



Prevena™
Incision Therapy

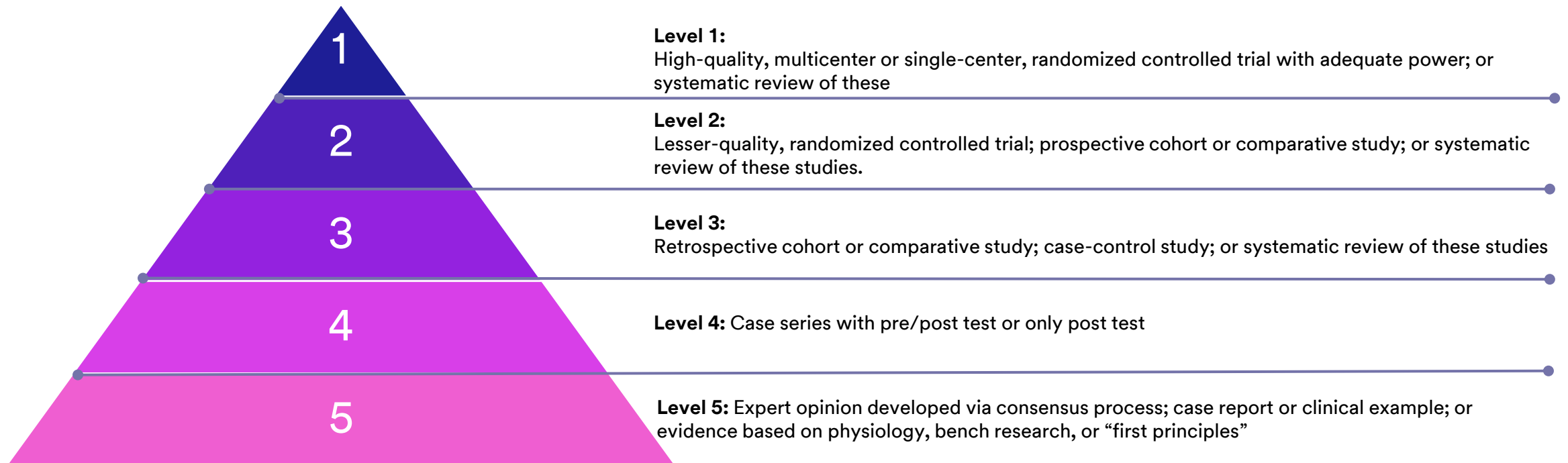
Clinical Evidence Summaries

General Surgery



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 200+ journal publications focused on closed incision negative pressure therapy (ciNPT)/3M™ Prevena™ Therapy
- The Prevena Therapy clinical evidence summaries presented adhere to the American Society of Plastic Surgeons (ASPS) Evidence Rating Scale¹ 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 Prevena Therapy has been growing steadily since its launch in 2010
- The table listed below is based on the Evidence Rating Scale for Therapeutic Studies developed by the American Society of Plastic Surgeons (ASPS)¹

Surgery Type	ASPS Level of Evidence	First Author (Year) (OUS)	Surgical Incision Type	Standard Dressing	Postoperative Clinical Endpoints* and institutional Health Economics
Laparotomy	1	Javed (2019)	Open pancreaticoduodenectomy	Standard wound closure	Surgical Site Infection (SSI), Superficial SSI (sSSI), Cost of SSI
	3	Zaidi (2016)	High-risk general surgery laparotomy	Adherent Gauze Dressing	Wound Complication, Deep SSI (dSSI)
		Curran (2019)	High-risk colorectal surgery laparotomy	Standard postoperative wound care	Wound Complication, Unplanned Readmission
Emergency Laparotomy	3	Chung (2021)	Emergency Laparotomy	Opsite dressing	SSI
		Liu (2021)	Emergency Laparotomy	Opsite Post-Op	SSI, Wound complication, Hospital Length of Stay (LOS), Wound-related readmissions
Abdominal Wall Reconstruction	3	Ayuso (2021)	Open abdominal wall reconstruction with Concomitant Panniculectomy	Standard Surgical Dressing	Wound complication, wound breakdown, ROR
		Licari (2020)	Ventral hernia repair	Adherent gauze dressings	sSSI, dSSI, Major Wound Complications, LOS, HE: cost per Patient

* 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.

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

Reduced the risk of Surgical Site Infections & lower Cost of Care with 3M™ Prevena™ Therapy

Javed A, Teinor J, Wright M, Ding D, Burkhart R, Hundt J, Cameron J, Makary M, He J, Eckhauser F, Wolfgang C, Weiss M. Negative pressure wound therapy for surgical-site infections: A randomized trial. *Annals of Surgery*. 2019; 269(6):1034-1040.

Study Design

Randomized Controlled Trial, Single-Center

Study Purpose

The purpose of the Javed RCT was to evaluate efficacy of closed incision negative pressure therapy (ciNPT), Prevena Therapy, to decrease surgical site infections (SSI) after open pancreaticoduodenectomy.

Methods

- Patients undergoing pancreaticoduodenectomy procedures were eligible if considered to be high-risk for SSI.
- Patients who received neoadjuvant chemotherapy and/or preoperative biliary stents were considered high risk.
- A total of 123 patients analyzed: Prevena Therapy (n=62) v. operative dressings (removed on postoperative day two) (n=61)
- Preoperative and operative characteristics were not significantly different between the two groups.
- The primary outcome was 30-day SSI (superficial or deep). Secondary outcomes included length of ICU stay, length of hospital stay, reoperation, readmission, and allergic reactions.

Key Results

Surgical Site Infections

↓ 69%

Reduction in SSIs*

9.7% (6/62) Prevena Therapy vs. 31.1% (19/61) Standard Dressing (p=0.003)*

Superficial Surgical Site Infection (sSSI)

↓ 77%

Reduction in superficial SSI*

6.5% (4/62) Prevena Therapy vs. 27.9% (17/61) Standard Dressing (p=0.002)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study

* Statistically significant (p<0.05)

Summary

- This randomized controlled trial from Johns Hopkins Hospital demonstrated significantly lower SSI rates in high-risk patients receiving Prevena Therapy after pancreaticoduodenectomy surgery (31.1% vs. 9.7%; p=0.003)*.
- The SSI rate for all patients (low and high risk) undergoing pancreaticoduodenectomy at this institution during the same time period was 16.3%.
- The authors noted 30-day readmission rate of 19.7% in the standard dressing group vs. 8.1% in the Prevena Therapy group, however this was not statistically significant (p = 0.07). There were no statistically significant differences in the other secondary outcome measures.
- SSIs resulted in an increased hospitalization cost of \$9,778 per patient as determined by the authors.
- Implementing Prevena Therapy into surgical practice can help reduce potential complications and associated costs to patient health and care.

Illustration of the 3M™ Prevena™ Therapy Incision Management System Cost-Effectiveness Based on Javed et al Outcomes

Hypothetical Economic Model	Prevena Therapy	Standard Dressing
Number of Patients (n)	62	61
Number of Infections(a)	6	19
Cost per SSI ¹ (b)	\$18,533	\$18,533
Per Patient Infection Cost [c=(a*b)/n]	\$1,794	\$5,773
Per Patient Therapy Cost* (d)	\$830	---
Total Cost Per Patient (c+d)	\$2,624	\$5,773
Potential Per Patient Savings Using Prevena Therapy	\$3,149	

1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2022 Nov 8;11:1-18.

*3M™ Prevena™ Plus Customizable Dressing 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 Standard of Care. 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.

Reference: Javed A, Teinor J, Wright M, Ding D, Burkhart R, Hundt J, Cameraon J, Makary M, He J, Eckhauser F, Wolfgang C, Weiss M. Negative pressure wound therapy for surgical-site infections: A randomized trial. Annals of Surgery. 2019; 269(6):1034-1040

Complication reduction in high-risk general surgery patients following laparotomy

Zaidi A, El-Masry S. Closed-incision negative-pressure therapy in high-risk general surgery patients following laparotomy: a retrospective study. *Colorectal Dis.* 2017;19(3):283-287.

Study Design

Retrospective observational study (Level III)

Study Purpose

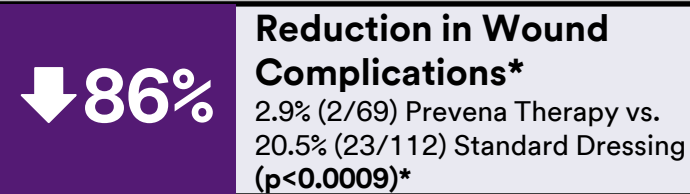
The aim of this study was to compare the rate of wound complications requiring intervention in high-risk surgical patients who received closed incision negative pressure therapy (ciNPT), 3M™ Prevena™ Therapy, or adherent gauze dressing following laparotomy

Methods

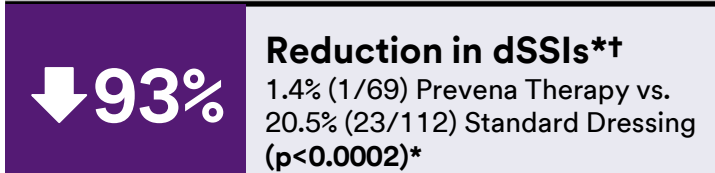
- Charts were retrospectively reviewed for 181 high-risk patients who presented for elective or emergency laparotomy; Prevena Therapy (n=69); Standard Dressing (n=112).
- High-risk inclusion criteria were obesity (BMI ≥ 35 kg/m²), or ≥ 2 of the following risk factors: malignancy, smoking, immunosuppression, malnutrition, emergency surgery, diffuse atherosclerotic disease.
- Prevena Therapy (n=69) was applied over the closed incision in the operating room immediately after skin closure and remained in place for 7 days.
- All patients were followed until postoperative day 30

Key Results

Wound Complication



Deep Surgical Site Infections (dSSIs)†



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

Summary

- Prevena Therapy was a safe and effective method of postsurgical management in general surgery patients considered to have risk of developing wound complications following emergency or elective laparotomy.
- The rate of deep SSI requiring intervention was significantly reduced in patients receiving Prevena Therapy (1.4%) vs. Standard Dressing (20.5%); (**p<0.0002**)*
- There was not a statistically significant difference in wound dehiscence.
- The study concluded that Prevena Therapy was associated with a positive clinical outcome.

† **NOTE:** The use of Prevena Therapy for reduction in the incidence of deep SSI has not been reviewed by the U.S. FDA

Illustration of the 3M™ Prevena™ Therapy Incision Management System Cost-Effectiveness Based on Zaidi et al Outcomes

Hypothetical Economic Model	Prevena Therapy	Standard Dressing
Number of Patients (n)	69	112
Number of Deep Surgical Site Infections (a)	1	23
Cost per Deep SSI ¹ (b)	\$21,142	\$21,142
Per Patient Infection Cost [c=(a*b)/n]	\$306	\$4,342
Per Patient Therapy Cost* (d)	\$830	---
Total Cost Per Patient (c+d)	\$1,136	\$4,342
Potential Per Patient Savings Using Prevena Therapy	\$3,205	

1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2022 Nov 8;11:1-18.

*3M™ Prevena™ Plus Customizable Dressing is an estimate; individual prices may vary

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Reference: Zaidi A, El-Masry S. Closed incision negative pressure therapy in high-risk general surgery patients following laparotomy: a Prevena™ study. Colorectal Disease 2016; 19(3):283-287

Reduction in Rates of Wound Complication and Unplanned Readmissions in High-Risk Open Colorectal Surgery

Curran T, Alvarez D, Pastrana Del Valle J, Cataldo TE, Poylin V, Nagle D. Prophylactic closed-incision negative-pressure wound therapy is associated with decreased surgical site infection in high-risk colorectal surgery laparotomy wounds. *Colorectal Dis.* 2019;21(1):110-118.

Study Design

Retrospective comparative cohort study (Level III)

Study Purpose

The aim of this study was to compare the incidence of surgical site infection (SSI) in colorectal surgery patients who received closed incision negative pressure therapy, 3M™ Prevena™ Therapy, or standard dressing following high-risk open colorectal surgery.

Methods

- National Surgical Quality Improvement Program (NSQIP) reviewed patients at high-risk for SSI undergoing open abdominal colorectal surgery were selected.
- NSQIP facilitated standardized assignment of SSI status with uniform 30-day follow-up
- High-risk defined patients defined as having ≥ 1 of the following risk factors: pre or post-operative stoma, diabetes, obesity, preoperative steroid or immunosuppressant use, contaminated or dirty wound.
- 77 patients received Prevena Therapy while 238 patients received Standard Dressings; within the Standard Dressing group a risk matched cohort subset of 79 patients was identified and presented here.
- Outcomes reported for matched cohort was a composite of superficial SSI, deep SSI or dehiscence at 30 days, as well as unplanned re-admission

Key Results

Overall Wound Complications

↓74%
Reduction in Wound Complications*
 6.5% (5/77) Prevena Therapy vs. 25.3% (20/79) Standard Dressing (p<0.01)*

Unplanned Readmissions

↓67%
Reduction unplanned readmissions*
 8% Prevena Therapy vs. 24% Standard Dressing (p<0.01)*

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

Summary

- The study concluded that Prevena Therapy was associated to a significant reduction in overall wound complications.
- In the overall patient population Surgical site infection was higher in patients receiving standard dressings 15% (35/238) compared to patients receiving Prevena Therapy 7% (5/77) (p = 0.05).
- Within the matched cohorts there was a significant reduction in wound complications, and superficial SSI (p<0.01)*. However differences in deep SSI and dehiscence were not significantly significant.
- In addition the authors conclude Prevena Therapy offers potential for improvement in quality outcomes for high-risk patients undergoing open colorectal surgery.

Illustration of the 3M™ Prevena™ Therapy Incision Management System Cost-Effectiveness Based on Curran et al Outcomes

Hypothetical Economic Model	Prevena Therapy	Standard Dressing
Number of Patients (n)	77	79
Number of Surgical Site Complications (a)	5	20
Cost per SSC ¹ (b)	\$17,142	\$17,142
Per Patient Complication Cost [c=(a*b)/n]	\$1,113	\$4,340
Per Patient Therapy Cost* (d)	\$830	---
Total Cost Per Patient (c+d)	\$1,943	\$4,340
Potential Per Patient Savings Using Prevena Therapy	\$2,397	

1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site complications on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2023 Aug;14:31-45.

*3M™ Prevena™ Customizable 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 Standard of Care. 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.

Reference: Curran T, Alvarez D, Pastrana Del Valle J, Cataldo T, Poylin V, Nagel D. Prophylactic closed incision negative pressure wound therapy is associated with decreased surgical site infection in high-risk colorectal surgery laparotomy wounds. Colorectal Disease. 2019; 21(1):110-118.

Reduction of Surgical Site Infections rates with 3M™ Prevena™ Therapy

Chung J, Ali O, Hawthornthwaite E, Watkinson T, Blyth U, McKigney N, Harji D, Griffiths B. Closed incision negative pressure wound therapy is associated with reduced surgical site infection after emergency laparotomy: A propensity matched-cohort analysis. *Surgery* 2021; 170(5):1568-1573.

Study Design

Retrospective comparative cohort study (Level III)

Study Purpose

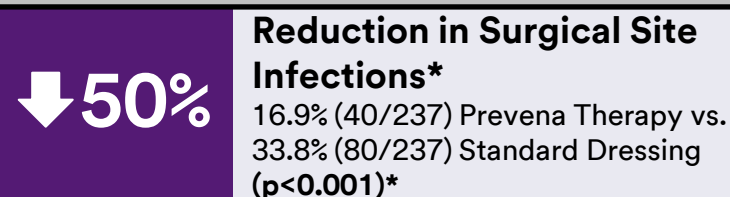
The purpose of the study was to evaluate with a propensity matched analysis whether the use of closed incision negative pressure therapy (ciNPT), Prevena Therapy, decreases surgical site infections (SSI) compared to standard surgical dressings after emergency laparotomy.

Methods

- A registry-based, cohort study was undertaken using data the NELA registry
- The National Emergency Laparotomy Audit (NELA) is part of the National Clinical Audit and Patient Outcomes Program (NCAPOP), overseen by the Healthcare Quality Improvement Partnership (HQIP) in the UK.
- 1484 patients identified from the NELA dataset
- Propensity score matching resulted in two equally matched cohorts with 237 patients in each arm
- Prevena Therapy applied of midline incision and left in situ for 7 days or until discharge if before
- Primary outcome was SSI per Centers for Disease Standard Dressing criteria. Secondary outcomes included 30-day postoperative morbidity and grade, duration of stay, 30-day mortality, and readmission rates.

Key Results

Surgical Site Infection (SSIs)



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

Additional Outcomes

Classification of Surgical Site Infection	Prevena Therapy	Standard Dressing
Superficial	8.0% (19/237)	19.8% (47/237)
Deep†	1.3% (3/237)	5.1% (12/237)
Organ Space	5.9% (14/237)	7.2% (17/237)
Unspecified	1.7% (4/237)	1.7% (4/237)

† NOTE: The use of Prevena Therapy for reduction in the incidence of deep SSI and organ space infections has not been reviewed by the U.S. FDA

Summary

- This registry-based cohort study using the NELA registry uses real world data to shows the use of Prevena Therapy in emergency laparotomy patients is associated with a significant reduction of surgical site infections (33.8% vs 16.9%; p<0.001*).
- The study also demonstrated a reduction in both superficial and deep SSI. However, secondary outcomes were not statistically significant.
- Bivariate logistic regression revealed the use of a standard surgical dressing and undergoing an emergency colorectal procedure were associated with a higher risk of developing an SSI (p = 0.01)*.

Illustration of the 3M™ Prevena™ Therapy Incision Management System Cost-Effectiveness Based on Chung et al Outcomes

Hypothetical Economic Model	Prevena Therapy	Standard Dressing
Number of Patients (n)	237	237
Number of Infections(a)	40	80
Cost per SSI ¹ (b)	\$18,533	\$18,533
Per Patient Infection Cost [c=(a*b)/n]	\$3,128	\$6,256
Per Patient Therapy Cost* (d)	\$830	---
Total Cost Per Patient (c+d)	\$3,958	\$6,256
Potential Per Patient Savings Using Prevena Therapy	\$2,298	

1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2022 Nov 8;11:1-18

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Reference: Chung J, Ali O, Hawthornthwaite E, Watkinson T, Blyth U, McKigney N, Harji D, Griffiths B. Closed incision negative pressure wound therapy is associated with reduced surgical site infection after emergency laparotomy: A propensity matched-cohort analysis. Surgery 2021; 170(5):1568-1573.

Reduction of Wound Complication rates and Associated Resource Burden after Emergency Laparotomy

Liu D, Cheng C, Islam R, Tacey M, Sidhu A, Lam D, Strugnell N. Prophylactic Negative-pressure Dressings Reduce Wound Complications and Resource Burden After Emergency Laparotomies. J Surg Res. 2021 Jan;257:22-31.

Study Design

Retrospective comparative cohort study (Level III)

Study Purpose

The purpose of study was to examine whether closed incision negative pressure therapy, 3M™ Prevena™ Therapy, reduced the rate of wound complications following emergency laparotomy surgery.

Methods

- 227 consecutive laparotomies reviewed retrospectively between Jan 2018 and October 2019 at Northern Hospital, Victoria, Australia.
- 70 patients receiving Prevena Therapy were 1:1 propensity score matched to patients receiving standard dressings.
- Prevena Therapy wounds closed with staples and NPD applied for 5-7 days. Standard dressings in the comparison group applied for 7 days.
- Primary endpoint was SSI
- Secondary Endpoints included length of post operative hospital stay, wound dehiscence, hematoma, hospital service utilization, and readmissions.

Key Results

Wound Complications

↓59% **Reduction in Wound Complications***
 12.9% (9/70) Prevena Therapy vs. 31.4% (22/70) Standard Dressing (p=0.010)*

Hospital Length of Stay

↓28% **Reduction in Length of Stay***
 10.5 ± 6.3 Prevena Therapy vs. 14.6 ± 11.2 Standard Dressing (p=0.010)*

Surgical Site Infections (SSIs)

↓68% **Reduction in SSI***
 8.6% (6/70) Prevena Therapy vs. 27.1% (19/70) Standard Dressing (p=0.006)*

Wound-related Readmissions

↓100% **Reduced hospital readmissions***
 0% (0/70) Prevena Therapy vs. 5.7% (4/70) Standard Dressing (p=0.042)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study

* Statistically significant (p<0.05)

Additional Outcomes

	Prevena Therapy	Standard Dressing	p-value
Wound Breakdown / Wound Dehiscence†	4.3% (3/70)	14.3% (10/70)	P=0.054

† NOTE: The use of Prevena Therapy for reduction in the incidence of dehiscence has not been reviewed by the U.S. FDA

Summary

- The use of Prevena Therapy reduced the rates of total wound complications, SSIs, and dehiscence following emergency laparotomy. This reduction in wound complication rates resulted in substantial health resource savings with reduced length of stay and wound-related readmissions to the hospital.
- Further multivariate analysis confirmed that Prevena Therapy was associated with reduced infection risk (OR 0.30; 95% CI: 0.12,0.78, P = 0.013) and reduced risk of wound breakdown (OR 0.18, 95% CI: 0.04-0.83, P = 0.034).

Illustration of the 3M™ Prevena™ Therapy Incision Management System Cost-Effectiveness Based on Liu et al Outcomes

Surgical Site Infections

Hypothetical Economic Model	Prevena Therapy	Standard Dressing
Number of Patients (n)	70	70
Number of Infections (a)	6	19
Cost per Infection ¹ (b)	\$18,533	\$18,533
Per Patient Infection Cost [c=(a*b)/n]	\$1,589	\$5,030
Per Patient Therapy Cost	\$830	---
Total Cost Per Patient (c+d)	\$ 2,419	\$5,030
Potential Per Patient Savings Using Prevena Therapy	\$2,612	

Wound Complications

Hypothetical Economic Model	Prevena Therapy	Standard Dressing
Number of Patients (n)	70	70
Number of Complications (a)	9	22
Cost per Complication ² (b)	\$17,142	\$17,142
Per Patient Complication Cost [c=(a*b)/n]	\$2,204	\$5,387
Per Patient Therapy Cost* (d)	\$830	---
Total Cost Per Patient (c+d)	\$3,034	\$5,387
Potential Per Patient Savings Using Prevena Therapy	\$2,354	

1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site infections on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2022 Nov 8;11:1-18.

2. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site complications on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2023 Aug;14:31-45.

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Reference: Liu DS, Cheng C, Islam R, Tacey M, Sidhu A, Lam D, Strugnell N. Prophylactic Negative-pressure Dressings Reduce Wound Complications and Resource Burden After Emergency Laparotomies. J Surg Res. 2021 Jan;257:22-31.

3M™ Prevena™ Therapy for open abdominal wall reconstruction with concomitant panniculectomy

Ayuso SA, Elhage SA, Okorji LM, et al. Closed-Incision Negative Pressure Therapy Decreases Wound Morbidity in Open Abdominal Wall Reconstruction With Concomitant Panniculectomy. Ann Plast Surg. 2022;88(4):429-433.

Study Design

Retrospective Cohort Study (Level III)

Study Purpose

To evaluate the use of closed-incision negative pressure therapy (3M™ Prevena™ Therapy) and its effects on postoperative wound complications in open Abdominal Wall Reconstruction (AWR) patients with Concomitant Panniculectomy (CP)

Methods

- Prospective institutional database identified 67 patients that received Prevena Therapy. These patients were matched 1:1 to 67 historical patients that received standard surgical dressings.
- In the study period, patient prehabilitation and perioperative protocols at the institution were the same which aids in eliminating confounders.
- Prevena Therapy was used for 7 days
- Concomitant Panniculectomy makes this a study on high-risk patients
- Primary outcomes: wound complications defined as seroma requiring drainage, cellulitis requiring antibiotics, deep wound infection, and superficial wound breakdown

Key Results

Wound Complications

↓ **56%**

Reduction in Wound Complications*
15.6% Prevena Therapy vs. 35.5% Standard Dressing (p=0.01)*

Return to Operating Room

↓ **100%**

Reduction in number of OR Visits*
0% Prevena Therapy vs. 13.3% Standard Dressing (p<0.01)*

Wound Breakdown

↓ **84%**

Reduction in Superficial Wound Breakdown*
3.1% Prevena Therapy vs. 19.7% Standard Dressing (p<0.01)*

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

† **NOTE:** The use of Prevena Therapy for reduction in the incidence of wound breakdown has not been reviewed by the U.S. FDA

Summary

- Patients undergoing abdominal wall reconstruction with concomitant panniculectomy can be at higher risk for wound complications due to the need for large incisions and tissue undermining.
- In this study, the use of Prevena Therapy significantly decreased the risk of postoperative wound complications, including superficial wound breakdown. Reductions in the other wound complication types were not statistically significant.
- The study also demonstrated the lessened need for wound-related reoperations in Prevena Therapy patients. Reductions in length of stay, readmission, and hernia recurrence were not statistically significant.
- Using the Carolinas Equation for Determining Associated Risks (CeDAR) application, the absolute risk reduction for wound complications was calculated to be 11.9% when Prevena Therapy was used.
- In a logistic regression analysis, the use of Prevena Therapy was predictive of a lower rate of wound complications (95% CI 0.14,0.86; p = 0.02).

Illustration of the 3M™ Prevena™ Therapy Incision Management System Cost-Effectiveness Based on Ayuso et al Outcomes

Hypothetical Economic Model	Prevena Therapy	Standard Dressing
Number of Patients (n)	100	100
Number of Surgical Site Complications (a)	16	36
Cost per SSC ¹ (b)	\$9,526	\$9,526
Per Patient Complication Cost [c=(a*b)/n]	\$1,524	\$3,429
Per Patient Therapy Cost* (d)	\$830	---
Total Cost Per Patient (c+d)	\$2,354	\$3,429
Potential Per Patient Savings Using Prevena Therapy	\$1,075	

1. Hou Y, Collinsworth A, Hasa F, Griffin L. Incidence and impact of surgical site complications on length of stay and cost of care for patients undergoing open procedures. Surg Open Sci. 2023 Aug;14:31-45

*3M™ Prevena™ Plus Customizable Dressing 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 Standard Dressings. This model is an illustration and not a guarantee of actual individual costs, savings, outcomes or results. Results are based on selected study data and may not be typical. The hospital is advised to use this model as an illustration only to assist in an overall assessment of products and pricing.

Reference: Ayuso SA, Elhage SA, Okorji LM, et al. Closed-Incision Negative Pressure Therapy Decreases Wound Morbidity in Open Abdominal Wall Reconstruction With Concomitant Panniculectomy. Ann Plast Surg. 2022;88(4):429-433



Reduction of Wound Complication Risk and Length of Stay with 3M™ Prevena™ Therapy (1/2)

Level of Evidence

3

Abdominal Wall Reconstruction

Licari L, Campanella S, Carolla C, Viola S, Salamone G. Closed incision negative pressure therapy achieves better outcome than standard wound care: clinical outcome and cost-effectiveness analysis in open ventral hernia repair with synthetic mesh positioning. Cureus. 2020. 12(5):e8283

Study Design

Retrospective comparative cohort study (Level III)

Study Purpose

The purpose of the study was to evaluate closed incision negative pressure therapy (ciNPT), Prevena Therapy, to Standard Dressing in regard to post-operative clinical outcomes and economical benefits for use in ventral hernia repair (VHR) with use of synthetic mesh.

Methods

- Patients who underwent elective open VHR with synthetic mesh from January 2015 to December 2017 at a single center in Italy.
- Prevena Therapy (n=70) v. Standard Dressing (n=110)
- Patients followed for 90 days postoperatively
- High Risk Inclusion Criteria: ≥ 1 risk factor
 - Age > 65
 - Pre-existing wound infection
 - pulmonary disease
 - BMI > 25
 - Malnutrition
 - Ascites
 - Hypertension
 - Diabetes
 - active smoking
 - previous radiation therapy
 - steroid use
 - immunosuppression
 - chronic inflammatory disease

Key Results

Major Wound Complications

↓71%

Reduction in Major Complications*
12.8% (9/70) Prevena Therapy vs. 43.6% (48/110) Standard Dressing (p<0.00001)*

Hospital Length of Stay

↓50%

Reduction in mean in-hospital stay*
3 ± 1.37 Prevena Therapy vs. 6 ± 2.39 Standard Dressing (p<0.00001)*

Superficial Infection (sSSI)

↓81%

Reduction in Superficial Infections*
4.3% (3/70) Prevena Therapy vs. 22.7% (25/110) Standard Dressing (p=0.0006)*

Reduced Total cost per patient

↓26%

Reduced mean estimated cost per patient*
Prevena inpatient cost: 4,230 € ± 1,928.56
Standard Dressing inpatient cost: 5,695 € +3,142.27; (p=0.02)*
Per Patient Cost Saving: 1,465€

Deep Infections (dSSI)†

↓100%

Reduction in Deep Infections†**
0% (0/70) Prevena Therapy vs. 6.4% (7/110) Standard Dressing (p=0.04)*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study

* Statistically significant (p<0.05)

† **NOTE:** The use of Prevena Therapy for reduction in the incidence of deep SSI has not been reviewed by the U.S. FDA



Reduction of Wound Complication Risk and Length of Stay with 3M™ Prevena™ Therapy (2/2)

Licari L, Campanella S, Carolla C, Viola S, Salamone G. Closed incision negative pressure therapy achieves better outcome than standard wound care: clinical outcome and cost-effectiveness analysis in open ventral hernia repair with synthetic mesh positioning. Cureus. 2020. 12(5):e8283

Study Design

Retrospective comparative cohort study (Level III)

Study Purpose

The purpose of the study was to evaluate closed incision negative pressure therapy (ciNPT), Prevena Therapy, to Standard Dressing in regard to post-operative clinical outcomes and economical benefits for use in ventral hernia repair (VHR) with use of synthetic mesh.

Methods

- Patients who underwent elective open VHR with synthetic mesh from January 2015 to December 2017 at a single center in Italy.
- Prevena Therapy (n=70) v. Standard Dressing (n=110)
- Patients followed for 90 days postoperatively
- High Risk Inclusion Criteria: ≥ 1 risk factor
 - Age > 65
 - Pre-existing wound infection
 - pulmonary disease
 - BMI > 25
 - Malnutrition
 - Ascites
 - Hypertension
 - Diabetes
 - active smoking
 - previous radiation therapy
 - steroid use
 - immunosuppression
 - chronic inflammatory disease

Additional Outcomes

	Prevena Therapy	Standard Dressing	p-value
Re-hospitalization rate	2.8% (2/70)	10% (11/110)	p=0.08
Fever (minor complication)	28.6% (20/70)	54.4% (60/110)	p=0.0006*
Leukocytosis (minor complication)	21.4% (15/70)	45.4% (50/110)	P=0.001*

Calculation(s) are derived based on the relative patient group incidence rate reported in this study

* Statistically significant (p<0.05)

† **NOTE:** The use of Prevena Therapy for reduction in the incidence of fever and leukocytosis has not been reviewed by the U.S. FDA

Summary

- The use of Prevena Therapy significantly decreased the rate of complications and reduced the length of stay for high-risk populations following VHR with synthetic mesh significantly while the rate of seroma and dehiscence was not statistically different.
- The improved clinical outcome with Prevena Therapy resulted in a positive economic outcome based on reduced cost for surgery related inpatient stay as well as reduced cost to manage complications post discharge (readmissions and outpatient care).

3M™ Prevena™ Therapy for the high-risk General abdominal surgery patient

Inclusion criteria for patients at high-risk for complications:

Open Colorectal Surgery

Curran T, Alvarez D, Pastrana Del Valle J, Cataldo T, Poylin V, Nagel D. Prophylactic closed incision negative pressure wound therapy is associated with decreased surgical site infection in high-risk colorectal surgery laparotomy wounds. *Colorectal Disease*. 2019; 21(1):110-118.

Patient Risk Factors:

- Diabetes
- Obesity
- preoperative steroid or immunosuppressant use

Procedure & Wound Risk Factors:

- Pre- or post-operative stoma,
- contaminated or dirty wound

Pancreaticoduodenectomy

Javed A, Teinor J, Wright M, Ding D, Burkhardt R, Hundt J, Cameron J, Makary M, He J, Eckhauser F, Wolfgang C, Weiss M. Negative pressure wound therapy for surgical-site infections: A randomized trial. *Annals of Surgery*. 2019; 269(6):1034-1040.

Patients are high-risk if they have a risk score of ≥ 1 **

- preoperative bile stent/drain (1 point)
- neoadjuvant chemotherapy (1 point)

**Poruk et al. A novel, validated risk score to predict surgical site infection after pancreaticoduodenectomy. *HBP (Oxford)*. 2016;18:893-899.

Laparotomy

Zaidi A, El-Masry S. Closed incision negative pressure therapy in high-risk general surgery patients following laparotomy: a PREVENA™ study. *Colorectal Disease* 2016; 19(3):283-287

Patients are high-risk if they are obese (BMI ≥ 35 kg/m²) or have ≥ 2 of the following risk factors:

- Malignancy
- Smoking
- Immunosuppression
- Malnutrition
- diffuse atherosclerotic disease
- emergency surgery

Ventral Hernia Repair

Licari L, Campanella S, Carolla C, Viola S, Salamone G. Closed incision negative pressure therapy achieves better outcome than standard wound care: clinical outcome and cost-effectiveness analysis in open ventral hernia repair with synthetic mesh positioning. *Cureus*. 2020. 12(5):e8283

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

Patient Risk Factors:

- Age > 65
- active smoking
- BMI > 25
- Malnutrition
- Diabetes
- Hypertension
- pulmonary disease
- steroid use or Immunosuppression
- chronic inflammatory disease

Procedure & Wound Risk Factors:

- Pre-existing wound infection
- Ascites
- previous radiation therapy

High risk procedures (All Patients high risk)

Abdominal Wall Reconstruction with Concomitant Panniculectomy

Ayuso SA, Elhage SA, Okorji LM, Kercher KW, Colavita PD, Heniford BT, Augenstein VA. Closed-Incision Negative Pressure Therapy Decreases Wound Morbidity in Open Abdominal Wall Reconstruction With Concomitant Panniculectomy. *Ann Plast Surg*. 2022; 88(4):429-433

Emergency Laparotomy

Chung J, Ali O, Hawthornthwaite E, Watkinson T, Blyth U, McKigney N, Harji D, Griffiths B. Closed incision negative pressure wound therapy is associated with reduced surgical site infection after emergency laparotomy: A propensity matched-cohort analysis. *Surgery* 2021; 170(5):1568-1573.

Liu DS, Cheng C, Islam R, Tacey M, Sidhu A, Lam D, Strugnelli N. Prophylactic Negative-pressure Dressings Reduce Wound Complications and Resource Burden After Emergency Laparotomies. *J Surg Res*. 2021 Jan;257:22-31.