3M | Prevena™
Incision Therapy

PROMISES study data suggests 3M™ Prevena™ Therapy can help advance the standard of care

Promising new data from a randomized controlled trial further affirms that Prevena Therapy significantly reduces the risk of 90-day surgical site complications (SSCs) and postop readmissions.

Clinical Evidence Summary

The PROMISES (Post-market, Randomized, Open-Label, Multicenter Study to evaluate Effectiveness) trial

The effectiveness of closed incision negative pressure therapy versus silver-impregnated dressing in mitigating surgical site complications in high-risk patients after revision knee arthroplasty.

Higuera-Rueda CA, Emara AK, Nieves-Malloure Y, Klika AK, Cooper HJ, Cross MB, Guild GN, Nam D, Nett MP, Scuderi GR, Cushner FD, Piuzzi NS, Silverman RP. J. Arthroplasty 2021; doi: 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 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

- Compared to SOC, patients in the Prevena Therapy group demonstrated:
  - Significantly decreased rates of surgical site complications (ciNPT 3.4% vs. SOC 14.3%, **p=0.0013***)
  - Significantly lower readmission rates (ciNPT 3.4% vs. SOC 10.2%, **p=0.0208***)
  - Reduced dressing changes (ciNPT 1.1+0.29 vs. SOC 1.3 +0.96, **p=0.0003***)

Conclusions

- 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.

Patients treated with 3M™ Prevena™ Therapy were:

4X* less likely to experience a post-operative 90-day surgical site complication

3X* less likely to be readmitted compared to the standard of care group

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

Note: Specific indications, contraindications, warnings, precautions and safety information exist for these products and therapies. Please consult a clinician and product instructions for use prior to application. This material is intended for healthcare professionals.

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