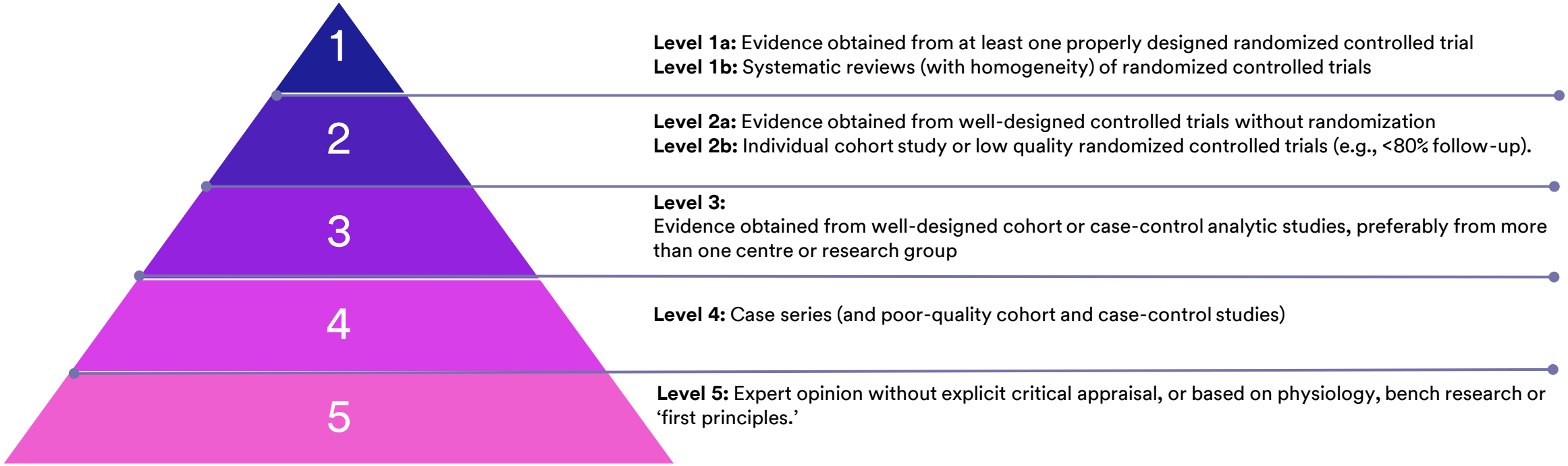
Clinical Evidence

Orthopedics: TKA and THA

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.



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

3M™ Prevena™ Therapy evidence

- The body of evidence for using ciNPT has been growing steadily since 2006
- The table listed below is based on the Evidence Rating Scale for Therapeutic Studies developed by the American Society of Plastic Surgeons (ASPS)

Surgical Incision	ASPS Level of Evidence	First Author (Year)	Surgical Incision Type	Control	Postoperative Clinical Endpoints*
Orthopedic Joint	1	Higuera (2021)	rTKA	Silver-impregnated dressing	Surgical Site Complications (SSC); Readmission; Dressing Changes
		Newman (2018)	rTHA; rTKA	Silver-impregnated dressing	SSC
		Pachowsky (2012)	THA	Standard postop dressing	Seroma
	2	Redfern (2017)	THA; TKA	Standard postop dressing	Surgical Site Infection (SSI); Hematoma; Edema; Wound dehiscence
	3	Anatone (2018)	THA; TKA	Silver-impregnated dressing	SSC, Risk Stratification
		Cooper (2016)	rTHA; rTKA	Silver-impregnated dressing	SSC; SSI
		Doman (2021)	TKA	Silver-impregnated dressing	SSC

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

Incision Type Key	
THA	Total Hip Arthroplasty
TKA	Total Knee Arthroplasty
rTHA	Revision Total Hip Arthroplasty
rTKA	Revision Total Knee Arthroplasty

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 Controlled Trial. J Arthroplasty. 2021 Jul;36(7S):S295-S302.e14

1 LOE

rTKA

Study Design

Multi-centre randomized controlled trial

Study Purpose

Evaluate the effectiveness of closed incision negative pressure therapy (ciNPT) versus standard of care (SOC) dressings in reducing surgical site complications (SSCs) in high-risk patients after revision knee arthroplasty (rTKA).

Methods

- 294 high-risk rTKA patients (15 centres) randomized to ciNPT (n=147) or SOC (n=147).
- Inclusion criteria: exhibit at least one risk factor for postoperative SSC: BMI > 35kg/m^2 use of non-aspirin blood thinners postoperatively; current/previous diagnosis of peripheral vascular disease; current tobacco use; history of prior infection history at operative site; operative limb lymphedema; insulin-dependent diabetes; current use of immunomodulators or corticosteroids; ongoing malignancy excluding localized skin cancer; rheumatoid arthritis; renal failure or dialysis; malnutrition; liver disease; solid organ transplant recipients; or human immunodeficiency virus infection.
- Primary outcome was 90-day incidence of SSCs. 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

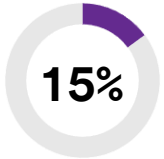
Reduction in SSCs*
3.4% (5/147) Prevena Therapy vs.
14.3% (21/147) SOC
(p=0.0013)*

Readmissions

3x

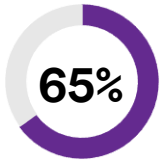
Reduction in Readmission Rates*
3.4% (5/147) Prevena Therapy vs.
10.2% (15/147) SOC
(p=0.0208)*

Dressing Changes



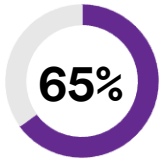
Fewer Mean Dressing Changes*
1.1 ± 0.3 Prevena Therapy vs.
1.3 ± 1.0 SOC
(p=0.0003)*

Superficial SSI



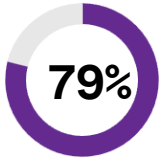
Reduction in superficial SSIs
0.7% (1/147) Prevena Therapy vs.
2.0% (3/147) SOC
(p=0.6221)

Deep SSI



Reduction in deep SSIs
0.7% (1/147) Prevena Therapy vs.
2.0% (3/147) SOC
(p=0.6221)

Dehiscence



Reduction in dehiscence
0.7% (1/147) Prevena Therapy vs.
3.4% (5/147) SOC
(p=0.2133)

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

Key Points

- 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

rTKA

PROMISES RCT data demonstrates 3M™ Prevena™ Therapy can help reduce overall cost.

Cooper HJ, Bongards C, Silverman RP. Cost-effectiveness of closed incision negative pressure therapy for surgical site management after revision total knee arthroplasty: Secondary analysis of a randomized clinical trial. Presented at: American Association of Hip and Knee Surgeons Annual Meeting, November 11-14, 2021, Dallas, Texas.

Study Design

Health Economic assessment of RCT study

Study Purpose

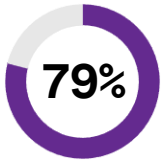
The aim of this study was to determine the cost-benefit of ciNPT in post-rTKA surgical site management by reducing 90-day cost for SSC-related interventions based on RCT study data.

Methods

- Study data were used to determine type and frequency of SSC-related interventions, which were clustered into surgical and non-surgical.
- A health economic model was used to determine the mean per-patient costs, including costs for post-operative dressings, surgical interventions, readmission, and non-surgical interventions.
- A sub-analysis was also performed by dividing patients into “lower risk” (Charlson Comorbidity Index [CCI] <2) and “higher risk” (CCI ≥2) groups.

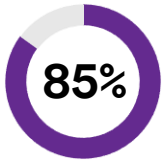
Results

Non-surgical SSC intervention



Reduction in Non-Surgical SSC intervention*
2.7% Prevena Therapy vs.
12.9% SOC
(p=0.0017)*

Surgical SSC intervention



Reduction in Surgical SSC intervention
0.7% Prevena Therapy vs.
4.8% SOC
(p=0.0666)

Cost of Care

1.9x

Reduction in Per-Patient Cost of Care
$1,047 Prevena Therapy vs.
$2,036 SOC

Cost of Care

	ciNPT	SOC
Mean Product Cost	$ 666	$ 52
Mean Readmission Cost	$ 231	$ 970
Mean Surgical costs	$ 135	$ 944
Mean Non-Surgical costs	$ 15	$ 70
TOTAL	$ 1,047	$ 2,036

Key Points

Summary

Despite having higher upfront costs for postoperative dressings, ciNPT was cost-effective, decreasing the costs of surgical site management after rTKA by 49% in this study population and by 72% in higher-risk patients.

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

Potential reduction of complications with 3M™ Prevena™ Therapy.

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

1 LOE rTHA/rTKA

Study Design

Prospective, single-centre, randomized controlled trial

Study Purpose

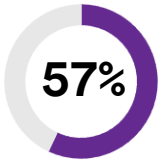
The purpose of the Newman study was to compare the use of Prevena Therapy to a sterile antimicrobial dressing (AQUACEL® Ag SURGICAL cover dressing) in revision arthroplasty (rTHA, rTKA) patients at high-risk to develop wound complications.

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 (SSC including: SSIs, drainage and cellulitis), readmission and reoperation rates.
- Data collected at 2, 4 and 12 weeks postoperatively.

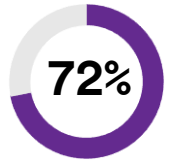
Results

Wound Complications



Reduction in Wound Complications*
10.1% (8/79) Prevena Therapy vs.
23.8% (19/80) SOC
(p=0.022)*

Periprosthetic Joint Infections

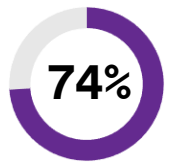


Reduction in Periprosthetic Joint Infections
2.5% (2/79) Prevena Therapy vs.
8.8% (7/80) SOC

Reoperations

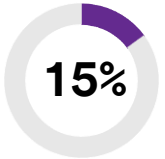
Fewer Returns to the OR*
2.5% (2/79) Prevena Therapy vs.
12.5% (10/80) SOC
(p=0.017)*

Dehiscence



Reduction in dehiscence
1.3% (1/79) Prevena Therapy vs.
5.0% (4/80) SOC

Readmissions



Fewer Readmissions
20.3% (16/79) Prevena Therapy vs.
23.8% (19/80) SOC
(p=0.595)

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

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 3M™ 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.

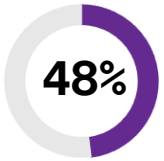
Key Points

- 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 multi-centre clinical trials to further strengthen the results as well as a cost-benefit analysis

Illustration of the 3M™ Prevena™ Therapy Incision Management System cost-effectiveness based on Newman et al outcomes.

Revision TKA Surgery in High-Risk Population Hypothetical Economic Model	3M™ Prevena™ Therapy	AQUACEL® Ag SURGICAL
Patients	79	80
Number of Surgical Site Complications (a)	8	19
Cost per SSC[1] (b)	$19,733	$19,733
Per Patient Complication Cost (a*b)/n	$1,610	$3,776
Per Patient Therapy Cost*	$495	$39
Total Cost Per Patient	$2,105	$3,815
Potential Per Patient Savings Using Prevena Therapy	**$1,710**	

Cost Savings



Reduction in per patient cost for SSC
$2,150 Prevena Therapy vs. $3,815 SOC

1. Hou Y. Incidence and impact of surgical site infections and surgical site complications on length of stay and cost of care in orthopedic open surgeries for spine, THA/TKA, and trauma. HEOR-2021-002-DAR.

Assumes cost per SSC for rTKA at higher end of total range of TKA/THA data.

*3M™ Prevena™ Peel and Place System Kit and AQUACEL® Ag SURGICAL price are an estimate; individual prices may vary.

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena Therapy or AQUACEL® Ag SURGICAL. This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.

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

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.

3 LOE

THA/TKA

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

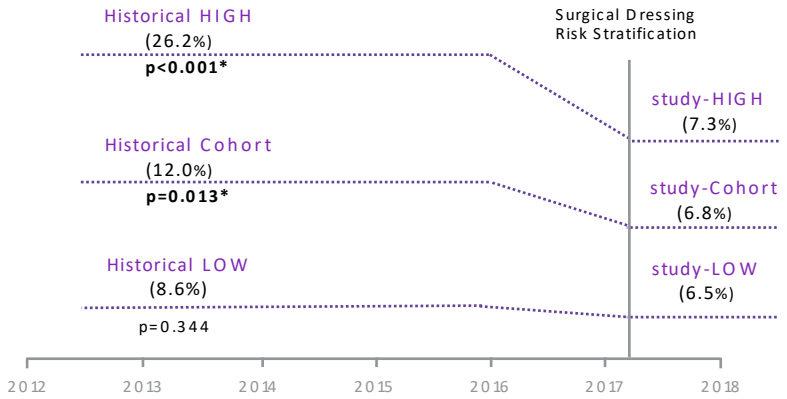
- Patients were considered low risk if their calculated risk score was <2 and patients were considered high-risk if their risk score was ≥2.
- A study population of 323 consecutive primary TJAs were evaluated, where 123 (38%) of those patients considered at elevated risk to receive Prevena Therapy. The 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 postoperative 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.

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

Key Points

Summary

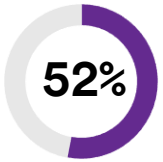
- Among high-risk patients, there was a marked improvement in the rate of SSCs when treated prophylactically with Prevena Therapy as compared with historical controls (26.2% vs. 7.3%; **p < 0.001).***
- Compared with historical controls, a modest but significant improvement in superficial SSCs after 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.

Illustration of the 3M™ Prevena™ Therapy Incision Management System cost-effectiveness based on Anatone et al outcomes.

Primary TKA and THA in High-Risk Population Hypothetical Economic Model	3M™ Prevena™ Therapy	AQUACEL® Ag SURGICAL
Patients	123	122
Number of Surgical Site Complications (a)	9	32
Cost per SSC[1] (b)	$15,332	$15,332
Per Patient Complication Cost (a*b)/n	$1,122	$4,022
Per Patient Therapy Cost*	$830	$39
Total Cost Per Patient	$1,952	$4,060
Potential Per Incision Savings Using Prevena Therapy	**$2,108**	

Cost Savings



Reduction in per patient cost for SSC in Primary TJA High-Risk Population
$1,952 Prevena Therapy vs. $4,060 SOC

1. Hou Y. Incidence and impact of surgical site infections and surgical site complications on length of stay and cost of care in orthopedic open surgeries for spine, THA/TKA, and trauma. HEOR-2021-002-DAR.

Cost per SSC is based on SSC cost for population with CCI>0 to represent High-Risk Study Population.

* 3M™ Prevena™ Plus Customizable Dressing and AQUACEL® Ag SURGICAL price are estimates; individual prices may vary.

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena Therapy or AQUACEL® Ag SURGICAL. This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.

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.

Efficacy of 3M™ Prevena™ Therapy 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.

Study Design

Single institution/single surgeon retrospective cohort study (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).

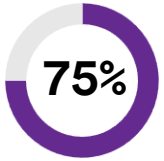
Methods

- 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.

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

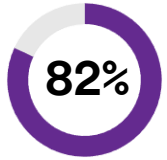
Results

Wound Complications



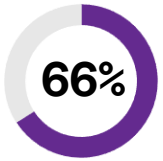
Reduction in Wound Complications*
6.7% (2/30) Prevena Therapy vs.
26.9% (29/108) Control
(p=0.024)*

Surgical Site Infections



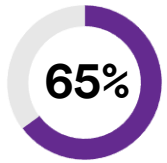
Reduction in SSIs*
3.3% (1/30) Prevena Therapy vs.
18.5% (20/108) Control
(p=0.045)*

Dehiscence



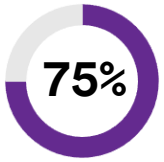
Reduction in Dehiscence
6.7% (2/30) Prevena Therapy vs.
19.4% (21/108) Control
(p=0.163)

Superficial SSI



Reduction in superficial SSIs
3.3% (1/30) Prevena Therapy vs.
9.3% (10/108) Control
(p=0.456)

Reoperations



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

Deep SSI

Reduction in deep SSIs
0% (0/30) Prevena Therapy vs.
9.3% (10/108) Control
(p=0.118)

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

Key Points

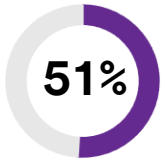
- rTHA and rTKA continue to place a burden on the healthcare system and have been a focus area for hospitals to improve quality and control costs
- Despite being at higher risk for development of postoperative wound complications, patients treated with ciNPT had fewer wound complications and SSIs than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

Illustration of the 3M™ Prevena™ Therapy Incision Management System cost-effectiveness based on Cooper et al outcomes.

Surgical Site Complications

Revision THA and TKA in high-Risk Population Hypothetical Economic Model	3M™ Prevena™ Therapy	AQUACEL® Ag SURGICAL
Patients	30	108
Number of Wound complications (a)	2	29
Cost per SSC[1] (b)	$19,733	$19,733
Per Patient Complication Cost (a*b)/n	$1,316	$4,299
Per Patient Therapy Cost*	$830	$39
Total Cost Per Patient	$2,146	$4,338
Potential Per Patient Savings Using Prevena Therapy	**$2,192**	

Cost Savings

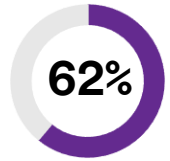


Reduction in per patient cost for SSC
$2,146 Prevena Therapy
vs. $4,338 SOC

Surgical Site Infections

Revision THA and TKA in high-Risk Population Hypothetical Economic Model	3M™ Prevena™ Therapy	AQUACEL® Ag SURGICAL
Patients	30	108
Number of Infections (a)	1	20
Cost per SSI[1] (b)	$22,244	$22,244
Per Patient Infection Cost (a*b)/n	$741	$4,119
Per Patient Therapy Cost*	$830	$39
Total Cost Per Patient	$1,571	$4,158
Potential Per Patient Savings Using Prevena Therapy	**$2,587**	

Cost Savings



Reduction in per patient cost for SSI
$1,571 Prevena Therapy
vs. $4,158 SOC

1. Hou Y. Incidence and impact of surgical site infections and surgical site complications on length of stay and cost of care in orthopedic open surgeries for spine, THA/TKA, and trauma. HEOR-2021-002-DAR.

Assuming cost per SSI or SSC for revision surgery at high end of total range of TKA/THA data.

* 3M™ Prevena™ Plus Customizable Dressing and AQUACEL® Ag SURGICAL price are estimates; individual prices may vary.

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena Therapy or AQUACEL™Ag SURGICAL. This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.

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.

Potential reduction of complications requiring medical or surgical intervention.

Redfern R, Cameron-Ruetz C, O'Drobinak S, Chen J, Beer K. (2017). Closed Incision Negative Pressure Therapy Effects on Postoperative Infection and Surgical Site Complication After Total Hip and Knee Arthroplasty. J Arthroplasty. 2017; 32(11), 3333–3339.

2 LOE THA/TKA

Study Design

Single-centre, prospective versus historic control comparative study (Level II)

Study Purpose

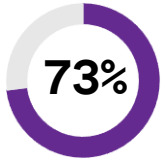
The purpose of the Redfern study was to examine the use of closed incision negative pressure therapy (ciNPT) over clean closed surgical incisions after primary total joint replacement and whether 3M™ Prevena™ Therapy would reduce the rates of wound complications.

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.

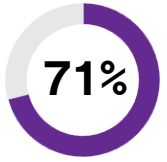
Results

Wound Complications



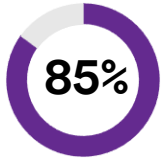
Reduction in Wound Complications*
1.5% (3/196) Prevena Therapy vs.
5.5% (22/400) Control
(p=0.02)*

Surgical Site Infections



Reduction in SSIs*
1.0% (2/196) Prevena Therapy vs.
3.5% (14/400) Control
(p=0.04)*

Edema/Swelling

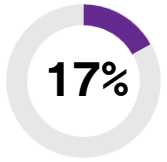


Reduction in Edema/Swelling*
0.5% (1/196) Prevena Therapy vs.
3.25% (13/400) Control
(p=0.02)*

Superficial SSI

Reduction in superficial SSIs*
0% (0/196) Prevena Therapy vs.
2.25% (9/400) Control
(p=0.03)*

Hospital Length of Stay



Reduction in Length of Stay*
1.9+0.6 Prevena Therapy vs.
2.3+0.5 Control
(p=0.0001)*

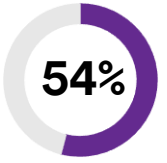
Deep SSI

Reduction in deep SSIs
1.0% (2/196) Prevena Therapy vs.
1.25% (5/400) Control
(p=0.81)

Pain Postop

Reduction in Pain 24h Postop*
2.6±1.8 Prevena Therapy vs.
3.6±2.2 Control
(p=0.0001)*

Dehiscence



Reduction in Dehiscence
1.5% (3/196) Prevena Therapy vs.
3.25% (13/400) Control
(p=0.2)

Key Points

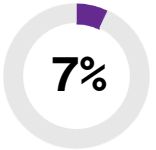
In this study, Prevena Therapy reduced the overall incidence of complications requiring medical or surgical intervention for hip and knee arthroplasty.

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

Illustration of the 3M™ Prevena™ Therapy Incision Management System cost-effectiveness based on Redfern et al outcomes.

Primary TKA/THA not limited to high-risk patients Hypothetical Economic Model	3M™ Prevena™ Therapy	SOC - Gauze Dressing
Patients	196	400
Number of Complications (a)	3	22
Cost per SSC[1] (b)	$13,902	$13,902
Per Patient Complication Cost (a*b)/n	$213	$765
Per Patient Therapy Cost*	$495	---
Total Cost Per Patient	$708	$765
Potential Per Incision Savings Using Prevena Therapy	**$57**	

Cost Savings



Reduction in per patient cost for SSC
$708 Prevena Therapy vs. $765 SOC

1. Hou Y. Incidence and impact of surgical site infections and surgical site complications on length of stay and cost of care in orthopedic open surgeries for spine, THA/TKA, and trauma. HEOR-2021-002-DAR.

*3M™ Prevena™ Peel and Place System Kit is an estimate; individual prices may vary.

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena Therapy or gauze dressing. This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.

Redfern R, Cameron-Ruetz C, O'Drobinak S, Chen J, Beer K. (2017). Closed Incision Negative Pressure Therapy Effects on Postoperative Infection and Surgical Site Complication After Total Hip and Knee Arthroplasty. J Arthroplasty. 2017; 32(11), 3333–3339.

Potential reduction in wound complications when using 3M™ Prevena™ Therapy.

3 LOE

TKA

Doman DM, Young AM, Buller LT, Deckard ER, Meneghini RM. Comparison of Surgical Site Complications With Negative Pressure Wound Therapy vs Silver Impregnated Dressing in High-Risk Total Knee Arthroplasty Patients: A Matched Cohort Study. Journal of Arthroplasty. 2021; 36(10):3437-3442

Study Design

Retrospective comparative cohort study (Level III)

Study Purpose

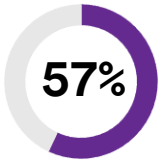
To compare high-risk primary TKA patients' rate of incisional and non-incisional wound complications, periprosthetic joint infections, and reoperations.

Methods

- The Prevena Therapy group comprised of 130 patients who had primary TKA between July 2018 and December 2019.
- The retrospective historical control group, (AQUACEL® Ag SURGICAL) consisted of 130 patients, propensity matched 1:1, who underwent surgery between December 2016 and June 2018.
- High-risk criteria included active tobacco use, diabetes mellitus, BMI > 35 kg/m^2, autoimmune disease, chronic kidney disease, *Staphylococcus aureus* nasal colonization, and non-aspirin anticoagulation.
- Study endpoints included incisional wound complications, defined as: cellulitis, focal swelling, suture reaction, dehiscence and hematoma. Non-incisional wound complications were also assessed and defined as dressing reactions, blistering and rashes.

Results

Incisional Wound Complications



Reduction in Incisional Wound Complications*
6.9% (9/130) Prevena Therapy vs.
16.2% (21/130) Control
(p=0.031)*

Drainage

Presence of Drainage
3.8% (5/130) Prevena Therapy vs.
5.4% (7/130) Control
(p=0.769)

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

Key Points

Summary

Among high-risk patients undergoing primary TKA, patients receiving Prevena Therapy had significantly fewer incisional wound complications when compared to patients receiving silver impregnated dressings.

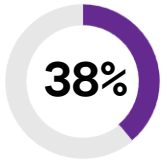
Although an increase in dressing reactions for Prevena Therapy patients was observed, the clinical impact was minimal.

Results support the use of ciNPT as part of a risk mitigation strategy to reduce post operative complications in primary TKA.

Illustration of the 3M™ Prevena™ Therapy Incision Management System cost-effectiveness based on Doman et al outcomes.

Primary Knee (TKA) Surgery in High-Risk Population Hypothetical Economic Model	3M™ Prevena™ Therapy	AQUACEL® Ag SURGICAL
Patients	130	130
Number of Surgical Site Complications (a)	9	21
Cost per SSC[1] (b)	$15,332	$15,332
Per Patient Complication Cost (a*b)/n	$1,061	$2,477
Per Patient Therapy Cost*	$495	$39
Total Cost Per Patient	$1,556	$2,516
Potential Per Incision Savings Using Prevena Therapy	**$960**	

Cost Savings



Reduction in per patient cost for SSC
$1,556 Prevena Therapy vs. $2,516 SOC

1. Hou Y. Incidence and impact of surgical site infections and surgical site complications on length of stay and cost of care in orthopedic open surgeries for spine, THA/TKA, and trauma. HEOR-2021-002-DAR.

Cost per SSC is based on SSC cost for population with CCI>0 to represent High-Risk Study Population.

*3M™ Prevena™ Peel and Place System Kit and AQUACEL® Ag SURGICAL price are estimates; individual prices may vary.

The above model uses selected study data to provide an illustration of estimates of costs for use of the Prevena Therapy or AQUACEL® Ag SURGICAL. This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.

Doman DM, Young AM, Buller LT, Deckard ER, Meneghini RM. Comparison of Surgical Site Complications With Negative Pressure Wound Therapy vs Silver Impregnated Dressing in High-Risk Total Knee Arthroplasty Patients: A Matched Cohort Study. Journal of Arthroplasty. 2021; 36(10):3437-3442

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

1 LOE

THA

Study Design

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

Study Purpose

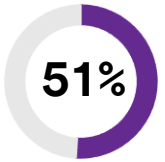
The purpose of the Pachowsky study was to evaluate the effect of closed incision negative pressure therapy (ciNPT) on incisional healing and the prevention of seromas in clean, closed incisions after total hip arthroplasty (THA).

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.

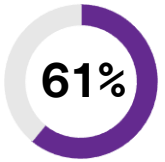
Results

Wound Complications



Fewer Patients with Seromas at Day 10
44% (4/9) Prevena Therapy vs.
90% (9/10) Control

Readmissions



Reduction in Mean Seroma Volume at Day 10*
1.97 mL Prevena Therapy vs.
5.08 mL Control
(p=0.021)*

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

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.

3M™ Prevena™ Therapy for the high-risk TKA or THA patient.

How to identify the patient as high-risk for surgical site infection or complication:

Primary hip and knee arthroplasty

Common risk factors to identify high-risk Patients:

- BMI > 35 kg/m^2
- non-aspirin anticoagulation
- active tobacco use
- diabetes mellitus
- autoimmune disease

Additional risk factors considered by Doman at al.

- chronic kidney disease
- *Staphylococcus aureus* nasal colonization

Additional risk factors considered by Anatone et al.

- prior surgery to the operative joint

Doman DM, Young AM, Buller LT et al. Comparison of Surgical Site Complications With Negative Pressure Wound Therapy vs Silver Impregnated Dressing in High-Risk Total Knee Arthroplasty Patients: A Matched Cohort Study. Journal of Arthroplasty. 2021; 36(10):3437-3442

Anatone A, Shah R, Jennings E et al. A risk-stratification algorithm to reduce superficial surgical site complications in primary hip and knee arthroplasty. Arthroplasty Today 2018; 4:493-498

Revision hip and knee arthroplasty

Patients are high-risk if they have ≥ 1 of the following risk factors:

- BMI > 35kg/m^2
- use of non-aspirin blood thinners postoperatively
- current/previous diagnosis of peripheral vascular disease
- current tobacco use
- history of prior infection history at operative site
- insulin-dependent diabetes
- current use of immunomodulators or corticosteroids
- ongoing malignancy excluding localized skin cancer
- rheumatoid arthritis
- renal failure or dialysis
- malnutrition
- liver disease
- solid organ transplant recipients
- human immunodeficiency virus infection

Higuera et al. include operative limb lymphedema as an additional risk factor;
Newman et al. included depression as an additional risk factor.

Higuera-Rueda C, Emara AK, Nieves-Malloure Y et al. 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 Controlled Trial. J Arthroplasty. 2021;36(7S):S295-S302.e14

Newman JM, Siqueira MBP, Klika A et al. 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. Journal of Arthroplasty 2019; 34(3):554-559

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