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The safety and efficacy of using negative pressure incisional wound VACs in pediatric and neonatal patients

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ABSTRACT

Background: Surgical site infection (SSI) rates are an important surgical quality metric. Decreased SSI rates have been demonstrated using negative pressure incisional wound vac device (NPIWV) dressings in adults but have not been studied in children.
Materials and methods: A retrospective review of patients treated with NPIWV at our institution between February 2016 and February 2018 was performed. NPIWV dressings were applied by previously described techniques. Using the same CPT codes from our study patients, we queried the National Surgical Quality Improvement Program-Pediatric (NSQIP-P) data between January 2014 and January 2016 to identify preimplementation controls (PIC). NPIWV patients were compared to historical controls to assess safety and efficacy of SSI prevention.
Results: There were 32 patients managed with NPIWV, and 65 patients in the PIC group. There were no NPIWV-associated complications. There was a trend toward reduced incidence of SSI in NPIWV patients, with 1 SSI in 32 cases (3.1%) versus 7 SSIs in the 65 historical control patients (10.8%) ($p = 0.22$).
Conclusions: Our study shows that NPIWV dressings can be used safely in pediatric and neonatal patients undergoing surgery, with a trend toward decreased SSI rates. These findings should be confirmed in a larger, prospective trial.
Type of study: Retrospective comparative study.
Level of evidence: Level III.

Surgical site infection (SSI) rates are an important quality metric in surgery, and one of the most common hospital-acquired infections worldwide [1]. Surgical site infections lead to increased postoperative length of stay and increased cost [1–4], and patients who experience surgical site infections are more likely to experience other surgical complications [5]. Surgical site infections are an important contributor to the growing cost of healthcare in the United States of America [6].

To prevent SSI, a variety of measures have been implemented and are frequently included in SSI prevention bundles. Some of the elements included in these bundles are preoperative washing with chlorhexidine, preoperative mechanical and antimicrobial bowel preparation, standardizing antibiotic administration, and standardized preparation of the surgical site [2,7]. One element which has decreased SSIs across a variety of indications in adults is the use of a Negative Pressure Incisional Wound Vacuum (NPIWV) dressings. These dressings are applied over a wound which has been approximated, and have been shown to decrease SSI rates in a variety of adult surgical procedures [8–11]. Specifically SSI rates have decreased by 30%–65% using NPIWV dressings in adult patients undergoing colorectal surgery and closure of loop ileostomies [10,11].

Although the incidence of SSI is higher in adults than it is in pediatric patients, SSI is an important target for quality improvement in children's surgery [12]. Similar to adult surgery, many pediatric studies have been published on the impact of bundled interventions including preoperative skin cleansing, intraoperative skin preparation, and optimal timing of perioperative antibiotics on the incidence of SSI [13]. However, no studies have examined the safety or efficacy of NPIWV dressings in pediatric patients. Since NPIWV dressings have shown beneficial effects in adults, we hypothesized that the use of NPIWV dressings would similarly reduce SSI rates in pediatric patients.

1. Materials and methods

1.1. Strip vac application

The NPIWV was introduced at our institution, a single free-standing children's hospital, in 2016 to assist with closure of contaminated

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wounds in elective and urgent/emergent cases. Patients were selected for NPIWV based on surgeon preference of closure technique for clean–contaminated, contaminated, and dirty/infected cases. Application of NPIWV dressings was performed by approximating the skin edges with buried, absorbable sutures, using either Polygalactin 910 (Ethicon, Somverville, NJ) or Poliglecaprone 25 (Ethicon, Somerville, NJ). The size suture was similar to what would be used to close skin in a similarly sized patient (usually 4-0 or 5-0 depending on the size of the patient). Approximately 1 cm strips of adhesive barrier included in the Vacuum Assisted Closure (V.A.C.) GranuFoam dressing kit (KCI, San Antonio, TX) were then cut to the length of the wound. The strips were placed longitudinally immediately adjacent to the wound, without covering the incision itself. The small V.A.C. GranuFoam sponge was then cut to cover the incision with a thin layer of foam, and occlusive dressing was applied over the sponge. A hole approximately 2 cm by 2 cm was cut in the occlusive dressing and the SensaT.R.A.C. pad (KCI, San Antonio, TX) was placed over the hole (See Fig. 1). The NPIWV was used across all ages and placed to either −125 mmHg for children 9 years old and older, and −50 mmHg for children less than 8 years old, infants, and neonates (including former premature infants admitted to our Neonatal Intensive Care Unit). The NPIWV dressing was left in place for up to 4 days and removed prior to discharge if the patient was ready for discharge prior to that time. The application and maintenance of the NPIWV dressing were standardized between patients.

1.2. Study design

We performed a retrospective review of all patients who underwent surgery and received a NPIWV dressing over a 2-year period from February 2016 to February 2018. The current procedural terminology (CPT) codes were collected (Appendix 1). To identify outcomes prior to implementation of NPIWV dressings, we queried the National Surgical Quality Improvement Program-Pediatric (NSQIP-P) data from our institution using the same CPT codes (Appendix 1). Our institutional NSQIP-P data were queried between January 2014 and January 2016, and these patients were designated as preimplementation controls (PIC). We performed retrospective chart review of patients treated with NPIWV, and PIC patient data were extracted from NSQIP-P. Preimplementation control patient wounds were closed based on surgeon preference. Prior to implementation of NPIWV dressings, enterostomy closures were closed loosely to allow for drainage or left open with packing. Open procedures were closed tightly with subcuticular sutures or staples. All patients in both cohorts were followed for at least 30 days. The Nemours Institutional Review Board approved this study.

1.3. Variables

The main independent variable was use of NPIWV. The main dependent variable of interest was incisional SSI [14,15]. Covariates measured in each cohort, included: operation type, length of operation, wound

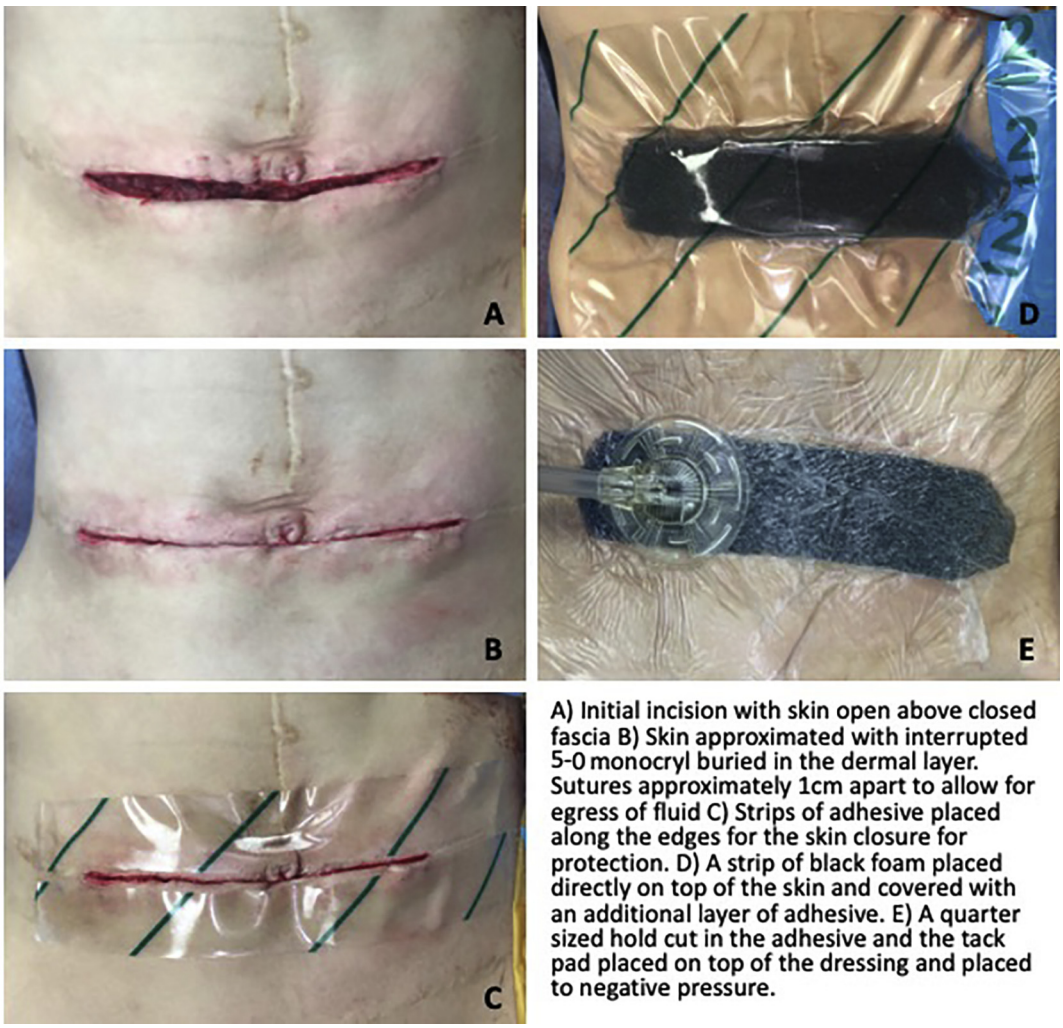

Fig. 1. Detailed instructions on placement of Negative Pressure Incisional Wound Vac (NPIWV) dressing.

class in the operative record, timing of operation, length of stay, and patient demographics. In order to assess the safety of NPIWV, we tracked the rate of NPIWV-related complications such as skin injury from adhesive or need for sedation for dressing removal.

1.4. Statistics

We compared characteristics of NPIWV patients and PIC patients using either a Mann–Whitney test for nonnormal, continuous variables or chi-square analysis for categorical variables, in order to ensure that the two groups were comparable. We compared SSI rates in NPIWV patients and PIC patients using chi square analysis. We then performed multivariable logistic regression analysis in order to assess association between use of NPIWV and postoperative SSI rates after adjusting for other patient characteristics (emergent/elective case classification, wound class, gender, length of stay, operative time, age, weight, and obesity). We included age, gender, and length of stay in our model because variation in demographic and case characteristics across comparison groups may result in selection bias, and their inclusion in the model allows adjustment for differences between groups. The cut points were chosen based on the median weight, operative time, age, and length of stay of the overall cohort. Analysis was performed using Statistical Analysis Software (SAS) (Cary, NC).

2. Results

Thirty-five patients underwent surgery and had NPIWV dressings placed for wound closure. Sixty-five patients were identified in our PIC and underwent standard wound closure. The groups were comparable across demographic, patient, surgical characteristics, and timing of preoperative antibiotics (Table 1). The only differences between the groups were a higher rate of elective procedures and a higher median BMI in the NPIWV cohort (Table 1). Additionally, the rates of clean–contaminated (73.8% vs 62.5%), contaminated (13.8% vs 28.1%), and dirty/infected (10.8% vs 9.4%) procedures were similar between the PIC and NPIWV groups ($p = 0.36$, Table 2).

In the 32 patients treated with NPIWV dressings, including infants and neonatal patients (9 patients <9 months old, 6 patients <4 months old, and 1 patient <1 month old), there were no complications as a result of NPIWV use. We saw no injury to the skin around the incision as a result of negative pressure, or skin tears with removal of the adhesive dressing barrier. No patients required sedation or additional procedures for the removal of the wound vac, including a patient with severe autism who removed his own strip vac with coaching and relaxation techniques.

When we examined the rates of incisional SSIs in the NPIWV group, there was one incisional SSI in 32 cases (3.1%). The PIC patients were noted to have 7 SSIs (including both superficial and deep SSIs as tracked by NSQIP-P) in the 65 patients (10.8%) (Fig. 2). We did not examine the rate of organ space SSI as we did not feel that NPIWV would affect organ space SSI rates. While there was a trend toward a decrease in incisional wound infections in the patients who had an NPIWV, the difference in SSI rates did not reach statistical significance ($p = 0.25$).

Table 2
Comparison of wound class in surgeries performed in the preimplementation cohort (PIC) and the patients treated with Negative Pressure Incisional Wound Vac (NPIWVC) dressings.

Wound Closure by Wound Class				
Closure Type	Clean	Clean–Contaminated	Contaminated	Dirty/Infected
Preimplementation	1	48	9	7
NPIWV	0	20	9	3

$p = 0.36$ by Fisher's Exact Test.

On further analysis using multivariate logistic regression (Table 3), none of the examined factors reached statistical significance, indicating similarities in the PIC and NPIWV cohorts. However, the use of NPIWV dressings showed a similar trend toward reducing incisional SSI (OR: 0.13, CI [0.1–1.84]) after adjusting for emergent vs elective case status, wound class, gender, postoperative length of stay, operative time, age, weight and obesity.

3. Discussion

In this small case series, we have demonstrated that the use of NPIWV dressings is feasible and safe in pediatric patients, and that there is a trend toward decreased incidence of SSI in NPIWV patients. This is the first study to demonstrate the safety and potential efficacy of NPIWV dressings in the prevention of incisional SSI in pediatric patients.

While no previous study has examined the safety of NPIWV dressings, our study showed that in 35 patients there were no complications. This adds to the potential armamentarium of interventions for pediatric surgeons attempting to decrease incisional SSIs without the morbidity of leaving an incision open or performing delayed primary closure in contaminated wounds. We anticipate that by demonstrating the safety of this dressing in pediatric and neonatal populations its use may increase.

This is the only study in the literature which examines the use of NPIWV therapy in children using consistent measurable negative pressure. Two earlier studies have been identified in which suction dressings were placed at the time of either skin closure

Table 1
Comparison of demographic data between patients treated in the preimplementation cohort (PIC) and the patients treated with Negative Pressure Incisional Wound Vac (NPIWV) dressings.

	NPIWV ($n = 32$)	No NPIWV ($n = 65$)			
Category		IQR		IQR	p-value
Median Age (years)	2.2	0.8–14.8	4.2	0.2–12.0	0.22
Sex (No. female (rate %))	11 (31.4%)	28 (43.1%)			0.39
Number of Elective Procedures (rate %)	29 (82.8%)	40 (61.5%)			0.04
Median Weight (kg)	13.1	7.1–54.1	17.4	4.3–36.2	0.2
Median BMI (kg/m^2)	17.5	15.8–25.5	15.7	14.3–18.7	0.01
Median Length of Surgery (min)	160.0	108.0–244.0	132.0	105.5–194.0	0.15
Median Length of Stay (days)	7.0	3.0–22.0	7.0	3.0–22.0	0.85
Median Wound Class (1–4)[a]	2.0	2.0-3.0	2.0	2.0–2.5	0.23
Number appropriately timed abx (rate %)[b,c]	31 (100%)	60 (96.8%)			

[a] Wound class 1 = Clean, 2 = Clean Contaminated, 3 = Contaminated, 4 = Dirty Infected.
[b] Considered appropriately timed if given within 60 min of incision.
[c] Data were available for 31 patients managed with NPIWV dressing and 62 patients managed without NPIWV. The percentages were calculated from patients with whom data were available.

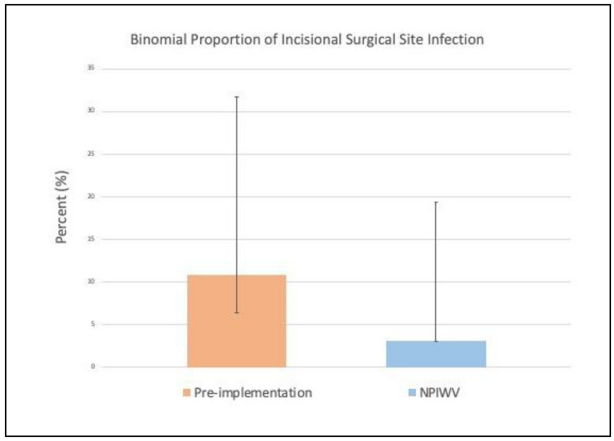

Fig. 2. Comparison of superficial surgical site infection rates between patients treated with standard wound closure in the preimplementation cohort (10.8%) and patients treated with a Negative Pressure Incisional Wound Vac (NPIWV) dressing (2.8%).

after single-site-laparoscopic appendectomy or for any number of procedures with an umbilical incision [16,17]. Both studies examined the use of a translucent occlusive dressing and the application of negative pressure using syringe aspiration. Muensterer et al. examined the use of their dressing after surgical closure of umbilical port sites in pediatric appendectomy [16], and noted a decrease in the rate of surgical site infections at the umbilicus (3.8% to 1%, $p < 0.05$). Seifarth et al., used a similar dressing, but were able to measure the negative pressure under the dressing using an arterial line transducer in 10 consecutive patients and noted pressures from −35 mmHg to −65 mmHg, but unfortunately did not report rates of SSI in their cohort [17]. Additionally, Seifarth and colleagues only measured aspirated pressure at the time of dressing placement and not pressure over time. The use of standardized, continuous, measured pressure in pediatric patients and the report of our incisional SSI rate pre- and postimplementation all make this study unique.

Previously published results using the NSQIP-P database show an overall SSI rate of 5.9% in colorectal surgery. However, SSI rates ranged from 5.0% to 11.4% depending on type of surgery, and from 14.2% to 24.9% in specific disease states [18,19]. These data demonstrate that our SSI rates in both the PIC patients and patients treated with NPIWV dressings fall within previously published ranges. However, our subgroup analysis based on previously identified risk factors for incisional SSI did not reach significance.

The magnitude of the decrease in incisional SSIs rate following introduction of NPIWV that we observed is similar to the decreases seen in larger adult studies [10,11], and trended toward significance in both univariate and multivariable logistic regression analysis. The most likely explanation for our results not reaching statistical significance is the small sample size; however, we recognize that it is possible that the NPIWV offers no therapeutic effect related incisional SSI prevention. Additionally, the increased rate of elective procedures in the NPIWV group may also contribute to the null result of our study; however, surprisingly this effect was reversed on multivariable logistic regression. Specifically, we saw that elective surgery classification trended toward increasing the risk of SSI. In February 2018, a more comprehensive SSI prevention bundle was introduced at our institution, and while the NPIWV dressings were used even after SSI bundle implementation, at accruing additional patients beyond SSI bundle implementation would not be a fair comparison to historical practices. Thus, no additional patients were added to our NPIWV cohort; however, future studies on the effectiveness of our entire SSI bundle may allow us to control for NPIWV use. Additionally, the current retrospective study demonstrated safety and potential efficacy of the technique and is worthy of dissemination.

De Lissovoy and colleagues have demonstrated that surgical site infections increase the mean length of stay by 9.7 days and the cost per admission by approximately $20,000 [4]. Our institutional research into the cost effectiveness of this dressing noted that the price, to our institution, for each refurbished InfoV.A.C. Therapy Unit (KCI, San Antonio, TX) is approximately $18,500. Our cost for V.A.C. canisters and small V.A.C. GranuFoam sponge is approximately $30 and $35, respectively. The largest cost associated with our dressing is the upfront purchase of the reusable therapy unit and would be paid for by the prevention of a single SSI. While this study does not examine the costs associated with the episodes of care for each patient, we feel that the cost for using the NPIWV dressing is not prohibitive and is likely to be cost effective.

Our study has the inherent limitations of a single-institution, retrospective case series. Specifically, the approaches used for preop antibiotics, preoperative skin preparation, wound closure and other measures that may have an impact on SSI rate were not standardized between the two groups and are difficult to compare retrospectively owing to documentation. Finally, as previously mentioned, the small sample size makes it difficult to reach definitive conclusions on the efficacy of the intervention. However, this pre- and postimplementation approach is the best way to identify the possible effect of our use of the NPIWV dressings.

Our study found that NPIWV dressings are safe to use in children and neonates, and that their use may decrease the rate of incisional SSIs. As such, we will continue to use NPIWV dressings at our institution. Larger, prospective studies are needed to confirm the results of our small retrospective study, but we believe that NPIWV is a safe and easy intervention that is likely to reduce SSI in infants and children undergoing high-risk procedures. However, if larger studies are able to confirm a significant reduction in the rate of SSI, the use of NPIWV has the potential to save significant health care dollars and have profound impact on one of the most important quality metrics in surgery by decreasing SSI burden for high-risk colorectal procedures.

Table 3
Multivariable logistic regression analysis — comparison between the preimplementation cohort (PIC) and the patients managed with Negative Pressure Incisional Wound Vac (NPIWV) dressings.

Effect	Odds Ratio	95% Wald Confidence Limits	P value
Strip Vac Use	0.13	0.01–1.84	0.13
Emergent vs. Elective Case Classification	0.24	0.02–2.93	0.26
Wound Class (3, 4 vs. 1, 2)	0.68	0.06–7.8	0.76
Male vs Female	0.6	0.12–2.96	0.53
Length of Stay (LOS) (>1 week vs. <1 week)	0.89	0.18–4.4	0.89
Operative Time Above the Median (>140 min)	1.57	0.31–7.92	0.58
Age Below the Median (<2 years old vs > 2 years old)	1.17	0.08–16.29	0.91
Weight < 14 kg vs > 14 kg	1.09	0.07–16.68	0.95
Obese vs Nonobese (Based on BMI > 25)	3.54	0.21–61.1	0.38

Appendix 1. CPT Codes and standard procedural names of procedures performed in patients managed with NPIWV Dressings. These were used to query institutional data for the National Surgical Quality Improvement Project-Pediatric (NSQIP-P) database to identify a Preimplementation Cohort (PIC).

CPT Codes Used for Database Query	Procedure Name	Preintervention	NPIWV Cohort
43,840	Gastrorrhaphy suture-perforated ulcer	3	1
44,120	Enterectomy, single anastomosis	11	1
44,160	Ileocecal resection	6	1
44,620	Enterostomy (large or small intestinal closure)	12	7
44,625	Closure of enterostomy, large or small intestine, with resection	8	7
44,147, 45,120	Partial colectomy, abdominal and transanal approach, proctectomy with pullthrough	0, 1	1
51,960	Enterocystoplasty, including intestinal anastomosis	0	1
44,626	Enterostomy closure, with resection and colorectal anastomosis	3	3
47,135	Liver allotransplantation	0	1
49,560	Repair, initial incisional or ventral hernia	0	1
44,005	Enterolysis	13	1
44,620, 44,120, 44,140	Enterostomy (large or small intestinal closure), enterectomy with single anastomosis, partial colectomy with single anastomosis	12, 11, 5	1
49,000, 44,800, 44,130	Exploratory laparotomy, excision of Meckel's diverticulum, enteroenterostomy	20, 4, 8	1
44,050, 44,238, 44,120, 44,955	Reduction of volvulus, unlisted laparoscopic procedure, enterectomy single anastomosis, appendectomy	8, 0, 11, 4	1
43,831, 44,620[a]	Gastrostomy tube placement, Enterostomy (large or small intestinal closure)	1, 12	1
49,002	Reopening of recent laparotomy	0	1
44,620, 44,120, 44,995	Enterostomy (large or small intestinal closure), Enterectomy, single anastomosis, appendectomy	12, 11, 4	1
50,360, 50,325	Renal allotransplantation, backbench living donor preparation	0, 0	1

[a] Patient case who developed and incisional surgical site infection. Occurred 3 weeks postoperatively and required incision and drainage in the operating room

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