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Pain Reduction with Negative Pressure on Surgical Site Incisions

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ABSTRACT

Postoperative pain management for surgery in the lower extremities has historically been managed mechanically through the use of elevation, ice, compression and drains. Pharmacological management includes the use of nerve blocks and analgesics. Due to the current opioid crisis, new methods are being sought to reduce post-operative pain so that patients are at lower risk for opioid addiction. Postoperative 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 contribute to edema reduction, and thereby reduce pain and incisional tension. This report introduces a new method for post-operative pain control in lower-extremity surgery. In the author's present clinical experience with 15 patients, the application of negative pressure at the incision site using the PREVENA™ Incision Management System (KCI USA, Inc., San Antonio, TX) was associated with a decrease in post-operative pain as well as a decrease in the use of narcotics for post-operative pain management.

BACKGROUND

Increased edema in the lower extremities associated with foot and ankle surgery leads to increased pain.[1] Thus, post-operative edema control is vital to reduce tension on the incision, and thereby attenuate pain at the surgical site. Microcirculation in the lower extremities has been reported to take over 72 hours to return to normal after foot and ankle surgery.[1] Therefore, patients have been recommended to elevate the extremity for up to 5 days post-operatively, to reduce swelling. Hematomas and seromas also play a major role at incision sites, since they may have a balloon effect. For example, just as too much air in a balloon will cause stretching of the balloon wall, hematomas and seromas at surgical incisions cause stretching of the entire area, which may result in edema and increased tension at the incision site. This ultimately can lead to increased pain. This can also lead to increased tension at the incision edges, thereby increasing the risk for surgical incision dehiscence.

The PREVENA™ Incision Management System (KCI USA, Inc., San Antonio, TX) 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] Wilkes et al.[3] used a finite element analysis to assess how PREVENA™ Therapy affects the various directions and magnitudes of tension

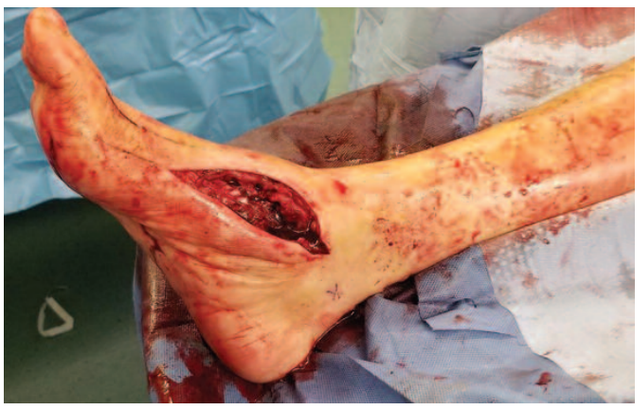

Figure 1a. Intraoperative photograph in a patient undergoing medial column fusion for Charcot reconstruction (Patient 4).

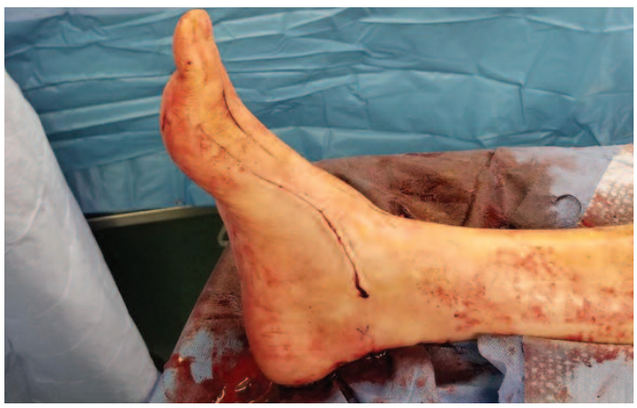

Figure 1b. The incision has been closed.

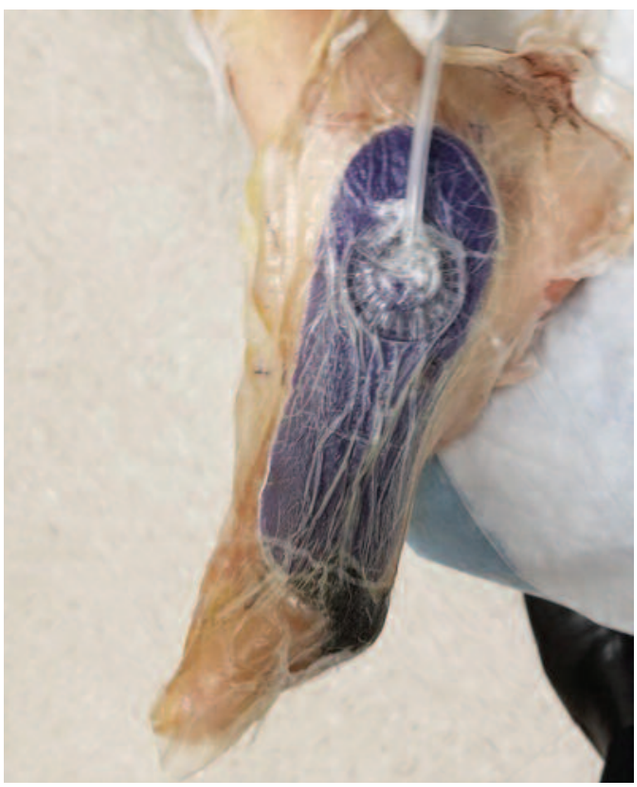

Figure 1c. PREVENA™ device in place immediately following surgery.

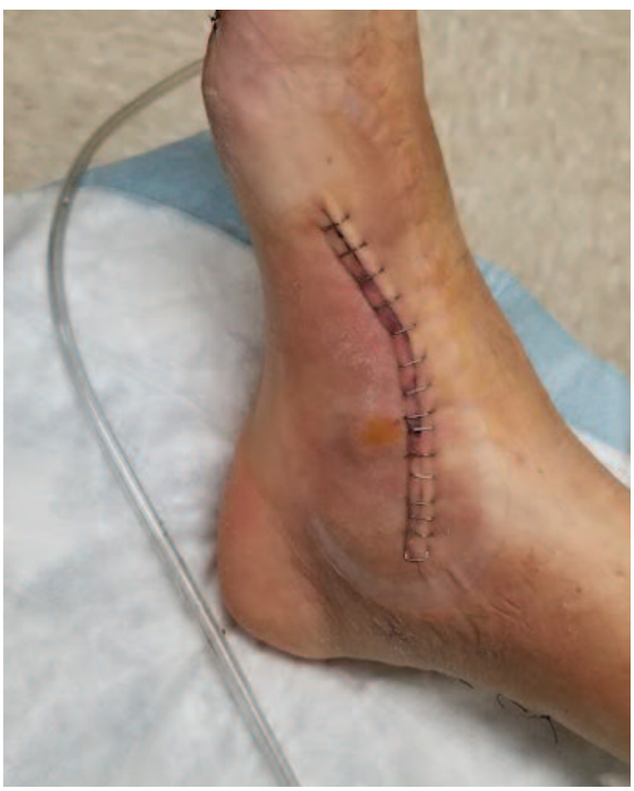

Figure 1d. PREVENA™ device removed on post-operative day 7. Minimal edema was observed.

Table I
Characteristics of the PREVENA™-treated group

Patient	Age (y)	Sex	Procedure	Incision location	NRS Day 1	NRS Day 3	NRS Day 7	Opioid meds - days taken (as of POD 14)	Was surgery less painful than expected? (as of POD 14)	Did device affect ADLs? (as of POD 14)
1	56	F	Bunionectomy	dorsal foot	1	1	0	0	Yes	No
2	43	F	Mass excision	plantar heel	1	0	0	1	Yes	No
3	67	M	Ankle fusion	lateral ankle	2	1	0	0	Yes	No
4	75	M	Medial column foot fusion	medial foot	2	2	0	1	Yes	No
5	52	M	Ankle Fusion	lateral ankle	2	2	0	0	Yes	No
6	45	M	Bunionectomy	dorsal foot	0	0	0	0	Yes	No
7	22	F	Bunionectomy	dorsal foot	2	0	0	0	Yes	No
8	37	M	Ankle ligament repair	lateral ankle	1	0	0	1	Yes	No
9	62	M	Exostectomy cuboid	lateral foot	1	0	0	1	Yes	No
10	45	F	Post tib tendon repair	medial foot	2	1	0	1	Yes	No
11	36	M	Achilles repair	posterior ankle	2	1	0	1	Yes	No
12	58	F	Achilles repair	posterior ankle	0	0	0	0	Yes	No
13	51	M	Ankle ligament repair	lateral ankle	2	0	0	2	Yes	No
14	29	M	Fracture ankle	lateral ankle	2	1	1	2	Yes	No
15	33	M	Fracture lis-franc	medial foot	2	1	0	1	Yes	No
				AVG	1.47	0.7	0.07	0.7		

ADLs, activities of daily living; POD, post-operative day; NRS, Numerical Rating Scale: patients rated their pain from 1 to 10.

around the incision line. The computer model they developed predicted that lateral tension around the incision would be decreased by 50% with PREVENA™ Therapy, which is important because the literature suggests that excessive tension at the wound site can lead to wound failure.[4-7] Their model predicted that, before PREVENA™ Therapy is applied, there are high levels of tension, especially in the epidermis. The model also predicted that there are void spaces between the different levels of sutures. Finally, there is misalignment of the forces around the incision. Following the application of PREVENA™ Therapy, the lines of tension around the incision become realigned parallel to the skin surface, the void space between the sutures decreases greatly and the magnitude of tension in the upper levels of the skin is significantly decreased.[3]

Kilpadi and Cunningham showed that the mean difference between nanospheres originating from PREVENA™ Therapy Incision Dressing-treated sites (as a measure of lymph clearance) and contralateral standard-of-care-treated sites was 60 ± 27 µg;[8] there were 54% more nanospheres in the lymph

Table II
Characteristics of the non-PREVENA™-treated group

Patient	Age (y)	Sex	Procedure	Incision location	NRS POD 1	NRS POD 2	NRS POD 14	Opioid meds - days taken (as of POD 14)
1	50	M	Bunionectomy	dorsal foot	7	4	2	7
2	45	F	Mass excision	plantar heel	8	6	3	6
3	60	M	Ankle fusion	lateral ankle	7	5	3	14
4	65	F	Medial column foot fusion	medial foot	9	5	3	10
5	50	M	Ankle Fusion	lateral ankle	8	6	3	14
6	50	F	Bunionectomy	dorsal foot	6	4	2	7
7	29	F	Bunionectomy	dorsal foot	7	4	2	9
8	40	M	Ankle ligament repair	lateral ankle	9	6	3	9
9	57	F	Exostectomy cuboid	lateral foot	6	5	2	6
10	48	F	Posterior tibial tendon repair	medial foot	9	5	3	11
11	39	M	Achilles repair	posterior ankle	7	6	3	12
12	50	M	Achilles repair	posterior ankle	8	4	2	11
13	52	M	Ankle ligament repair	lateral ankle	7	5	3	10
14	22	M	Fractured ankle	lateral ankle	9	4	1	13
15	43	F	Lisfranc fracture	medial foot	9	5	0	14
				AVG	7.73	4.93	2.33	10.2

POD, post-operative day; NRS, Numerical Rating Scale: patients rated their pain from 1 to 10.

nodes under PREVENA™ Therapy than under standard-of-care treatment (170 ± 37 µg vs. 111 ± 36 µg). This increased lymph clearance may explain, in part, the 63% decrease in hematoma/seroma with PREVENA™ Therapy compared to standard-of-care, even when fluid was not removed from the subcutaneous void into a negative-pressure canister.[8]

To date, no data have been collected regarding other potential benefits of the PREVENA™ system for incisions. One of these potential benefits is post-operative pain reduction. Use of the PREVENA™ Incision Management System may reduce post-operative pain through several mechanisms. First, the reduction of lateral tension on the incision edges with increased appositional strength and a normalized stress distribution for incisions could reduce inflammation, and thus reduce pain. Second, the decrease in the subcutaneous formation of hematoma and seroma could cause less tension, and thus less pain. Last, the increased lymph node clearance with the PREVENA™ Incision Management System could lead to decreased swelling, which would also reduce pain.

This report describes the author's experience with the PREVENA™ Incision Management System in 15 patients who underwent various foot surgeries, particularly with regard to the patients' post-operative pain.

METHODS

This study was a retrospective chart review that compared patients in whom PREVENA™ was used in surgery to patients in whom PREVENA™ was not used (control), i.e., before the author began using the device. The surgeries that included the PREVENA™ system were performed between January 2017 and December 2017 at the author's private office. Fifteen consecutive sensate and opioid-naive patients (10 males, 5 females; age 22-75 y) underwent various foot surgeries (Table I). Diabetics were not included due to the prevalence of neuropathy. For the post-operative

dressing, a PREVENA™ PEEL & PLACE™ Incision Management System (13 cm or 20 cm) was placed on the incision. No surgical drains were necessary. All of the PREVENA™ Systems were removed on day 7 (Fig. 1).

The non-PREVENA™ group consisted of 15 patients who were selected so that the procedures in the two groups were similar (Table II).

All of the patients in both groups were interviewed on post-operative days 1, 3 and 14 to determine their pain level (Numerical Rating Scale score (NRS)). At 1 week and 2 weeks post-op, the patients were asked whether they were still taking their pain medications and, in the PREVENA™ group, whether the surgery was more or less painful than expected.

RESULTS AND DISCUSSION

At each of the time points examined after surgery, PREVENA™-treated patients reported less average pain than the non-PREVENA™ controls. In addition, opioid use in the PREVENA™ group was much less than that in the non-PREVENA™ group (0.7 days vs. 10.2 days, respectively.)

Overall, the PREVENA™ patients reported dramatically less pain associated with the surgical procedures compared to what they had expected. In addition, the PREVENA™ Incision Management System did not interfere with their usual activities of daily living. Anecdotal feedback from patients who had experienced previous surgeries (including foot surgeries) was that the post-operative experience with the PREVENA™ Incision Management System was less painful than their previous surgery. Two patients who needed elective surgery on their contralateral foot demanded use of the PREVENA™ Incision Management System following the second surgery.

All patients reported an increase in swelling and pain the first three days after removal of the PREVENA™ Incision Management System unit on post-operative day 7. However, none needed to take opioids for the pain. This swelling was expected as a rebound effect that should be accompanied by a slight increase in pain. In fact, all of the patients reported this increased pain at post-op day 14 (one week after removal of the PREVENA™ Therapy Unit). The patients were carefully educated regarding device removal and the potential for an increase in swelling. It is important for patients to understand that this swelling is normal.

The author has used the PREVENA™ Incision Management System in over 200 surgeries; initially in high-risk wounds and now also in "regular"-risk elective surgeries. There are many reasons for this evolution. First, there is a reduction of surgical site infections (SSIs), as well as a reduction in incision closure time.[9,10] In addition, as suggested in this study, patients report less pain than what they expected. There is also a reduction in the use of pain medications and requests for refills. With the increased awareness surrounding opioid addiction, use of the PREVENA™ Incision Management System may play an important role in improving public health and reducing 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, some factors in incision healing can be controlled, such as edema and bleeding. The author's clinical experience with use of the PREVENA™ Incision Management System has shown that it reduces post-operative swelling and thereby reduces post-operative pain.

CONCLUSION

In this group of patients, use of the PREVENA™ Incision Management System was associated with a decrease in post-operative pain as well as a decrease in the use of narcotics for post-operative pain management. STI

AUTHOR'S DISCLOSURES

The author is a consultant for KCI USA, Inc.

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