ORIGINAL ARTICLE

Revised: 14 September 2020



Negative pressure wound therapy in spinal fusion patients

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Funding information Acelity KCI

Abstract

Post-operative wound complications are some of the most common acute complications following spine surgery. These surgical site infections (SSI) contribute to increased healthcare related costs. Negative pressure wound therapy (NPWT) has long been used for treatment of soft tissue injury or defects. NPWT may reduce the incident of SSI following spinal fusion procedures; however, its potential applications need further clarification. Thus, we conducted a retrospective analysis of two cohorts to compare NPWT to traditional sterile dressings following spinal fusions in regards to post-operative outcomes. Following institutional review board approval, 42 patients who had a NPWT were matched by type of surgery to 42 patients who had traditional dressings. A retrospective chart-review was completed. Outcome measures, particularly SSI and need for reoperation, were analyzed using one-way ANOVA for both univariate and multivariate analysis. When controlled for sex and body-mass index, the use of a NPWT was independently correlated with decreased SSI (P = .035). Superficial dehiscence, seroma, need for additional outpatient care, and need for operative revision were all found to occur at higher rates in the traditional dressing cohort. Closed incisional negative pressure wound therapy provides a cost-effective method of decreasing surgical site infection for posterior elective spine surgeries.

K E Y W O R D S

fusion, negative pressure wound therapy, outcomes, spine, surgical site infection

1 | INTRODUCTION

Post-operative incisional and wound complications, including wound infections, wound dehiscence, and seromas are some of the most common complications following spinal operations, and in particular fusion surgery where instrumentation is implanted.¹ Surgical site infections (SSI) increase health care related costs due to

prolonged inpatient stay, repeat surgery, and need for frequent follow-ups.²⁻⁴ Multiple risk factors for SSI in spine surgery have been identified, including the type and duration of procedure, inclusion of spinal instrumentation and fusion, and number of operative levels.^{5,6} Patient associated risk factors include medical comorbidities, such as, diabetes and malignancy, nutritional status, obesity, and smoking status.⁷⁻⁹

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Negative pressure wound therapy (NPWT), also known as vacuum-assisted wound closure (VAC), has long been used for the treatment of soft tissue injury or defects and open wounds. In more recent years, the use of NPWT has expanded to include closed surgical wounds. Studies in other surgical specialties have shown the benefits incurred by closed incision negative pressure therapy (ciNPT) include lower incidence of SSI, seroma formation, and re-operation rates following soft tissue closure.^{10,11} The use of NPWT in spine surgery has traditionally been in the treatment of post-operative wound complications, including SSI.^{12,13} More recently, it has been suggested that the use of ciNPT may reduce the incidence of SSI following spinal fusion procedures.^{14,15} However, its potential applications in spinal surgery needs further clarification.

We present a retrospective analysis of patients treated with ciNPT compared with traditional sterile dressings following spinal fusion with respect to post-operative complications and health care economics. The study aimed to determine if ciNPT provided superior decrease in post-operative wound complications.

2 | METHODS

Following institutional review board approval, patients undergoing elective posterior spinal fusion surgery at The Ohio State University Wexner Medical Center were retrospectively reviewed from January 2018 to June 2019. In December 2018, a shift was made in practice, based on surgeon preference, to use the PREVENATM incision management system for posterior fixation surgeries. Patients aged 18 to 80 years old who underwent posterior cervicothoracic, thoracic, thoracolumbar, or lumbar fusions were included. Both cohorts, traditional dressing and ciNPT, were selected from consecutive series between January 2018 to December 2018, and January 2019 to June 2019, respectively. Those who were treated with the PREVENATM system were matched with a patient cohort who had traditional dressings. Cohorts were comprised of consecutive retrospective cases matched by type of surgery. Posterior instrumented cases including cervicothoracic fusions, mid thoracic fusions, thoracolumbar fusions, transforaminal lumbar interbody fusions, and fusions involving deformity correction with instrumentation to the pelvis were included. As these were performed by one attending surgeon, surgical techniques including instrumentation materials, interbody material, and bone graft selection did not vary within each of these case types.

Demographic data including age, sex, and body mass index (BMI) were evaluated, along with clinical data including relevant medical history, diabetes, and

Key Messages

- Post-operative surgical site infection (SSI) is a common complication of spinal surgery. Negative pressure wound therapy (NPWT) has been well elucidated in surgical specialties to promote wound healing and prevent SSIs. To date, there are no studies evaluating the use of NPWT on spinal surgery.
- The goal of this paper was to demonstrate that the use of NPWT does decrease the rate of post-operative SSI in posterior spinal surgeries.
- A retrospective chart review on patients who underwent posterior spinal fusions was completed, separating groups into two cohorts: those who received NPWT and those who received traditional wound dressing. Cohorts were matched by type of posterior spinal fusion. SPSS and regression analysis were completed on our collected data.
- We demonstrated a statistically significant difference in post-operative SSI for patients who received NPWT verse those who received only traditional wound care.

smoking status. (Table 1) Surgical factors evaluated include type of surgery performed, number of levels treated, length of surgery, and estimated blood loss. Laboratory and radiographic factors were also evaluated for the two cohorts.

Closure of the surgical procedure was the same between the two groups until dermal closure. All patients had their wounds irrigated with a copious amount of bacitracin-impregnated saline, and vancomycin powder was applied to the incision prior to closure. All patients underwent standard drain placement per surgeon protocol. Standard closure was performed, fascial layers were approximated tightly with interrupted 0-0 vicryl and 2-0 vicryl suture, and the dermis was approximated with inverted interrupted 2-0 vicryl. In the PREVENA™ system cohort, the skin was approximated with staples and a PREVENATM system applied. The traditional group had the skin approximated with running subcuticular monocryl and covered with topical skin adhesive. All patients were provided with two doses of perioperative antibiotics within the first 24 hours of surgery.

The PREVENATM System was left in place for a total of 7 days, as this was the battery life of the unit, unless it had to be removed earlier due to patient compliance or

TABLE 1 Univariate analysis (independent sample *t* test, 2-tailed) of baseline demographics

Patients	PREVENATM	Control	P-value
	42	42	N/A
Male sex	66.7%	40.5%	0.016
Age	59.7 (9.4)	57.5 (10.8)	0.328
Levels	6.2 (3.1)	6.6 (4.1)	0.609
Revision	7.1 %	0.0%	0.079
DM	28.6%	33.3%	0.642
HTN	64.3%	64.3%	0.999
CKD	7.1%	4.8%	0.649
COPD	4.8%	4.8%	0.999
Any tobacco	69.1%	73.8%	0.634
Current tobacco	35.7%	16.7%	0.048
BMI	28.9 (6.0)	32.6 (8.1)	0.021
Obesity	7.1%	20.0%	0.094

Abbreviations: BMI, body mass index; CKD, chronic kidney disease; COPD, chronic obstructive pulmonary disease; DM, diabetes mellitus; HTN, hypertension; N/A, not applicable.

technical issue. Length of stay was not affected by the PREVENATM unit as patients who met discharge criteria were discharged home with the battery-powered unit. For those that had traditional dressings placed, the dressings were changed on post-operative day 2 with recommended daily dressing changes, thereafter. Those patients within the PREVENATM System cohort required staple removal around post-operative day 14. Patients in both cohorts were seen in clinic for a wound check between post-operative day 7 and 6 weeks. At the post-operative clinic visit, incisions were evaluated for the presence of superficial dehiscence, post-operative seroma, and SSI.

We analysed those patients that required additional outpatient wound care and those that required operative wound revisions within the two groups. Statistical analysis was performed using univariate analysis with 2-tailed *t* test for patient demographics. Outcome measures were analysed using one-way ANOVA for both univariate and multivariate analysis. *P*-values of \leq .05 were considered statistically significant. Data are presented as percentages of variables for each respective cohort.

3 | RESULTS

3.1 | Patient demographics and comorbidities

A total of 42 patients, who had a ciNPT placed were identified for inclusion in this study. An additional 42 patients who had traditional dressings placed were identified and matched by type of surgery. Types of surgery included cervicothoracic (n, ciNPT = 13, n, traditional = 13), transforaminal lumbar interbody fusion (TLIF) (n, ciNPT = 12, n, traditional = 11), thoracolumbar (n, ciNPT = 13, n, traditional = 12), and mid-thoracic (n, ciNPT = 4, n, traditional = 6). There was no statistically significant difference between types of surgery between the two groups (P < .05). There was a male predominance in the ciNPT group (n = 28) compared with females (n = 14), whilst the traditional dressing group was predominantly female (25 females versus 17 males). This difference reached statistical significance (p = 0.016). Other baseline information, including age $(59.7 \pm 9.4 \text{ vs})$ 57.5 ± 10.8), comorbidities of diabetes (28.6% vs 33.3%), hypertension (64.3% vs 64.3%), chronic kidney disease (7.1% vs 4.8%), COPD (4.8% vs 4.8%), history of tobacco abuse (69.1% vs 73.8%), and number of spinal levels treated (6.2 \pm 3.1 vs 6.6 \pm 4.1), was not significantly different between ciNPT and control groups, respectively (Table 1). Differences in BMI (28.9 vs 32.6, P = .021) and current tobacco use (35.7% vs 16.7%, P = .048) did reach statistical significance. In the ciNPT cohort, three patients had prior same-site surgeries, compared with two patients in the traditional dressing cohort. None of these patients had any major post-operative complications, and therefore, this factor was not included in the statistical analysis.

3.2 | Outcomes and cost

Within the control cohort, three patients were ultimately lost to follow-up, but importantly did not present to our institution with wound or surgical complications. Their inclusion did not alter the statistical significance of outpatient care. Examining the incisional and wound complications, in the ciNPT cohort, only one patient had a superficial wound dehiscence, which did require operative revision (2.4%). One patient was noted to have a post-operative seroma, which was managed conservatively and resolved on routine follow up (2.4%). One patient required an additional clinic follow up for delaved wound healing (Table 2). In the traditional dressing cohort, three patients required operative revision (7.1%), for superficial wound dehiscence, dehiscence with infection, and one for a questionable culturenegative infection. Of the three patients with SSI or concern for SSI (7.1%), two were managed operatively, and one was treated with a course of oral antibiotics for erythema surrounding the wound. Two patients developed post-operative seroma, one of which had subsequent wound dehiscence necessitating operative revision.

TABLE 2 Univariate analysis (one-way ANOVA) of outcome measures

Patients	PREVENATM	Control	P-value
	42	42	N/A
Readmissions	21.4%	21.4%	0.930
SSI	0.0%	7.1%	0.034
Superficial dehiscence	2.4%	7.1%	0.276
Outpatient care	2.4%	9.5%	0.145
Seroma	2.4%	4.8%	0.519
Operative revision	2.4%	7.1%	0.276
Any wound complication	7.1%	14.3%	0.296

Abbreviations: N/A, not applicable; SSI, surgical site infection.

Three patients required additional clinic follow up appointments.

Comparing the ciNPT cohort to the traditional dressing cohort, there was no difference in the rate of readmission between the two cohorts (Table 2). There were higher numbers of SSI (7.1% vs 0%), superficial dehiscence (7.1% vs 2.4%), seroma (4.8% vs 2.4%), need for additional outpatient care (9.5% vs 2.4%), and need for operative revision (7.1% vs 2.4%) in the traditional dressing group. Similarly, wound complications were higher in the traditional group compared with the ciNPT group (14.3% vs 7.1%), although this did not reach statistical significance. (Table 2) SSI was the only factor to reach statistical significance (P = .034).

Amongst potential demographic and baseline confounding variable in this analysis, the variance in sex and BMI between the groups could potentially play a role in the observed difference in SSI between groups. Whilst tobacco use was also significantly different between groups, it was observed with higher incidence in the ciNPT cohort (35.7% vs 16.7%). After controlling for these variables (one-way ANOVA), the use of a ciNPT was independently correlated with decreased SSI (F statistic = 4.60, P = .035).

4 | DISCUSSION

Surgical site infections and wound complications are an unfortunate complication associated with spinal fusion operations. Spinal wound infection rates vary from 1% to 12% in the literature.^{1,16} The use of preoperative and intraoperative antibiotics, copious irrigation, and topical antibiotics has decreased the incidence of SSI.¹⁷ Treatment of spinal SSI may include wound care, antibiotics, debridement, and repeat surgery; however, prevention remains the ultimate goal.

There is literature to support improved wound healing with the use of closed incision negative pressure therapy (ciNPT) in multiple surgical specialties, including trauma and acute care surgery,^{18,19} orthopaedics,^{20,21} cardiothoracic,^{22,23} vascular,^{24,25} obstetrics,²⁶ and plastic and reconstructive surgery.^{27,28} The proposed mechanisms by which ciNPT speeds wound healing include increasing blood flow, enhancing angiogenesis, stimulating growth factors, and removal of interstitial fluid.²⁹ In closed incisions, there is the added benefit of providing a barrier between the incision and the environment, thus reducing bacterial burden, as well as decreasing distracting forces thereby maintaining approximation of wound edges.³⁰

Our retrospective review demonstrated some important preliminary findings. Not only did we demonstrate a decrease in post-operative wound complications with the use of ciNWPT, including a trend towards decrease in seroma formation, superficial dehiscence, and the need for outpatient wound care and operative revision, but we also demonstrated a decrease in the number of SSI. There were significantly fewer SSI in the ciNPT group (0%) as compared with the control (9.5%). SSI was the only factor to reach statistical significance (P = .034), and this held true when controlling for the confounder of male sex and BMI differences between the two groups. For the one patient in the ciNPT cohort who had superficial dehiscence requiring operative revision, the patient's glucose was noted to be greater than 300 mg/dl at the time of readmission. A ciNPT dressing was placed following the revision surgery, and no further wound complications were noted.

Whilst our 7.1% rate of SSI in the control group does appear abnormally high, it is important to note that of the 3 of 42 patients who make up this percentage, only one required revision surgery, whilst two were treated with oral antibiotics for suspicion of superficial infections. None of the three had any further wound complications. This elevated percentage was a driving force in switching from traditional dressings for our posterior fixation surgeries to using ciNPT by our surgeons, which is a confounding factor. Staples were used as the NPWT system is not functional over DERMABONDE[®] (applied over the monocryl suture).

Potential confounders to this study include the disparity between the number of male and female patients and BMI. After controlling for these, the difference in SSI remained significant (P = .035). Although the sex of the patient should have little effect on the potential for development of post-operative wound complications, it will nevertheless be important in future studies to have an equal number of male and female patients in each group. An additional confounding factor that differed between \perp WILEY_ \square

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those who received ciNWPT and traditional dressings was current smoking status. Smoking has been associated with a higher rate of wound complications.³¹ Our cohort with ciNPT had 35.7% current smokers compared with 16.7% in those with traditional dressings (P = 0.048). This difference would be expected to increase SSI in the ciNPT cohort and argues for the greater efficacy of ciNPT in preventing wound complications.

The cost of delivering healthcare is an important topic to consider. Although the initial cost of our ciNPT system is higher than the cost of traditional dressings, the overall cost could be lower when considering the lower rate of SSI. Vuerstaek et al.³² demonstrated in a prospective randomised control trial assessing NPWT in chronic leg ulcers that there was significant cost savings (P = .001) with faster wound healing times (P = .001) when compared with traditional dressings. Blumberg et al.³³ found that the direct hospital cost for a single readmission for treatment of spinal SSI was \$13,302, with an average readmission length of stay of 7.4 days. Whilst the cost of our ciNPT system ranges from \$495 to \$595, the potential savings in decreased SSI with the use of ciNPT are potentially substantial.

These study results are limited by the retrospective nature of the study and hence selection bias, the small sample size, and other confounders that were not accounted for in this study. The surgeon transition from traditional dressings to ciNPT was driven by two subsequent wound issues in posterior cervicothoracic fusions, thus biassing the traditional dressing group to a likely higher surgical site complication rate. Furthermore, three patients were lost to follow-up in the control arm. Although certain wound complication parameters did not reach statistical significance, the trend towards reduction in complications and the resulting clinical and financial implications have potential for immense impact. This highlights the need for additional large-scale prospective studies on the use of ciNPT in spinal fusion operations.

5 | CONCLUSION

Closed incisional negative pressure therapy demonstrated a decrease in seroma formation, superficial dehiscence, and the need for outpatient wound care and operative revision. When controlled for gender and BMI, there was a statistically significant decreased rate of surgical site infections. Surgeons should consider this option as a costeffective addition for their patients.

CONFLICT OF INTEREST

This retrospective study was conducted using funding provided by Acelity KCI.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

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How to cite this article: Akhter AS, McGahan BG, Close L, et al. Negative pressure wound therapy in spinal fusion patients. *Int Wound J.* 2021;18:158–163. <u>https://doi.org/10.1111/</u> iwj.13507