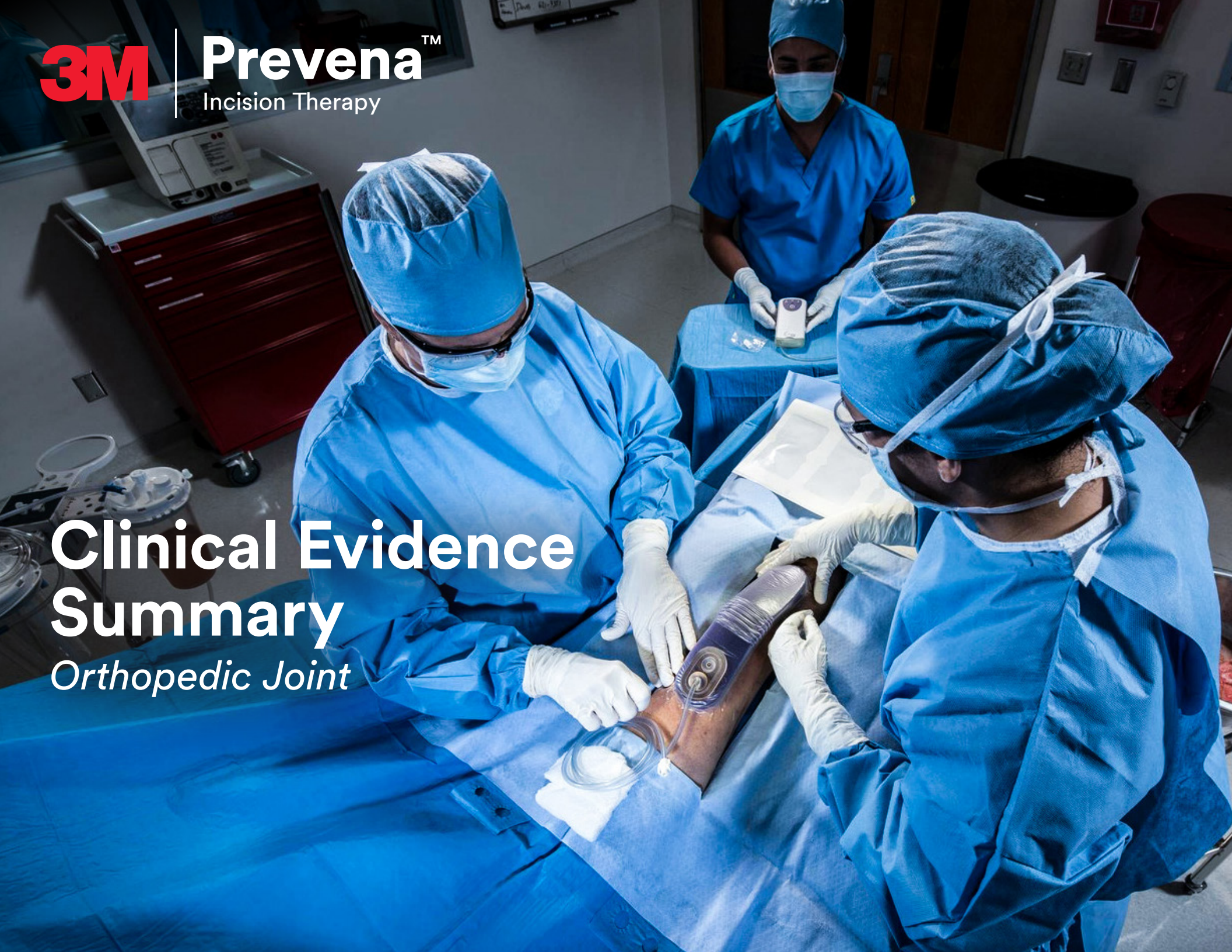
3M | Prevena™
Incision Therapy



Clinical Evidence Summary

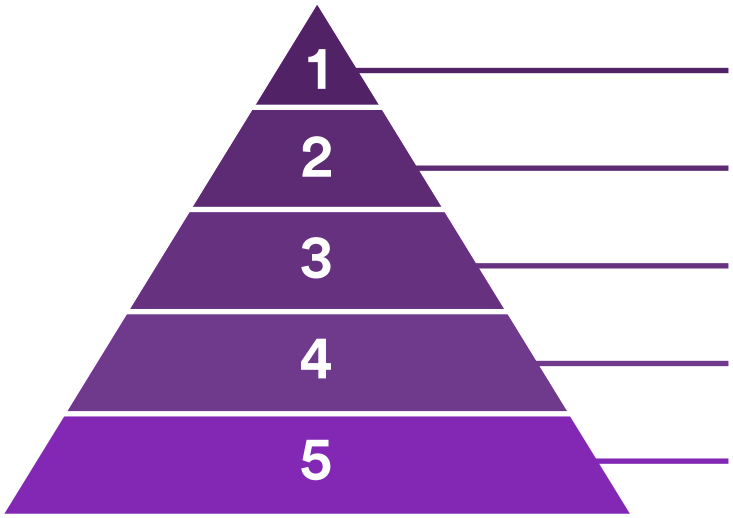
Orthopedic Joint

Negative Pressure Therapy for Incision Management

For over 25 years, negative pressure vacuum-assisted closure (V.A.C.®) technology has been clinically shown to promote wound healing by reducing edema and promoting granulation tissue formation and perfusion through the removal of exudate and infectious materials.

3M extended the use of its negative pressure technology to closed surgical incisions with similarly positive clinical results, outlined in more than 70+ journal publications focused on closed incision negative pressure therapy (ciNPT), with nearly half of the evidence specific to orthopedic cases.

The 3M™ Prevena™ Incision Management System clinical evidence summaries presented adhere to the American Society of Plastic Surgeons (ASPS) Evidence Rating Scale[1] and reflect the benefits of ciNPT for different incision types and surgical outcomes compared to the standard of care.



Level 1a: Evidence obtained from at least one properly designed randomized controlled trial
Level 1b: Systematic reviews (with homogeneity) of randomized controlled trials

Level 2a: Evidence obtained from well-designed controlled trials without randomization
Level 2b: Individual cohort study or low-quality randomized controlled trials (e.g., <80% follow-up)

Level 3: Evidence obtained from well-designed cohort or case-control analytic studies, preferably from more than one center or research group

Level 4: Case series (and poor-quality cohort and case-control studies)

Level 5: Expert opinion without explicit critical appraisal, or based on physiology, bench research or “first principles”

Reference:
1. Sullivan D, Chung KC, Eaves FF, Rohrich RJ. The Level of Evidence Pyramid: Indicating Levels of Evidence in Plastic and Reconstructive Surgery Articles. Plast Reconstr Surg 2011;128(1):311-314

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INCISION TYPE KEY

- THA — Total Hip Arthroplasty
- TJA — Total Joint Arthroplasty
- TKA — Total Knee Arthroplasty
- PPFX — Periprosthetic Fracture Surgery (Hip or Knee)
- rTHA — Revision Total Hip Arthroplasty
- rTKA — Revision Total Knee Arthroplasty

*Clinical endpoints reflect the conditions and methods specific to each publication and should not be interpreted as general outcomes related to 3M™ Prevena™ Therapy. Individual results for each case may vary, depending on the patient, circumstances, and conditions.

1 LOE

rTKA

Study data suggests 3M™ Prevena™ Therapy could challenge the standard of care

Higuera-Rueda C, Emara AK, Nieves-Malloure Y, Klika AK, Cooper HJ, Cross MB, Guild GN, Nam D, Nett M, Scuderi GR, Cushner FD, Piuzzi NS, Silverman RP. The Effectiveness of Closed Incision Negative Pressure Therapy versus Silver-Impregnated Dressings in Mitigating Surgical Site Complications in High-Risk Patients after Revision Knee Arthroplasty: The PROMISES Randomized ControlledTrial. J Arthroplasty (2021), doi: https://doi.org/10.1016/j.arth.2021.02.076

STUDY DESIGN

Post-market, randomized, open-label, multicenter study

STUDY PURPOSE

Evaluate the effectiveness of closed incision negative pressure therapy (ciNPT) versus standard of care (SOC) dressings in reducing surgical site complications (SSCs).

METHODS

- A total of 294 revision total knee arthroplasty (rTKA) patients (15 centers) at high-risk for wound complications were randomized to ciNPT or SOC (n=146 each) and stratified by revision type (aseptic vs. septic). Demographics, comorbidities, causes of revision and duration of treatment were similar between cohorts (p>0.05).
- 242 patients with incisions completed follow-up, including 124 patients treated with 3M™ Prevena™ Therapy (ciNPT) and 118 patients treated with an antimicrobial silver-impregnated dressing (SOC).
- Primary outcome was the 90-day incidence of SSCs with stratification in accordance with revision type. Secondary outcomes were the 90-day health care utilization parameters (readmission, reoperation, dressing changes, and visits) and patient-reported outcomes (PRO). Treatment-related adverse events were compared and stratified as severe and non-severe.

RESULTS

WOUND COMPLICATIONS

4x

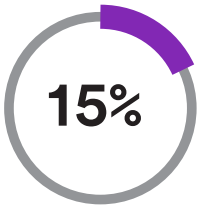
Reduction in SSCs*
3.4% (5/147) Prevena Therapy vs.
14.3% (21/147) SOC
(p=0.0013)*

READMISSIONS

3x

Reduction in readmission rates*
3.4% (5/147) Prevena Therapy vs.
10.2% (21/147) SOC
(p=0.0208)*

DRESSING CHANGES



Fewer mean dressing changes*
1.1±0.3 Prevena Therapy vs.
1.3±1.0 SOC
(p=0.0003)*

*Calculation(s) are derived based on relative patient group incidence rate reported in this study.
*Statistically significant (p=<0.05)

KEY POINTS

SUMMARY

- Prevena Therapy significantly mitigated 90-day surgical site complications, readmission rates, and reduced frequency of dressing changes compared with the standard of care among high-risk rTKA patients.
  - Treatment-related adverse effects were similar between both cohorts.
  - The benefit of ciNPT on specific SSCs and post-rTKA patient-reported outcomes (PRO) was not established and further studies are warranted

1 LOE

rTHA rTKA

Potential reduction of complications with ciNPT

Newman JM, Siqueira MBP, Klika AK, Molloy RM, Barsoum WK, Higuera CA. Use of closed incisional negative pressure wound therapy after revision total hip and knee arthroplasty in patients at high risk for infection: A Prospective, Randomized Clinical Trial. J Arthroplasty. 2019 Mar;34(3):554-559

STUDY DESIGN

Prospective, single-center, randomized control trial (Level I)

STUDY PURPOSE

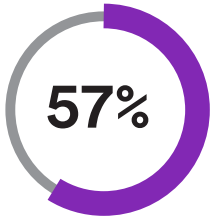
The purpose of the Newman study was to compare the use of Prevena Therapy to a sterile antimicrobial dressing (AQUACEL® Ag SURGICAL cover dressing) in revision arthroplasty (rTHA, rTKA) patients at high risk to develop wound complications.

METHODS

- 160 patients undergoing elective rTHA and rTKA were prospectively randomized to receive Prevena Therapy or AQUACEL® Ag at a single institution.
- Patients had at least one risk factor for developing a wound complication.
- All patients received perioperative treatment and antibiotics.
- Study endpoints included wound complications (such SSIs, drainage and cellulitis), readmission and reoperation rates.
- Data collected at 2, 4 and 12 weeks postoperatively.

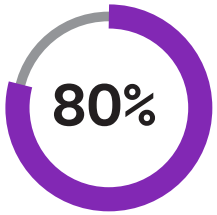
RESULTS

WOUND COMPLICATIONS



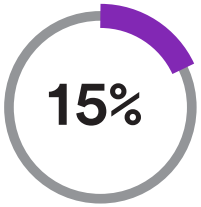
reduction in wound complications*
10.1% (8/79) Prevena Therapy vs.
23.8% (19/80) Control
(p=0.022)*

REOPERATION



fewer returns to the OR*
2.5% (2/79) Prevena Therapy vs.
12.5% (10/80) Control
(p=0.017)*

READMISSIONS



fewer readmissions
20.3% (16/79) Prevena Therapy vs. 23.8% (19/80) Control (p=0.595)

* Statistically significant (p=≤0.05)
Calculation was derived based on relative patient group incidence rate reported in this study.

KEY POINTS

SUMMARY

- High-risk patients could benefit from closed incision negative pressure therapy (ciNPT) to help reduce the risk of wound complications and reoperations after rTHA and rTKA.
- The authors suggest future multicenter clinical trials to further strengthen the results as well as a cost-benefit analysis.

†Although the authors reported use of Prevena Therapy for a mean of 3.6 days (ranging from 2 to 15 days), this mean 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 3M.

1 LOE

THA

Reduction of seromas in closed incisions

Pachowsky, M., Gusinde, J., Klein, A., Lehrl, S., Schulz-Drost, S., Schlechtweg, P., Pauser, J., Gelse, K., & Brem, M. H. (2012). Negative pressure wound therapy to prevent seromas and treat surgical incisions after total hip arthroplasty. International orthopaedics, 36(4), 719–722. https://doi.org/10.1007/s00264-011-1321-8

STUDY DESIGN

Prospective, single-center, randomized control trial (Level I)

STUDY PURPOSE

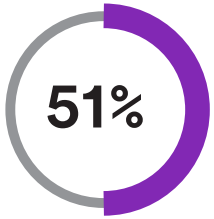
The purpose of the Pachowsky study was to evaluate the effect of closed incision negative pressure therapy (ciNPT) on incisional healing and the prevention of seromas in clean, closed incisions after total hip arthroplasty (THA).

METHODS

- Patients were randomized into two groups: 10 patients with a standard dressing, consisting of a dry wound coverage; and nine patients with ciNPT placed over the sutured wound area for five days.
- Ultrasound was used to detect and measure seromas in both groups on days 5 and 10 postoperatively. Patients underwent ultrasound of the surgical site preoperatively as a control to assess for potential soft tissue abnormalities.
- Groups were comparable in age and incision size. All patients received perioperative treatment and antibiotics.
- Study endpoints included the number of patients with seromas and average volume size of seroma.

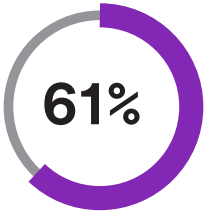
RESULTS

NUMBER OF PATIENTS WITH SEROMAS



fewer patients with seromas at day 10
44% (4/9) Prevena Therapy vs. 90% (9/10) Control

SEROMA VOLUME



reduction in mean seroma volume at day 10*
1.97 mL Prevena Therapy vs. 5.08 mL Control
(p=0.021)*

* Statistically significant (p=≤0.05)
Calculation was derived based on relative patient group incidence rate reported in this study.

KEY POINTS

SUMMARY

The authors concluded that application of 3M™ Prevena™ Therapy on closed incisions after orthopedic surgery might help reduce the complications of a prolonged wound healing and postoperative seroma in the wound area.

2 LOE

THA TKA

Potential reduction of complications requiring medical or surgical intervention

Redfern, R. E., Cameron-Ruetz, C., O'Drobinak, S. K., Chen, J. T., & Beer, K. J. (2017). Closed Incision Negative Pressure Therapy Effects on Postoperative Infection and Surgical Site Complication After Total Hip and Knee Arthroplasty. The Journal of arthroplasty, 32(11), 3333–3339. https://doi.org/10.1016/j.arth.2017.06.019

STUDY DESIGN

Single-center, prospective, comparative study (Level II)

STUDY PURPOSE

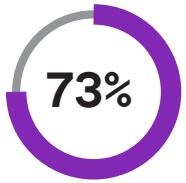
The purpose of the Redfern study was to examine the use of closed incision negative pressure therapy (ciNPT) over clean closed surgical incisions after total joint replacement and whether 3M™ Prevena™ Therapy would reduce the rates of wound complications.

METHODS

- The Prevena Therapy group was comprised of 192 patients representing 196 incisions, who were actively enrolled from 2013 to 2014. The historical control group consisted of 400 patients who underwent surgery from 2011 to 2012.
- Prevena Therapy was applied over the closed incision for 6-8 days postoperatively. The control group standard of care included a sterile gauze dressing with standard dressing changes.
- Study endpoints included the rate of surgical site complications requiring medical or surgical intervention, including surgical site infections (deep and superficial infections), wound dehiscence, hematomas, seromas, edema/swelling, and drainage were compared between groups.

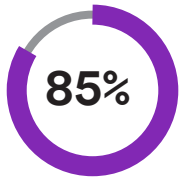
RESULTS

TOTAL COMPLICATIONS



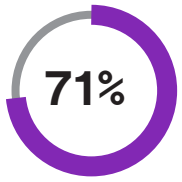
reduction in total complications*
1.5% (3/192) Prevena Therapy vs. 5.5% (22/400) Control
(p=0.02)*

EDEMA/SWELLING



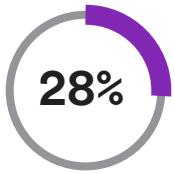
reduction in edema/swelling requiring medical or surgical intervention*
0.5% (1/192) Prevena Therapy vs. 3.25% (13/400) Control
(p=0.02)*

SURGICAL SITE INFECTIONS



reduction in SSIs*
1.0.% (2/192) Prevena Therapy vs. 3.5% (14/400) Control
(p=0.04)*

PAIN MANAGEMENT



reduction in pain management 24h postop*
2.6±1.8 Prevena Therapy vs. 3.6±2.2 Control
(p=<0.0001)*

* Statistically significant (p=≤0.05)
Calculation was derived based on relative patient group incidence rate reported in this study.

Although not statistically significant, there was a reduction in deep infection (1.0% vs 1.25%; p=0.81), wound dehiscence (1.5% vs. 3.25%; p=0.2), seromas (0.0% vs. 0.5%; p=0.16), and drainage (1.0% vs. 3.25%; p=0.07) requiring medical or surgical intervention in the Prevena Therapy group when compared with the Control group.

KEY POINTS

SUMMARY

In this study, Prevena Therapy reduced the overall incidence of complications requiring medical or surgical intervention for hip and knee arthroplasty but did not significantly impact the rate of deep infection.

Although the authors reported use of ciNPT for a mean of 7.07 ± 1.16 days (range: 6-8 days), this mean 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 2 days up to a maximum of seven days." Use for greater than 7 days is not recommended or promoted.

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3 LOE

PPFX

Potential clinical value of ciNPT as a treatment in PPFX surgeries

Cooper HJ, Roc GC, Bas MA, Berliner ZP, Hepinstall MS, Rodriguez JA, Weiner LS. Closed incision negative pressure therapy decreases complications after periprosthetic fracture surgery around the hip and knee. Injury. 2018 Feb;49(2):386-391.

STUDY DESIGN

Single institution/single surgeon retrospective review of records (Level III)

STUDY PURPOSE

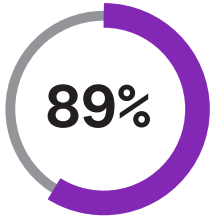
The purpose of the Cooper study was to evaluate the effectiveness of 3M™ Prevena™ Therapy versus standard of care antimicrobial dressing in mitigating perioperative wound complications in patients who underwent lower extremity periprosthetic fracture surgery (PPFX).

METHODS

- Sixty-nine (69) patients, who underwent lower extremity PPFX surgeries, were identified for the retrospective study (Jan. 2010 – July 2016).
- Prevena Therapy (-125 mmHg) was administered over closed incisions (27 total) up to the maximum of 7 days. The standard of care incisions (40 total) were treated with AQUACEL® Ag SURGICAL cover dressing for a minimum of five days.
- There were no baseline demographic differences between the two groups, and all patients received perioperative treatment and antibiotics.
- Study endpoints included wound complications, surgical site infections (SSIs) and reoperation rates.

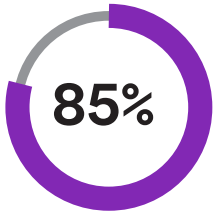
RESULTS

WOUND COMPLICATIONS



reduction in wound complications*
3.7% (1/27) Prevena Therapy vs. 35.0% (14/40) Control
(p=0.002)*

REOPERATION



fewer returns to the OR*
3.7% (1/27) Prevena Therapy vs. 25.0% (10/40) Control
(p=0.021)*

* Statistically significant (p=≤0.05)
Calculation was derived based on relative patient group incidence rate reported in this study.

KEY POINTS

SUMMARY

- The findings suggest that Prevena Therapy applied after PPFX surgeries involving hip or knee implants effectively decreased wound complications, SSIs and surgical revisions.
- The authors adopted closed incision negative pressure therapy (ciNPT) as the standard of care for PPFX surgeries.
- Results still require validation by large, prospective studies to further define the efficacy and cost-effectiveness of ciNPT.

3 LOE

TJA

Identifying patients who may benefit from 3M™ Prevena™ Therapy

Anatone AJ, Shah RP, Jennings EL, Geller JA, Cooper J. A risk-stratification algorithm to reduce superficial surgical site complications in primary hip and knee arthroplasty. Arthroplasty Today. 2018;4(4):493-498. doi:10.1016j. artd.2018.09.00

STUDY DESIGN

Single institution retrospective review of records (Level III)

STUDY PURPOSE

The purpose of the Anatone study was to evaluate when to use Prevena Therapy in primary total joint arthroplasties (TJAs). The author's risk stratification can be used as a potential guideline to identify patients that may benefit from Prevena Therapy.

METHODS

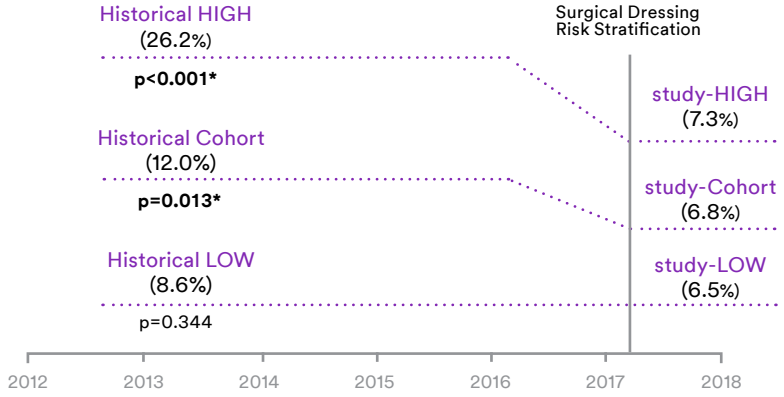
- Patients were considered low risk if their calculated risk score was <2 and patients were considered high risk if their risk score was ≥2.
- A study population of 323 consecutive primary TJAs were evaluated, where 123 (38%) of those patients considered at elevated risk were risk-stratified to receive Prevena Therapy. The remaining 200 patients received the standard postop dressing (AQUACEL® Ag SURGICAL cover dressing).
- A historical control population of 643 patients was identified who all received the standard postop dressing to test the impact of this risk score.
- Skin closure procedure was the same in both groups, and dressings were applied under sterile conditions in the operating room at the conclusion of the surgical procedure.
- The primary outcome measure was any post-operative surgical site complication (SSC*) that required intervention during the initial 90-day post-operative period.

RISK-STRATIFICATION ALGORITHM SCORING SYSTEM

Risk Factor	Weight
BMI	
<18.5 kg/m2	1
18.5-29.9 kg/m2	0
30-34.9 kg/m2	1
35-39.9 kg/m2	2
>40 kg/m2	3

Risk Factor	Weight
Diabetes mellitus	2
Immunodeficiency	1.3
Active smoking	1
Non-ASA anticoagulation	1
Prior surgery	2

RESULTS



GUIDANCE

The authors' risk stratification can be used as a potential guideline to identify patients who may benefit from Prevena Therapy.

* Statistically significant (p=≤0.05)
Calculation was derived based on relative patient group incidence rate reported in this study.

KEY POINTS

SUMMARY

- Among high-risk patients, there was a marked improvement in the rate of SSCs when treated prophylactically with Prevena Dressings as compared with historical controls (26.2% vs. 7.3%; **p < 0.001**).*
- Compared with historical controls, a modest but significant improvement in superficial SSCs after implementation of risk-stratification (12.0% vs 6.8%; **p = 0.013**) was observed.*
- Low-risk patients who continued to be treated with standard postop dressings in historical controls demonstrated no significant improvement (8.6% vs 6.5%; p = 0.344).

*SSC was defined as any dehiscence, suture granuloma, drainage occurring beyond postoperative day 5, significant hematoma formation, or SSI as defined by the CDC that required unplanned postoperative interventions.

3 LOE

rTHA rTKA

Efficacy of ciNPT compared to an antimicrobial dressing

Cooper HJ, Bas MA. Closed-Incision Negative-Pressure Therapy Versus Antimicrobial Dressings After Revision Hip and Knee Surgery: A Comparative Study. J Arthroplasty.2016;31(5):1047-1052. https://doi.org/10.1016/j.arth.2015.11.010

STUDY DESIGN

Single institution/single surgeon retrospective review of records (Level III)

STUDY PURPOSE

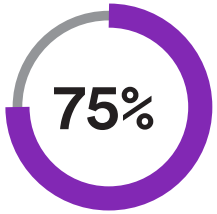
The purpose of the Cooper study was to evaluate the efficacy of closed incision negative pressure therapy (ciNPT) compared to a sterile antimicrobial dressing (AMD) on wound complications, surgical site infections (SSIs) and reoperations after hip or knee revision surgery (rTHA, rTKA).

METHODS

- Charts were reviewed from 138 patients who underwent rTHA and rTKA by a single surgeon over a 34-month period.
- Prevena Therapy was used selectively in 30 patients with multiple risk factors for SSIs over the last 15 months of the study period. The AMD dressing was used in 108 patients.
- All patients received standard perioperative SSI prevention measures when possible, including preoperative and postoperative antibiotics.
- Rates of wound complications, SSIs and reoperation were compared.

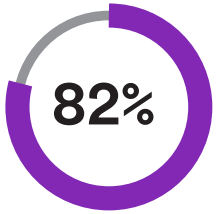
RESULTS

WOUND COMPLICATIONS



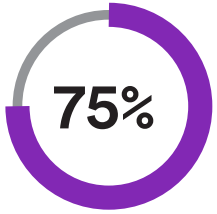
reduction in wound complications*
6.7% (2/30) Prevena Therapy vs.
26.9% (29/108) Control
(p=0.024)*

SURGICAL SITE INFECTIONS



reduction in SSIs*
3.3% (1/30) Prevena Therapy vs.
18.5% (20/108) Control
(p=0.045)*

REOPERATION



fewer returns to the OR
3.3% (1/30) Prevena Therapy vs.
13.0% (14/108) Control
(p=0.191)

* Statistically significant (p=≤0.05)
Calculation was derived based on relative patient group incidence rate reported in this study.

KEY POINTS

SUMMARY

- rTHA and rTKA continue to place a burden on the healthcare system and have been a focus area for hospitals to improve quality and control costs.
- Despite being at higher risk for development of postoperative wound complications, patients treated with ciNPT had fewer wound complications and SSIs than patients treated with an AMD.

Although the authors reported use of ciNPT for a mean of 9.2 days (ranging from 6 to 14 days), this mean 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 3M.

INDICATION STATEMENT AND SAFETY INFORMATION

3M™ Prevena™ Therapy Indication For Use

The FDA granted the following Indications for Use: 3M™ Prevena 125 and 3M™ Prevena™ Plus 125 Therapy Units manage the environment of closed surgical incisions and remove fluid away from the surgical incision via the application of -125mmHg continuous negative pressure. When used with legally marketed compatible dressings, Prevena 125 and Prevena Plus 125 Therapy Units are intended to aid in reducing the incidence of seroma and, in patients at high risk for postoperative infections, aid in reducing the incidence of superficial surgical site infection in Class I and Class II wounds.

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

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