A Prospective Study of a Single Use Negative Pressure Wound Therapy System in a High-risk Revision Total Hip or Knee Arthroplasty Cohort

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BACKGROUND

- Total hip arthroplasty (THA) and total knee arthroplasty (TKA) are two of the most common surgical procedures performed in the US every year. One in 20 TKAs will require revision within 10 years.[1]
- Rates of complication are low in primary procedures (<3%) but occur in as many as 37.2% of revisions.[2]
- Closed incisional negative pressure therapy (ciNPT) has been shown to reduce length of hospital stay and lower re-operation rates following THA or TKA,[3] and decrease the frequency of post-operative dressing changes.[4]
- Despite these advantages, application of ciNPT may be associated with the development of skin blisters around the incision,[3] which can delay healing progress and cause pain.

STUDY AIM

To assess post-operative outcomes in patients who had a canister-based, single-use, NPWT system* applied following revision THA or TKA at orthopedic surgery centers in the US.

STUDY DESIGN

- Prospective, non-comparative design (full details at clinicaltrials.gov NCT06661473).
- 7 centers in the US (Oct/2024 to Oct/2025).
- NPWT system* applied in the operating room (OR) for a maximum of 14 days post-surgically.

Inclusion/Exclusion

Inclusion: Adults ≥18 years of age; elective unilateral revision THA or TKA.

Exclusion: Emergency surgery; a multiple incision approach; bilateral revision TKA or THA surgery; active prosthetic joint infection; active skin or systemic infection; history of infections in the target joint; use of surgical glue as part of the incisional closure method.

Outcome measures

Primary endpoint:
Proportion of patients with at least one of the following:
- Surgical site infection (SSI)
- Wound dehiscence
- Persistent drainage
- Hematoma
- Seroma

Secondary endpoint:
incidence of each of the above at 30 and 90 days, and drainage within 14 days.

*Avance® Solo, Mölnlycke Health Care #Safetac® technology

The Avance Solo NPWT System has been cleared by FDA under K203369, and is indicated for patients who would benefit from wound management via the application of negative pressure wound therapy, particularly as the device may promote wound healing through the removal of exudate, infectious material. The Avance Solo NPWT System is not cleared by FDA to reduce wound complications. The safety and effectiveness of using the Avance Solo NPWT System for reducing wound complications has not been established.

PATIENT POPULATION

→ 101 participants were recruited at 7 high volume orthopedic surgical centers (Figure 1). Characteristics of the study cohort are presented in Table 1.

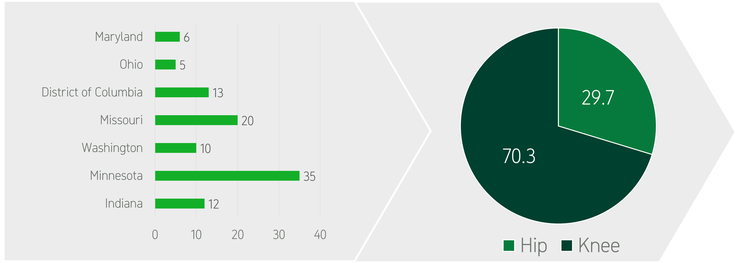

Figure 1: Enrollment at seven study sites was distributed across a broad geography in the US. More participants underwent rTKA (71/101, 70.3%) than rTHA (30/101, 29.7%). Participant retention was high (98.0%, 99/101) at 30 days, and protocol adherence was strong.

Table 1: Patient characteristics (n=101)

Age (years; mean ± SD and median [range])	66.6 ± 8.19 68.0 [41- 84]
BMI (kg/m^2; mean ± SD and median [range])	30.4 ± 5.79 29.5 [19- 47]
Sex	
Female	61.4% (62/101)
Male	38.6% (39/101)
Comorbidities	
Diabetes mellitus	12.9% (13/101)
Prior infection in the target joint	15.8% (16/101)
Inflammatory arthritis	7.9% (8/101)
Renal disease or dialysis	5.9% (6/101)
Chronic obstructive pulmonary disease	5.9% (6/101)
Congestive heart failure	2.0% (2/101)
Peripheral arterial disease	1.0% (1/101)
Other relevant past/current medical conditions	94.1% (95/101)

STUDY OUTCOMES

Skin health

- No persistent drainage or maceration was observed in any subject, at any visit.
- Blistering was observed in 5 participants but was rated as 'mild' in all instances.
- None of the blisters were deroofed. In 2/5 cases, blistering was so mild that the peri-wound skin was still rated as 'healthy' by investigators at that visit

Peri-wound skin was rated as healthy at 99.0% [97.1%-99.8%] (300/303) of assessments (Figure 2).

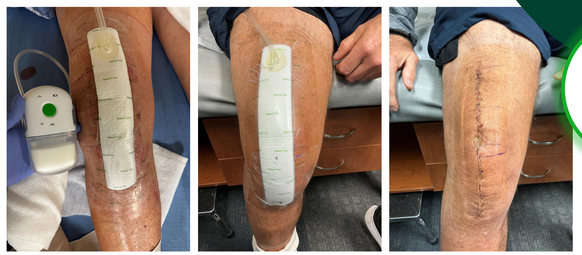

Figure 2: The ciNPT system was applied under sterile conditions in the OR (left panel), and removed at 14 days post-operatively (middle and right panels). Wound healing outcomes are presented in Table 2.

Dressing and device performance

- There were no reports of trauma to the wound site upon dressing removal for any patient, at any study follow-up visit.
- Pain at dressing change was low (Figure 3).
- Average pump use duration: 7.4 ± 3.67 days (aligns with typical postoperative recovery timelines).
- Mean dressing duration was 5.8 ± 1.74 days, with a median dressings use duration of 6.0 [0 -15] days.

Wound healing outcomes

- None of the reported SSIs were device related. A single incidence of dehiscence was related to one of the SSIs (Table 2).

Table 2: Primary study outcomes at 30 and 90 days

	30 DAY	90 DAY
SSI	3.0% (3/101) [95% CI 0.6-8.4%]	4.0% (4/101) [95% CI 1.1-9.8%]
Dehiscence	1/101	1/101
Hematoma	0	0
Seroma	0	0
Persistent drainage	0	0

DISCUSSION

- ciNPT has been adopted widely in orthopedic surgery due to well documented associations with improved post-operative outcomes.[3]
- Higher-pressure ciNPT systems (-125mmHg) generally outperform conventional dressings and lower-pressure ciNPT (-80mmHg) systems with respect to wound drainage following arthroplasty, and overall rates of complications.[5]
- Although the benefits of ciNPT post-operatively are well known, skin health-related complications can be high. Blistering rates in particular are marked.[3,6]
- Hip and knee arthroplasty patients have been reported to experience blisters due to ciNPT at rates 12-fold higher than standard dry dressings.[7]

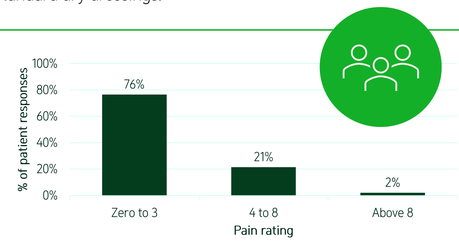

Figure 3: Patient pain rating on dressing change at Visit 1 (day 7 post-operatively) on a numerical rating scale ranging from 0 (no pain) to 10 (worst pain imaginable). The ciNPT system* studied uses a bordered dressing with soft silicone technology# which adheres to intact dry skin and is atraumatic upon dressing removal.[8-10]

- In this study, low rates of exudate, few infectious complications, and rare instances of mild blistering were reported over 90 days.
- The majority of patients reported low pain at dressing change, reflecting known skin-friendly properties of the soft-silicone dressing material used in this ciNPT system.

CONCLUSIONS

This study supports the conclusion that this ciNPT device* effectively removes exudate and infectious material post-operatively in revision TKA and THA procedures, and is gentle on skin.

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