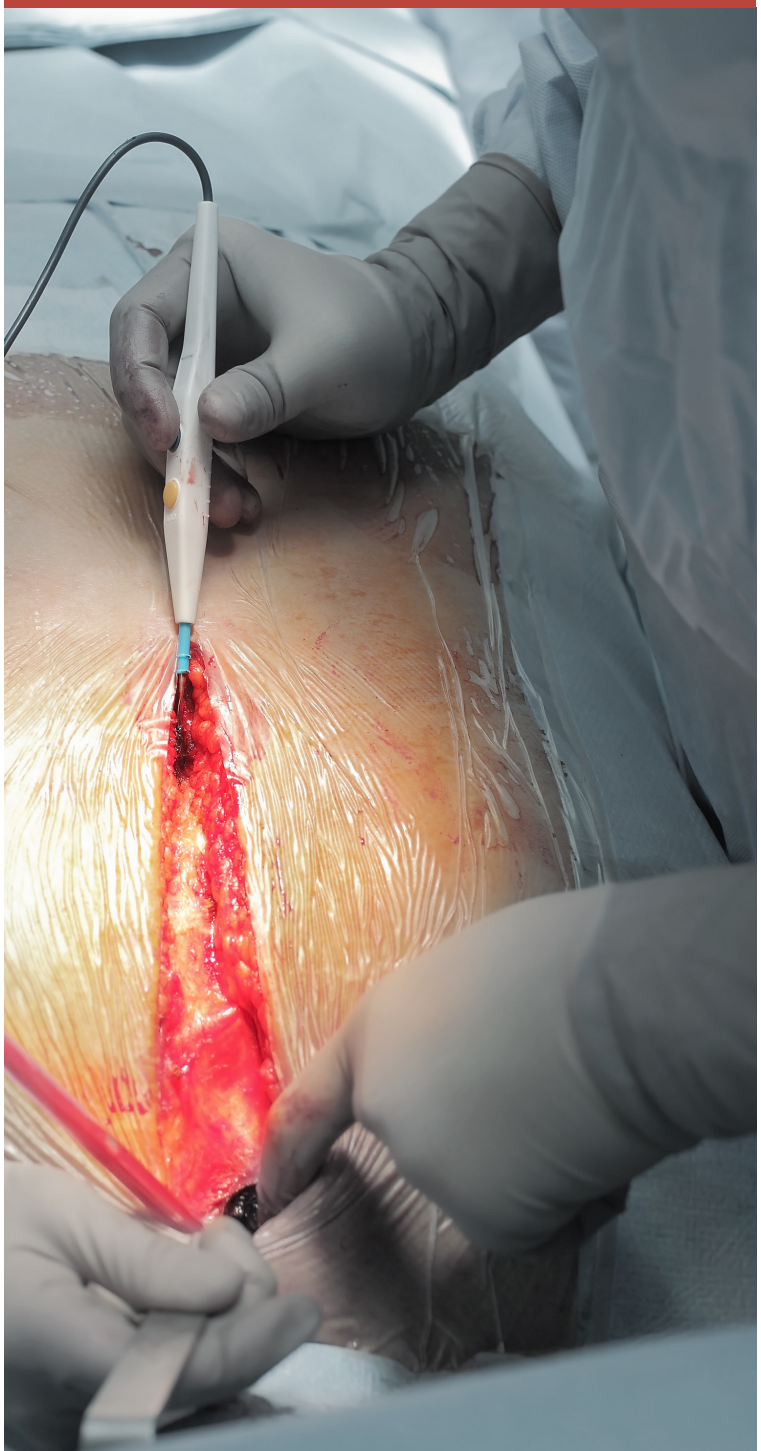
Volume 1 • Issue 2
WINTER 2017

The Chronicles of Incision Management

Clinical Insights, Perspectives, and Treatment Approaches



EDITORIAL BOARD

EDITOR'S WELCOME

GREETINGS,

Welcome to the second issue of *The Chronicles of Incision Management*! As we all know, poor incision healing can lead to serious patient consequences such as surgical site infection, dehiscence, hematoma or seroma. And timely incision management can also play a role in relieving the economic burden of wound care. For these reasons, we continue to be extremely proud of this publication and our continued leadership role in physician education.

This issue contains fascinating articles from our faculty that cover topics such as closed incision negative pressure therapy in obese patients undergoing Caesarean delivery and closed incision negative pressure therapy effects on postoperative infection and surgical site complication after total hip and knee arthroplasty. Additionally, you will find a thought-provoking article on the management of podiatric surgical site incisions with NPWT and a single-center experience on the use of closed incision negative pressure therapy over ischemic mastectomy skin flap incisions in immediate reconstruction.

As always, we hope these topics provide practical insight for you as you treat patients with a variety of wounds. We welcome your feedback and we encourage you to contribute to this publication if you have a case study to share! Please forward the publication link to a colleague so that we can continue to grow our readership.

Thank you,

Ronald P. Silverman, MD, FACS | Acelity
Senior Vice President and Chief Medical Officer

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Management of Podiatric Surgical Site Incisions with NPWT

By: Philip Wrotslavsky, MD

INTRODUCTION

Postoperative pain management in lower extremity surgical cases historically have been mechanically managed with elevation, ice, compression and drains. Pharmacological management includes nerve blocks and analgesics. With the rise of the current opioid crisis, new methods are being sought to reduce post-operative pain so that patients are at lower risk for opioid addiction.

The peer-reviewed literature has shown that increased edema in the lower extremity leads to increased pain.[1] Post-operative edema control is vital to reduce tension on the incision since increased incisional tension may cause an increase in pain at the surgical site. Ice, elevation, compression and drains all can contribute to edema reduction, and thereby reduce pain and incisional tension.

The authors of this study want to introduce a new method that adds to pain control post-operatively in lower extremity surgery. By applying incisional negative pressure in the form of the PREVENA™ Incision Management System, the author has found a significant decrease in post-operative reporting of pain as well as a significant decrease in the use of narcotics in post-operative pain management.

BACKGROUND

The Prevena™ Incision Management System is intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of negative pressure wound therapy.[2] However, no data has been collected regarding other benefits of the PREVENA™ Incision Management System on incisions. Microcirculation in the lower extremity has been reported to take over 72 hours to return to normal.[3] Recommendations have been made to elevate the extremity for up to 5 days. Hematomas and seromas also play a large role in incision sites since they may cause a balloon effect. For example, just as too much air in a balloon will cause stretching of the balloon wall, so too for surgical incisions cause stretching of the entire area, which may result in edema and increased tension on the incision site. This ultimately can lead to increased pain.

It is of the author's opinion that the use of the PREVENA™ Incision Management System reduces post-operative pain through multiple methods. First, the reduction of lateral tension on the incision edges with increased appositional strength and normalized stress distribution of the incisions reduces inflammatory markers and thus reduces pain. Second, the decrease in subcutaneous formation of hematoma and seroma causes less tension and thus less pain. Last, the increased lymph node clearance with the PREVENA™ Incision Management System use leads to decreased swelling, thereby also reducing pain.

METHODS

Fifteen sensate and opioid naive patients underwent various foot surgeries. Diabetics were not included due to the prevalence of neuropathy. For the post-operative dressing, either a PREVENA ™ PEEL & PLACE™ Incision Management System - 13cm or - 20 cm was placed on the incision. The unit was left on for 7 days in all patients. No surgical drains were necessary in these cases. Patients were interviewed at post-operative day 1, 3 and 7. All of the PREVENA™ Systems were removed on day 7. Patients were also interviewed on day 14 (at suture removal). Overall, there was a significant reduction of pain in these procedures than would normally be expected for similar foot and ankle surgeries as self-reported by the patients. As well, usage of opioids was reduced to less than one day on average per patient.

Anecdotal feedback from patients who had experienced previous surgeries (including foot surgeries) was that surgery with the use of the PREVENA™ Incision Management System was less painful. Two patients that needed an elective surgery on the other foot demanded use of the PREVENA™ Incision Management System in the contralateral foot as well. All patients reported an 'ease-of-use' dimension with the PREVENA™ Incision Management System that suggested no interference with usual daily activities of living, and that the surgeries they underwent were less painful than expected.

All patients reported an increase in swelling and pain the first three days after removal of the PREVENA™ Incision Management System unit. However, none needed to take opioids for the pain. The author observed this phenomenon and theorized that the surgical site would swell over the next 3 days as a rebound effect and that there would be a small increase in pain. All of the patients reported this at post op day 14 (one week after the removal of the PREVENA™ Therapy Unit). The author was careful to educate the patient around device removal and the potential for an increase in swelling. This patient education is important so they understand this swelling is normal.

CONCLUSIONS

The author has experience using the PREVENA™ Incision Management System in over 200 surgeries. His use has evolved from high-risk wounds to 'regular' risk elective surgeries. There are many reasons for this evolution. The author reports that, first, there is a reduction of surgical site infections as well as a reduction in incision closure time. The author also noticed that, over time, the author's patients reported a significant reduction in pain over what is normally expected. There was also a reduction in usage of pain medicine and requests for pain medicine refills. The author started to utilize the PREVENA™ Incision Management System on lower-risk incisions more commonly in order not only to reduce SSI's (surgical site infections) and closure time but as a potential approach to pain reduction. With the increased awareness surrounding opioid addiction, the author thinks the use of the PREVENA™ Incision Management System has the potential to play an important role in the improvement of public health and the reduction of opioid dependence as a byproduct of pain management.

While the basic biological pain response to incision healing and its release of local and systemic mediators cannot be stopped after an incision is made, there are factors that can be controlled in incision healing such as edema and bleeding. The use of the PREVENA™ Incision Management System in the author's clinical experience has shown to reduce post-operative swelling and thereby reduce post-operative pain.

Age	Sex	Procedure	Incision placement	VAS Day 1	VAS Day 3	VAS Day 7	Opioid meds days taken	Was surgery less painful than expected?	Was device burden-some?
56	F	Bunionectomy	Dorsal foot	1	1	0	0	Yes	No
43	F	Mass excision	Plantar heel	1	0	0	1	Yes	No
67	M	Ankle fusion	Lateral ankle	2	1	0	0	Yes	No
75	M	Medial column foot fusion	Medial foot	2	2	0	1	Yes	No
52	M	Ankle fusion	Lateral ankle	2	2	0	0	Yes	No
45	M	Bunionectomy	Dorsal foot	0	0	0	0	Yes	No
22	F	Bunionectomy	Dorsal foot	2	0	0	0	Yes	No
37	M	Ankle ligament repair	Lateral ankle	1	0	0	1	Yes	No
62	M	Exostecomy cuboid	Lateral foot	1	0	0	1	Yes	No
45	F	Post tib tendon repair	Medial foot	2	1	0	1	Yes	No
36	M	Achilles repair	Posterior ankle	2	1	0	1	Yes	No
58	F	Achilles repair	Posterior ankle	0	0	0	0	Yes	No
51	M	Ankle ligament repair	Lateral ankle	2	0	0	2	Yes	No
29	M	Fracture ankle	Lateral ankle	2	1	1	2	Yes	No
33	M	Fracture lisfranc	Medial foot	2	1	0	1	Yes	No
			AVG	1.46	0.66	0.06	0.73		

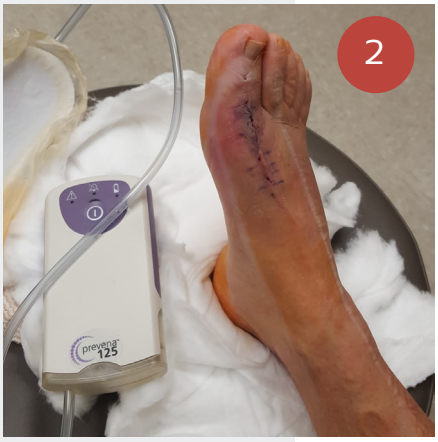
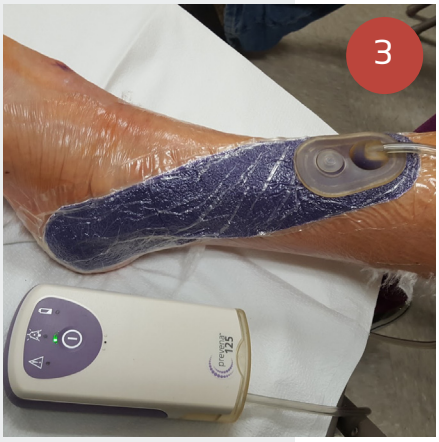


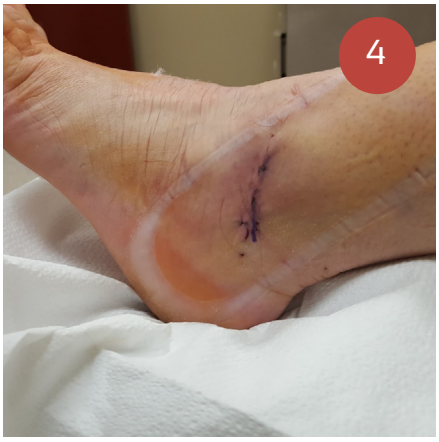
FIGURE 1: Immediate Post-operative PREVENA™ application Bunionectomy

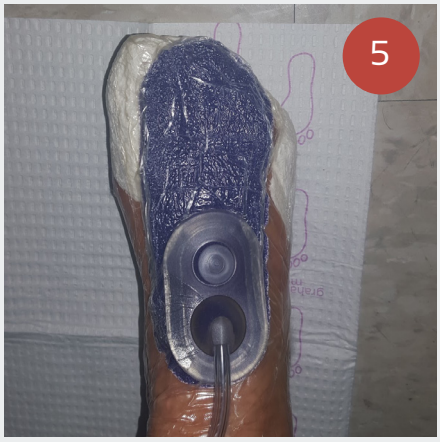
FIGURE 2: Seven days post-operative bunionectomy PREVENA™ removal

FIGURE 3: PREVENA™ application immediate post-operative lateral ankle stabilization

FIGURE 4: Seven days post-operative lateral ankle stabilization with PREVENA™ removal







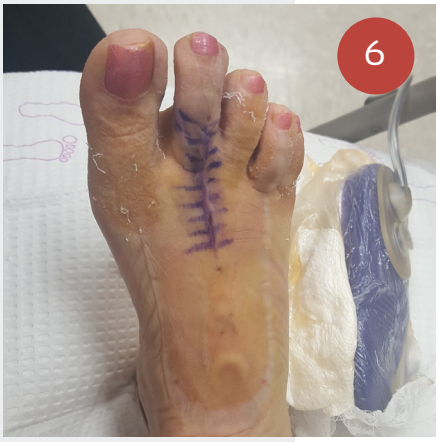
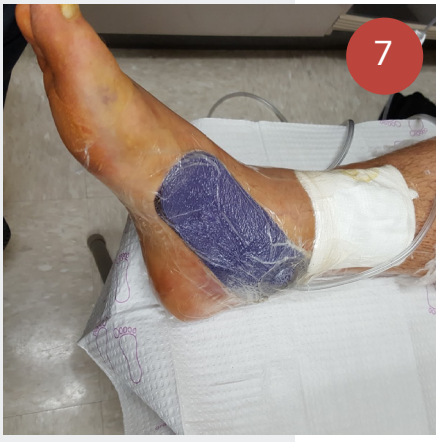


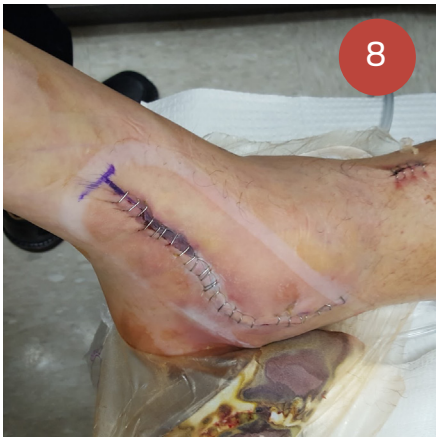
FIGURE 5: PREVENA™ application post-operative second MPJ resurfacing

FIGURE 6: Removal PREVENA™ 7 days Post-operative 2nd MPJ resurfacing

FIGURE 7: PREVENA™ application post-operative Midfoot reconstruction

FIGURE 8: Removal of PREVENA™ seven days post-operative midfoot reconstruction





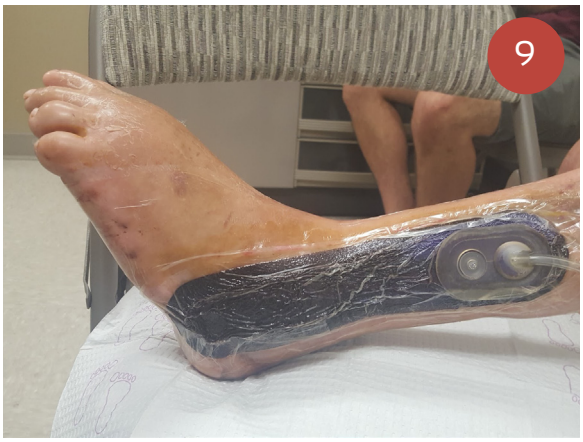


FIGURE 9: PREVENA™ application Immediate post-operative ankle fusion lateral extensile approach

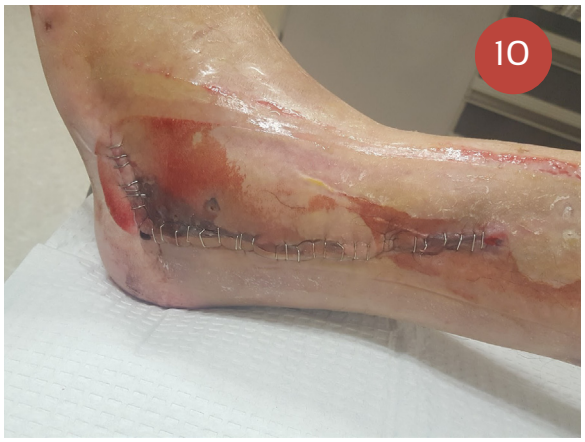


FIGURE 10: PREVENA™ removal seven days post-operative ankle fusion lateral extensile approach

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DR. PHILIP WROTSLAVSKY, MD

Dr. Philip Wrotslavsky is the Medical director of the Advanced Foot and Ankle Center of San Diego. He completed a limb lengthening fellowship at the International Center for Limb Lengthening in Baltimore MD. He his Board certified by the American College of Foot and Ankle Surgeons, His practice focuses on diabetic charcot foot and diabetic limb salvage. Dr. Wrotslavsky is a native of Brooklyn NY.

Use of Closed Incision Negative Pressure Therapy over Ischemic Mastectomy Skin Flap Incisions in Immediate Reconstruction

By: Allen Gabriel, MD, FACS

INTRODUCTION

Skin reducing mastectomies allow better shaping of the breast and long-term aesthetics, yet can result in complications post immediate breast reconstruction, particularly in obese (body mass index > 30kg/m2) patients and/or patients with large, pendulous breasts. The main limitations of the procedure are risks of seroma formation and ischemic necrosis of the thin flap, surgical site infection, and wound dehiscence. Positive clinical outcomes have been reported with use of closed incision negative pressure therapy (ciNPT; PREVENA™ Incision Management System) over various high-risk incision types, including arthroplasty, sternotomy, and cesarean.[1-5] ciNPT provides a closed system that helps hold incision edges together, removes infectious materials, and protects the incision from external contamination.[6] We have previously found that ciNPT is a viable option over incisions after immediate postmastectomy breast reconstruction.[7] Here, we describe our initial experience with the use of ciNPT in a mastectomy patient whose incision area was predetermined to be low in perfusion post immediate breast reconstruction.

CASE STUDY

Patient was a 65-year-old female with a body mass index of 28 kg/m2 (Figure 1A). She underwent a bilateral skin sparing mastectomy with immediate expander reconstruction and received an acellular dermal matrix, which was used to reinforce the weakened skin flaps. The patient did not receive chemotherapy or radiation. Following completion of the mastectomy flap, the port expander was placed and dye was injected into the breast followed by measurement of tissue perfusion using a near-infrared camera to visualize blood flow and tissue perfusion (Figure 1B). Incision areas of concern for low perfusion were marked, and ciNPT was applied over the marked incision area for 7 days at -125mmHg (Figure 1C). The incision remained closed on postoperative Day 7 (Figure 1D), and there were no incidences of ischemic flap necrosis during use of ciNPT or follow-up. Three months after mastectomy and immediate reconstruction, the expanders were replaced with implants. The patient remained healed with no complications at 4 months after second stage implant exchange (Figure 1E).

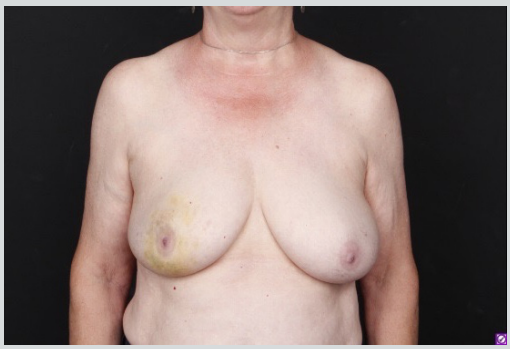

FIGURE 1A: Breasts prior to bilateral mastectomy with immediate prepectoral expander reconstruction

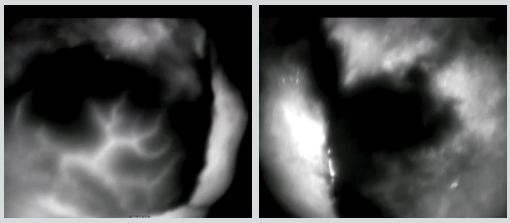

FIGURE 1B: Near-infrared camera images of right and left breasts showing level of perfusion throughout breasts before application of ciNPT

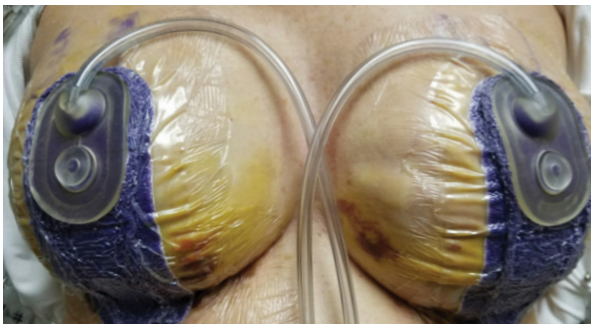

FIGURE 1C: ciNPT applied to vertical incision lines over areas of low perfusion post immediate reconstruction for 7 days

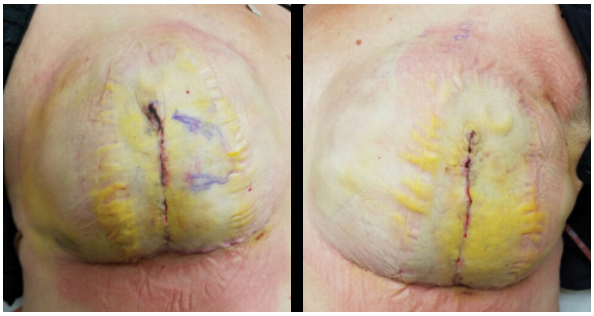

FIGURE 1D: Incisions on postoperative Day 7 following removal of ciNPT

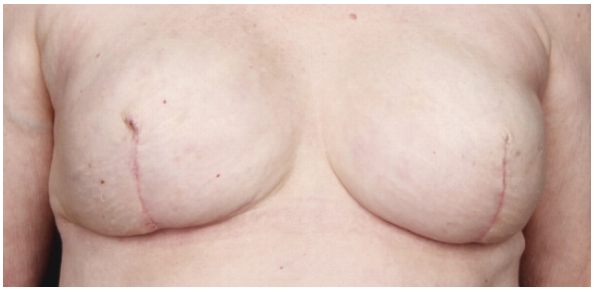

FIGURE 1E: Incisions 4 months after second stage implant exchange

CONCLUSIONS

Good aesthetic outcomes with no infection or implant loss were achieved in this patient with adjunctive use of ciNPT and well-planned operative procedures based on sound surgical principles. The thin flap incisions healed without complications over areas that were shown by near-infrared camera to have low perfusion immediately following breast reconstruction. In our experience, this technique allowed for optimal outcomes in a patient who previously may not have been considered for immediate prepectoral expander-implant breast reconstruction.

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ALLEN GABRIEL, MD

Dr. Allen Gabriel is a member of the American Society of Plastic Surgeons, and in 2001, Dr. Gabriel was chosen by the prestigious Loma Linda University to join the Integrated Plastic Surgery Residency Program. While at Loma Linda University, he volunteered on a medical mission to Ethiopia with Operation Good Samaritan. In addition, he served on several leadership committees and was the chief resident prior to completing his residency. In 2007, Dr. Gabriel was selected by world-renowned plastic surgeon Dr. G. Patrick Maxwell to enter a Breast and Aesthetic Surgery Fellowship in conjunction with Baptist Hospital in Nashville, Tennessee. Completion of this program provided him with advanced training in breast and aesthetic surgery.

Dr. Gabriel was one of the few medical students in the country to have received the prestigious Humanism in Medicine Award. This award lead to the creation of the University of Nevada's Humanism in Medicine Honor Society, of which Dr. Gabriel is still an active member. During medical school, he was involved with both clinical and basic science research, earning several research awards and publications prior to graduating. Dr. Gabriel is board certified in plastic surgery and has been invited to speak nationally and internationally on breast and aesthetic surgery.

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

Literature Synopsis of Redfern, Roberta E., et al. "Closed Incision Negative Pressure Therapy Effects on Postoperative Infection and Surgical Site Complication After Total Hip and Knee Arthroplasty." The Journal of Arthroplasty (2017).

ARTICLE SYNOPSIS

INTRODUCTION

Total knee and hip arthroplasty, already two of the most common orthopedic procedures, are becoming increasingly prevalent. Many people who undergo these operations have comorbid diseases that increase the risk of surgical wound complications, which sometimes require revision surgeries that pose risks to health and incur added costs.

Traditionally, complicated and non-healing wounds have been treated with negative pressure wound therapy (NPWT)[1,2] as a bridge between debridement and surgical closure. More recently, NPWT has also been used to manage closed wounds. In higher-risk patients (e.g., those with vascular surgeries or abdominal incisions), closed incision negative pressure therapy (ciNPT) may significantly reduce the burden of infection, postoperative hematoma, and seroma.[3-7] This study sought to determine whether ciNPT would reduce wound complications in a comprehensive cohort of patients undergoing hip and knee arthroplasty.

MATERIALS AND METHODS

This single-center, open-label, non-randomized study enrolled 193 patients undergoing elective hip or knee arthroplasty in 2013-14 and treated them with ciNPT using the PREVENA™ Incision Management System (ACELITY™, San Antonio, TX) for 6-8 days postoperatively. Patients with known or suspected contraindications to this therapy were excluded. The control group—a retrospective cohort of 400 patients who underwent hip/knee arthroplasty in 2011-12—followed a standard gauze dressing protocol.

With the exception of the dressing protocol, the control and treatment groups received the same care. All patients were treated within a single institution utilizing a uniform surgical

procedure, performed by a single surgeon. Wound closure and dressing was performed by the physician assistant and not the attending surgeon. Most knees were closed with staples, while hips were typically closed with sutures and glue. External pneumatic compression cuffs were used in all cases, and incision management systems were in place for an average of 7 days. All patients followed a deep venous thrombosis (DVT) prophylaxis protocol suited to their risk level.

Patient Demographics

Baseline data included BMI, comorbid conditions, and surgical site (Table 1). The ciNPT group had a significantly greater proportion of females (65.8%) than the control group (54%). The ciNPT group also had a higher incidence of heart disease, tobacco use, and history of cancer, while hypertension was more prevalent in the control group.

Data on tissue appearance, edema, drainage, tape trauma, and dressing reaction were collected 24 hours after surgery and at two postoperative follow-up assessments (at 1 and 6 weeks in the treatment group and at 2 and 6 weeks in the control group). The use of postoperative anticoagulants was similar in both groups.

Statistical Analysis

The size of the cohort enabled the study to achieve 80% power with 0.05 significance level. SAS version 9.2 was used for statistical analysis. Post-hoc logistical regression was used to determine the effect of various patient characteristics on outcome measures.

Characteristic	ciNPT group (n=196)	Control group (n=400)
Male	67 (34.2%)	184 (46.0%)
Female	129 (65.8%)	216 (54.0%)
Age (mean & range)	66.9 (42 – 88)	66.8 (22 – 91)
BMI (mean & range)	30.5 (15.5 – 44.3)	30.9 (16.8 – 44.6)
Hip arthroplasty	123 (62.8%)	236 (59%)
Knee arthroplasty	73 (37.2%)	164 (41%)
Diabetes	28 (14.29%)	48 (12%)
Hypertension	91 (46.43%)	237 (59.25%)
History of cancer/tumor	12 (6.12%)	6 (1.5%)
Inflammatory arthritis	10 (5.1%)	32 (8%)
MI/Heart disease	17 (8.67)	13 (3.25%)
Tobacco use	66 (33.67%)	73 (18.25%)

TABLE 1. Patient characteristics

RESULTS

The results of 196 incisions in 192 patients treated with ciNPT and of 400 control-group cases are reported here. The first follow-up assessment found no significant differences in skin color, swelling, drainage, infection, dehiscence, or seroma between the two study arms, although the incidence of ecchymosis was higher in the ciNPT group. At the second follow-up visit, none of these parameters (including ecchymosis) differed between the 2 groups.

Twenty-seven patients (13.7%) in the ciNPT group experienced blisters or reaction to the foam dressing, compared to 9 cases of tape trauma in the control group. Blister reactions were treated with topical antibiotics and resolved without further attention.

Table 2 lists the rates of clinically significant surgical site complications, defined as complications requiring surgical intervention or further physician visits. Relative to the control group, the treatment group had several favorable outcomes:

- A significantly lower rate of surgical site reaction (1.0% v 3.5%, p = 0.04)
- No hematomas requiring attention (vs. 9 in the control group)
- No seromas requiring attention (vs 2 seromas in the control group)
- Numerically lower rate of dehiscence with wound drainage (1.5% vs. 3.25%)
- Only 3 patients requiring reoperation, vs. 15 in the control group (1.5% vs. 3.75%, p = 0.14)
- In all, 3 patients with 5 complications requiring treatment (vs. 22 patients with 38 significant complications in the control group).

Complication rates were also evaluated based on surgical site of hip vs knee (p= 0.3625, OR=1.513, CI 0.620, 3.690). While infections (almost exclusively in the control group) occurred more frequently in the hip cohort, the surgical site did not affect the rates of hematoma, seroma, or dehiscence.

Complication Diagnosis/Symptoms	ciNPT (n, %)	Control (n, %)	p-value
Dehiscence	3 (1.5)	13 (3.25)	0.2
Hematoma	0 (0)	9 (2.25)	0.02
Seroma	0 (0)	2 (0.5)	0.16
Surgical site infection (all)	2 (1.0)	14 (3.5)	0.04
Deep	2 (1.0)	5 (1.25)	0.81
Superficial	0 (0.0)	9 (2.25)	0.03
Surrounding tissue appearance*	0 (0)	15 (3.25)	0.003
Edema/swelling	1(0.5)	13 (3.25)	0.02
Drainage*	2 (1.0)	12 (3.25)	0.07
Total patients with complication	3 (1.5)	22 (5.5)	0.02

TABLE 2. Clinically significant surgical site complications

The post hoc logistic regression analysis did not find age, BMI, surgical site, or relevant comorbidities to impact the rate of postoperative complications. The treatment group was the only significant variable: the rate of postoperative complications was apprixmately 4 times higher in the control group than in the treatment group (OR 4.251, p = 0.0277).

DISCUSSION

These results suggest that use of ciNPT may reduce the rate of clinically significant wound complications after total hip or knee arthroplasty by more than four-fold.

Previous case series have found ciNPT to have a significant benefit in patient populations and incision types at greatest risk of skin breakdown and dehiscence. A larger study of post-sternotomy wound infections in a comprehensive patient population found that ciNPT reduced infection rates from 3.4% to 1.3%, suggesting a broader role for the technique.[5] The current report lends further support to this view, with the caveat that ciNPT did not significantly reduce deep surgical site reactions and may thus be unwarranted for universal use.

While more prevalent in the treatment group, dressing reactions occurred at a lower rate than reported in previous studies of total knee replacement, possibly due to the unique knit polyester covering on the PREVENA™ Incision Dressing.[8-10] Of note, one report suggests that application technique (i.e., avoidance of stretching, application to a flexed knee) may also reduce blister formation.[11]

Proposed mechanistic explanations for the benefits of NPWT include reduction of edema, stimulation of perfusion, protection from external sources of infection, stimulation of granulation tissue, and reduction of lateral tension on surgical edges.34

As one of the largest observations of NPWT in clean closed surgical incisions, this study counts sample size as a major strength. Study limitations include the use of a historical control group, dissimilarity between the two groups upon study entry, lack of blinding, differences in time to first follow-up assessment, and possible underpowering to detect differences in infection rates.

Further studies to determine whether ciNPT has more pronounced benefits in high-risk patients, as well as a health-economic analysis of routine use in hip/knee arthroscopy patients, are advised.

IMPORTANT DISCLAIMER:

Although the authors reported use of ciNPT for 6-8 days post-operatively, this time of application is outside the recommendations for Optimum Use as stated in the PREVENA™ Incision Management System Clinician Guide Instructions for Use: "*The PREVENA™ Incision Management System is to be continuously applied for a minimum of two days up to a maximum of seven days.*" Use for greater than 7 days is not recommended or promoted by KCI.

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CASE REPORT

V.A.C.® Therapy Assists In Closure Of Complex Sternal Wound After Failure Of Initial Management

By: Anthony N. Dardano, DO FACS, Sana Quiresi, MD, Andrew Klapper, MD
Boca Raton Regional Hospital, Florida Atlantic University, Schmidt College Of Medicine

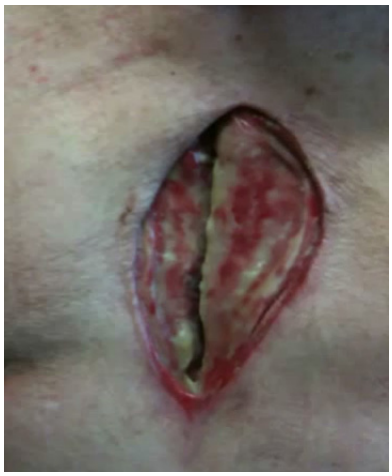

FIGURE 1. Wound at presentation

We present the case of a 72-year-old male with atrial fibrillation, prior tobacco use, coronary artery bypass graft (CABG), and an aortic valve repair at another hospital. He underwent several attempts at surgical debridement and pectoralis muscle flap closure of dehisced sternal wound by a cardiothoracic surgeon (see Figure 1).

His cultures remained positive for MRSA (methicillin resistant staph aureus) following the repair, and his wound dehisced again. He was discharged to a cardiac rehabilitation facility and nursing home with an open sternal wound.

His wound care consisted of wet-to-dry normal saline dressings. He was referred to the plastic surgery service for evaluation at which point the patient was admitted to the hospital and started on empiric IV vancomycin and cefepime. His cultures on admission were positive for MRSA and vancomycin-resistant enterococcus (VRE). He was taken to the operating room for surgical debridement of the sternum with washout of the wound and placement of V.A.C. ULTA™ Therapy System to be certain that the mediastinum and chest cavity was sealed.

He was taken back to the operating room on post-operative day 4 for placement of V.A.C. VERAFLO™ Dressing. It was safe to place the V.A.C. VERAFLO™ Dressing on the mediastinum since the mediastinum had developed a base of granulation with no communication with the pleural cavity. V.A.C. VERAFLO™ Therapy was initiated with normal saline with a soak time of 1 min and 1 hour of negative pressure wound therapy (NPWT 125 mmHg).

This was continued for 8 days until the wound cultures became negative. The patient was taken back to the OR for sternal reconstruction to stabilize the remaining bony sternum and ribs utilizing sternal reconstruction plates (DePuy Synthes). A rectus abdominis muscle flap was used to cover the plates and provide vascular coverage to the repair. The patient completed his course of antibiotics and his wound had completely healed. He was discharged home on clindamycin daily for life as prophylaxis.

NOTE: Specific indications, contraindications, warnings, precautions and safety information exist for KCI products and therapies. Please consult a clinician and product instructions for use prior to application. Rx only.

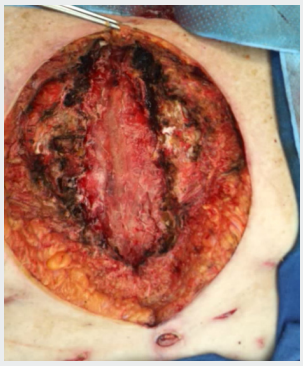

FIGURE 2. Status post-debridement

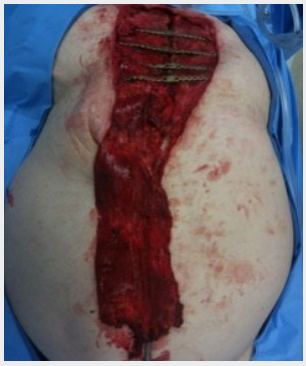

FIGURE 3. Status post-sternal plate reconstruction

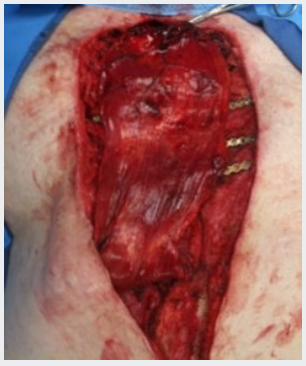

FIGURE 4. Rectus muscle flap

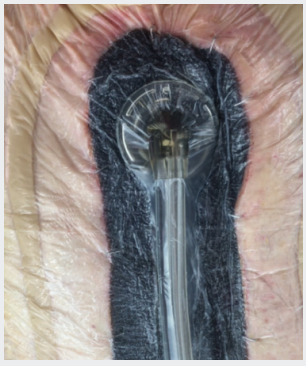

FIGURE 5. V.A.C. VERAFLO™ Therapy

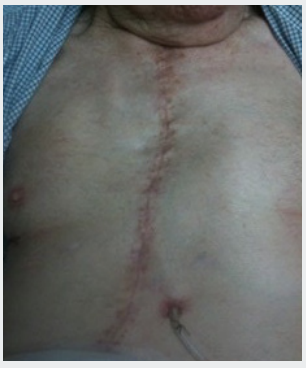

FIGURE 6. POD 14

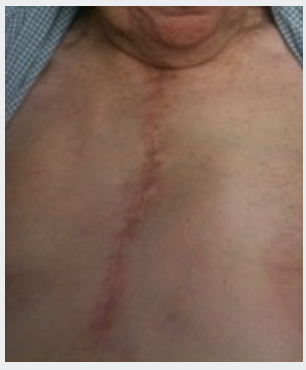

FIGURE 7. POD 42

DR. ANTHONY N. DARDANO, MD

Dr. Dardano's career began in Utica, New York. He completed his undergraduate studies in Syracuse, New York, and traveled to South Florida to attend medical school. Dr. Dardano studied general surgery at Sinai Hospital of Wayne State University in Detroit and completed five years of training which resulted in his board certification by the American Board of Surgery. He has been active both clinically and academically and has performed over 1,300 plastic surgery procedures during his training, and is the author and co-author of several papers and textbook chapters. He has presented his work at the prestigious Plastic Surgery Research Council, as well as the American College of Surgeons, and the American Society of Aesthetic Plastic Surgeons. He has also lectured internationally.

Closed Incision Negative Pressure Therapy in Obese Patients Undergoing Caesarean Delivery: A Randomized Controlled Trial

Literature Synopsis of Gunatilake, Ravindu P., et al. "Closed-incision negative-pressure therapy in obese patients undergoing cesarean delivery: a randomized controlled trial." American Journal of Perinatology Reports 7.03 (2017): e151-e157.

ARTICLE SYNOPSIS

INTRODUCTION

In the U.S., close to a third of all babies are born via Caesarean delivery,[1] making this procedure the most common surgery in the country. About 2-7% of such deliveries result in surgical site occurrences (SSOs) that raise the risk of infection, complicate recovery, and incur extra costs.[2,3] Maternal obesity (BMI > 30) is a key risk factor for post-Caesarean wound morbidity.[4,5]

Evidence from previous studies suggests that closed incision negative pressure therapy (ciNPT) may decrease the rate of postoperative infection and wound dehiscence.[6] This study sought to compare clinical outcomes in obese women who received ciNPT or standard-of-care (SOC) dressings following Caesarean delivery.

METHODS

Study design

This single-center post-marketing RCT enrolled 92 patients from Duke University Medical Center between 2012 and 2014. Subjects were ≥ 18 years old and had a BMI of ≥ 35 at the time of delivery. Women with skin, systemic, or chorioamniotic infections and those at high risk for anesthesia were excluded from participation.

Protocol

Participating clinicians used standard techniques to prepare subjects for the operation, perform it, and close the wounds. All women received preoperative antibiotics and post-operative pain medications as required (not standardized in the protocol). The peritoneum was left open and the adipose tissue was sutured if thicker than 2 cm. Once the closed wounds passed inspection, patients were randomized 1:1 to ciNPT and SOC groups.

Women in the ciNPT group received a sterile "peel-and-place" multilayer dressing over the closed incision. The dressing's tubing was then connected to a negative pressure unit that delivered -125 mmHg of continuous pressure to the dressing for 5 to 7 days and removed exudates. Women in the SOC group had their wounds dressed with Steri-Strips (Trademark of 3M Health Care, St. Paul, MN) sterile gauze, and Tegaderm (Trademark of 3M Health Care, St. Paul, MN) for 1-2 days. Subjects without complications were discharged from hospital 3-4 days postoperatively.

Endpoints

The primary endpoint was the presence of one or more postoperative SSOs (counted as one event per affected patient, regardless of the number of SSOs in that patient). These SSOs included inflammatory responses, prolonged drainage, fluid collection, dehiscence, and surgical site infections. A standardized wound-scoring system minimized bias. The secondary endpoint was the use of surgical interventions such as antimicrobials, surgical drainage, incision packing, adjunctive negative pressure therapy, debridement, and reoperation. Supplementary endpoints included postoperative pain scores ≥ 2 (Baker Faces Scale) at rest and with pressure. Medication use was also recorded.

Patient characteristics

Collected data included age, BMI, gestational age at delivery, and first vs repeat Caesarean section

CHARACTERISTIC	ciNPT (N = 46)	SOC (N = 46)	OVERALL
Mean age	30.4	29.7	30.0
Mean BMI	46.3	46.8	46.5
African American	29 (63%)	35 (76.1%)	64 (69.6%)
Caucasian	17 (37.0%)	10 (21.7%)	29.3%
Other (American Indian or Hispanic/Latino)	3 (6.5%)	3 (6.5%)	6 (6.5%)
First Caesarean	11 (23.9%)	15 (32.6%)	26 (28.3%)
Mean gestational age at delivery	38.1	37.9	38.0
Diabetes	8 (17.4%)	8 (17.4%)	16 (17.4%)
Mean incision length (cm)	16.3	16.3	16.3

TABLE 1. Patient characteristics in the intention-to-treat (ITT) population*

**Abbreviated version of the table in the original journal article*

(Table 1). The study population included ethnic groups described as African American, Caucasian, American Indian and Hispanic/Latino. Other than the higher proportion of African American subjects in the SOC group than the ciNPT group, patient characteristics were similar in the two groups.

RESULTS

Pain results are reported for the intention-to-treat (ITT) population (n = 96); all other results pertain to the per-protocol population (n = 92). Per-protocol results were analyzed using SAS version 9.2.

As detailed in Table 2, the ciNPT group had a 63% relative reduction in patients with SSOs compared to the SOC group, though the difference did not reach statistical significance. In terms of specific SSOs, the ciNPT group had:

- Fewer cases of fluid collection (1 vs 4, p = 0.36)
- Fewer cases of dehiscence (1 vs 5, p = 0.20)
- Fewer cases of surgical incision intervention (1 vs 6, p = 0.11)

CHARACTERISTIC (PER-PROTOCOL GROUP)	ciNPT (N = 39)	SOC (N = 43)	P VALUE
SSO (any)	2 (5.1%)	7 (16.3%)	0.16
Unanticipated local inflammatory response	0 (0%)	0 (0%)	n/a
Prolonged drainage	0 (0%)	0 (0%)	n/a
Fluid collection (seroma, hematoma, abscess)	1 (2.6%)	4 (9.3%)	0.36
Dehiscence	1 (2.6%)	5 (11.6%)	0.20
Surgical incision intervention (any)	1 (2.6%)	6 (14.0%)	0.11
Surgical site infection	1 (2.6%)	4 (9.3%)	0.36
Characteristic (ITT group)	ciNPT (n = 46)	SOC (n = 46)	P value
Postoperative pain at rest (any level of pain)	20 (43.5%)	39 (84.8%)	< 0.001
Postoperative pain with pressure applied	25 (54.3%)	42 (91.3%)	< 0.001

TABLE 2. Surgical site occurrences (SSOs) and complications

The ciNPT group had a significantly lower rate of postoperative pain at rest (43.5 vs. 84.8%, $p < 0.001$) and with pressure (54.3 vs 91.3%, $p < 0.001$). Total narcotic use was 30% lower in the ciNPT group than the SOC group ($p = 0.036$), while acetaminophen and NSAID use did not differ significantly between the groups.

DISCUSSION

This study demonstrated that, compared to the standard of care for women undergoing Caesarean deliveries, ciNPT is associated with a significant reduction in postoperative pain and with a trend toward reduced wound complications.

The reduction in incisional pain in the ciNPT group, corroborated by a lower use of narcotic medications, has significant implications, given that ineffective pain relief may affect breastfeeding and bonding as well as increasing the risk of thromboembolism.[7,8] While not statistically significant, the reduction in SSOs with ciNPT is also clinically relevant due to the substantial morbidity and costs of surgical site infections (a component of the primary outcome).

Previous investigations of post-Caesarean ciNPT have yielded mixed results. One case-control study found no reduction in surgical site infections with ciNPT compared to historical controls.[9] In contrast, a prospective case-control study found a significant 70% reduction in wound complications with ciNPT versus historical controls,[10] and a study of obese women yielded no postoperative complications in the ci-NPT-treated group (vs 10% in the control group).[11]

This study adds to the body of evidence regarding ciNPT following Caesarean delivery. There is a need for further, more strongly powered studies to examine the impact of ciNPT in risk-diverse obstetric populations.

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