidence and severity of postoperative hematoma and seroma [16–20]. This study sought to determine the effect of ciNPT on the incidence of surgical site complications in a comprehensive patient population undergoing primary THA and TKA. We hypothesized that the use of ciNPT on clean total joint arthroplasty incisions would significantly reduce the rate of wound complications, specifically surgical site infection (SSI).

Materials and Methods

This single center, open-label, nonrandomized study was open to prospective patient enrollment from April 2013 to November 2014. Patients undergoing elective primary TKA or THA were eligible for inclusion. A cohort of 192 consecutive patients representing 196 surgical incisions were treated with the ciNPT group using the Prevena Incision Management System (Acelity, San Antonio, TX), for 6-8 days postoperatively. A retrospective cohort of 400 consecutive patients undergoing surgery from October 2011 through December 2012 comprised the control group. All patients included in the control group received traditional gauze dressing with standard dressing changes. All patients were treated by 1 surgeon in a single institution; all incisions were closed and dressed by a single physician's assistant.

No changes in perioperative or postoperative care were instituted between the historical control period and the prospective data collection period, including deep vein thrombosis prophylaxis protocols. Intraoperatively, all patients were administered 15 mg/kg tranexamic acid at the time of incision. The anterior approach was used in the majority of THA cases, and anterolateral approach was used if anterior approach was not feasible. A midline parapatellar incision was used for all TKAs. Postoperatively, external pneumatic compression cuffs were used in all patients; those who were low risk for deep vein thrombosis (no history of venous thromboembolism) were given aspirin prior to and after discharge. Patients who were taking an anticoagulant prior to admission were continued on the same anticoagulant postoperatively and after discharge. Finally, subjects who had history of venous thromboembolism but were not prescribed anticoagulants prior to admission were discharged on rivaroxaban. Most knees were closed with staples and hips were typically closed with sutures and glue. Patients undergoing active cancer treatment, suffering from active systemic infection, or jaundice were not eligible for inclusion. Patients with known or documented allergy to silver or any other contraindication to use of the Prevena Incision Management System were excluded. Local Institutional Review Board approval of this study was obtained prior to study commencement; all patients in the prospective arm provided informed consent, while a waiver for consent was approved for the control group. This trial was registered in the ClinicalTrials.gov registry: identification number NCT01854138.

Demographic information, body mass index (BMI), comorbid conditions, preoperative presence of edema, and surgery site were collected. Postoperative information including surrounding tissue appearance, presence of edema, drainage, and presence of tape trauma or dressing reaction were collected at 24 hours after surgery and at postoperative follow-up in both groups. Surrounding tissue appearance was graded as normal, pink, red, or denuded; drainage and swelling were graded as none, mild, moderate, or gross. During follow-up assessments, signs of seroma, hematoma, dehiscence, or SSI were recorded dichotomously as present or not present by the surgeon author and a single physician's assistant in all patients. In the experimental group, follow-up assessment occurred at 1 week postoperatively in order to remove the wound vacuum and assess the surgical site; standard 2-week follow-up occurred in the control group. All patients were also reassessed at six weeks postoperatively. Medical records were reviewed to collect hospital length of stay and readmissions within 60 days of surgery due to wound dehiscence, seroma, hematoma, or SSI. Hospital databases were queried to verify and confirm readmission data.

Statistical Analysis

Power analysis was based on historical institutional infection rates, hypothesizing a 50% reduction in the rate of SSI. A study design utilizing a 1:2 ratio of patients in the experimental and control arm was used to improve power while maintaining feasibility. We calculated that 200 patients were needed in the experimental arm with 400 patients in the control arm in order to achieve 80% power with 0.05 significance level.

SAS version 9.2 (SAS Institute Inc, Cary, NC) was used for statistical analysis. Descriptive statistics detailed patient characteristics upon study entry. Chi-squared and Student's *t*-tests were used to investigate categorical and continuous variables, respectively. Post hoc logistic regression was used to determine the effect of treatment, gender, BMI, surgical site, and health status on outcome measures. Odds ratios to measure the risk differences associated with clinical outcomes were calculated. $P < .05$ was considered statistically significant.

Results

In total, 197 incisions in 193 separate patients were treated with ciNPT. One patient experienced a prosthetic fracture on postoperative day 2 and was omitted from analysis. Six patients who could not have Prevena placed due to inability to obtain a seal were excluded after consenting; therefore, we report the results of 196 incisions in 192 patients. Four hundred consecutive cases were included in the retrospective arm, representing 91% of eligible cases treated by this single surgeon during the control time period.

The ciNPT group included 129 women (65.8%), significantly more than the control group, which included 216 women (54%, $P < .001$). There were 28 patients (14.3%) in the ciNPT group with diabetes mellitus compared with 48 (12%) in the control arm ($P = .43$; Table 1). A higher incidence of hypertension was present in the control group (59.3% vs 46.4%, $P = .003$). The ciNPT group had a higher incidence of heart disease, tobacco use, and history of cancer (all $P < .01$; Table 1).