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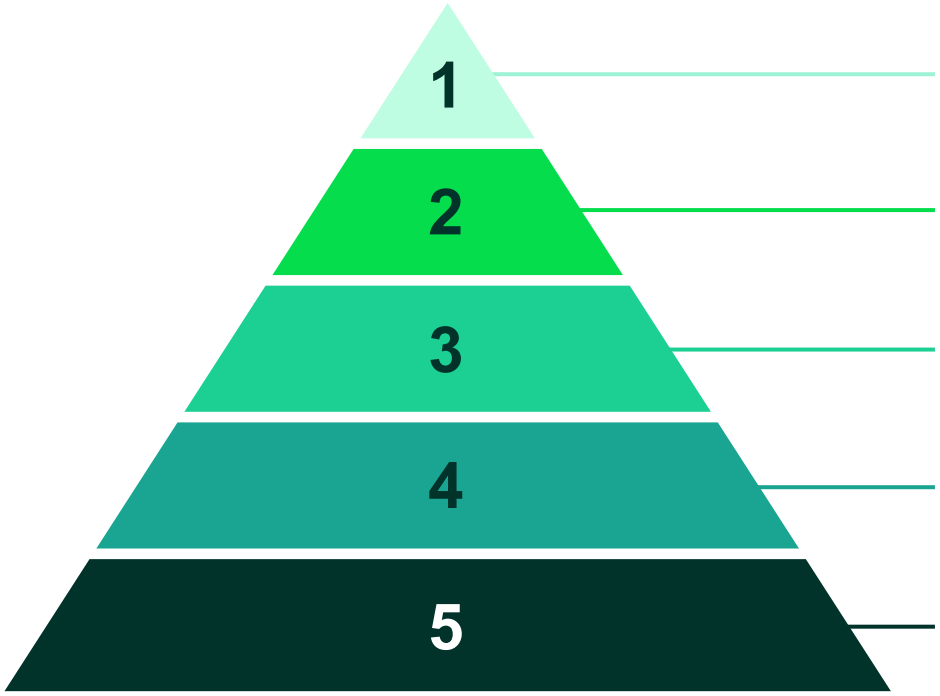
3M™ Veraflo™ Therapy Clinical Evidence Summary

Evidence Rating Scale[1]



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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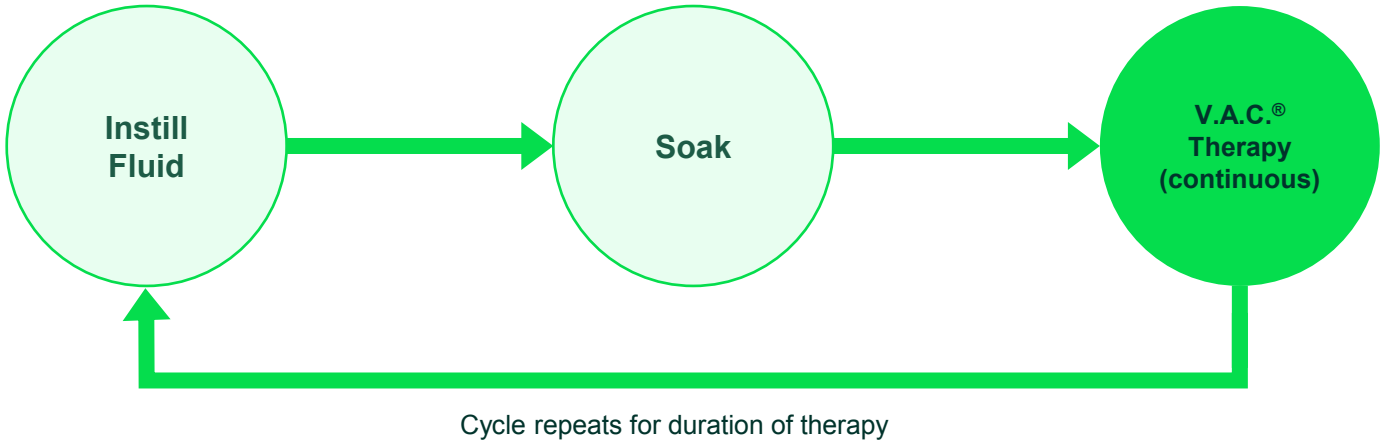
Solventum™ Veraflo™ Therapy			
First Author (Year)	**Surgical Specialty**	ASPS Level of Evidence (LOE)	Wound Type
Milcheski DA (2024)	**Trauma**	1	**Trauma Surgery**
O'Connor MJ (2024)	**Mixed**	2	**Surgical**
Afzal H (2024)	**General surgery**	3	**Necrotizing Fasciitis**
Collinsworth AW (2022)	**General wound care**	3	**Mixed**
Gabriel A (2021)	**Mixed**	2	**Surgical**
Kim PJ (2022)	**Multidisciplinary**	5	**Trauma Surgery**
Kim PJ (2020)	**Plastic surgery**	3	**Mixed, infected**
Cole W (2020)	**Vascular surgery**	3	**Mixed/chronic lower extremity**
Chowdhry SA (2019)	**Cardiothoracic surgery**	3	**Sternal**
Kim PJ (2015)	**Plastic surgery**	1b	**Infected wounds requiring surgical debridement**
Gabriel A (2014)	**Plastic surgery**	3	**Mixed complex or infected upper or lower extremity or trunk wounds**
Kim PJ (2014)	**Plastic and reconstructive**	3	**Mixed, infected**

3M™ Veraflo™ Therapy

Veraflo Therapy combines the benefits of 3M™ V.A.C.® Therapy with an instillation therapy option featuring both **automated volumetric delivery** of topical wound treatment solutions with a **programmable soak feature** which allows solution to dwell in the wound for thorough contact.

Veraflo Therapy (NPWTi-d)



Veraflo Therapy can help:

Cleanse the wound with instillation of topical wound cleansers in a consistent, controlled manner

Treat the wound with the instillation of appropriate topical antimicrobial and antiseptic solutions and the removal of infectious material

Prepare the wound for delayed primary or secondary closure

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Milcheski (2024)

A randomized controlled trial demonstrated 3M™ Veraflo™ Therapy can improve patient outcomes in acute traumatic complex wounds

Milcheski D, Clivatti G, Santos R, González C, Monteiro A, Gemperli R, Effectiveness of negative-pressure wound therapy with instillation compared to standard negative-pressure wound therapy and traditional gauze layer dressing for the treatment of acute traumatic wounds: A randomized controlled trial. *Journal of Plastic, Reconstructive & Aesthetic Surgery. Vol.10.* 208-218. Retrieved from https://doi.org/10.1016/j.bjps.2024.11.005. (https://www.sciencedirect.com/science/article/pii/S1748681524007010)

Study Reference Link

Wound Type
Trauma Surgery

Specialty
Trauma

Level of Evidence 1

Study design

Randomized Controlled Trial

Study purpose

Effectiveness comparison of traditional dressings, NPWT, and NPWTi-d in patients with acute traumatic complex wounds

Method

- This prospective study included adult patients (>18 years) treated for acute traumatic complex wounds within 72 hours of admission
- 120 patients were randomly assigned to the NPWTi-d (n=40), NPWT (n=40), or traditional dressing (n=40) groups.
- NPWTi-d treatment instilled normal saline 0.9% at 2-hour intervals with a 20-minute dwell time and -125 mmHg negative pressure.
- The NPWT group used continuous -125 mmHg and dressing changes every 2-4 days.
- The traditional dressing group received dressing changes every 24-48 hours.

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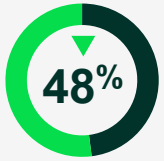
A randomized controlled trial demonstrated 3M™ Veraflo™ Therapy can improve patient outcomes in acute traumatic complex wounds

Results

Time to wound closure



Shorter time to wound closure (p<0.001)*

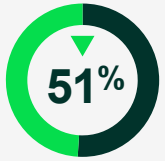
6.08 days NPWTi-d

9.98 days NPWT

11.7 days traditional dressing

* Note: percent reduction is NPWTi-d vs traditional dressing

Number of surgical procedures



Fewer surgical procedures (p<0.001)*

3.03 procedures with NPWTi-d

3.45 procedures with NPWT

6.21 procedures with traditional dressing

* Note: percent reduction is NPWTi-d vs traditional dressing

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

Key points

- Wound etiology was car accidents involving motorcycles, trucks and pedestrians. Wound types included degloving (62.5%), mixed (degloving and open fracture 21.7%), open fracture (9.2%), crushing (4.2%), and amputation (2.5%).
- Patients included in this study ranged from 18-86 years (mean 36.3 ± 14.2), most were males (79.2%), with at least 1 comorbidity (21%).
- Most wounds were located in a lower extremity (88.3%), the mean wound size was 184.3 ± 221.1 cm^2 (range 13.9 -1303 cm^2), and 27% had a positive bacterial burden biopsy.
- There was no significant difference in hospital length of stay between these three groups.
- Pairwise comparison showed:
  - NPWTi-d had a shorter wound closure time than NPWT (p<0.001) and traditional dressings (p<0.001)
  - NPWTi-d decreased the number of surgical procedures compared to NPWT (p=0.002) and traditional dressings (p<0.001)
- In this study, NPWTi-d decreased the time to wound closure and decreased the number of surgical procedures compared to NPWT and traditional dressings in patients treated for acute traumatic complex wounds.

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O'Connor (2024)

Literature review demonstrated 3M™ Veraflo™ Therapy is associated with high rates of breast pocket salvage and reduced time to implant reinsertion

O'Connor MJ, Huffman KN, Ho K, Marzouk S, Casas Fuentes RJ, Zhang KL, Melnick BA, Sparks PJ, Harris R, Bartler AV, Collinsworth A, Griffin L, Galiano RD. Negative Pressure Wound Therapy with Instillation for Periprosthetic Infection after Breast Reconstruction: A Systematic Review. Plastic and Reconstructive Surgery – *Global Open*. 2024;12(11):e6267. doi:10.1097/gox.0000000000006267

Study Reference Link

Wound Type
Surgical

Specialty
Mixed

Level of Evidence 2

Study design

Systematic Literature Review

Study purpose

To examine the impact of adjunctive use of NPWTi-d on breast pocket salvage rates, time to reinsertion, and related outcomes.

Method

- A literature search for full-text articles written in English and published between January 1, 2004, and April 1, 2023, was performed using PubMed, Cochrane, OVID, Scopus, and Embase databases.
- Peer-reviewed studies that reported the use of NPWTi-d in the treatment of infected breast pockets and used primary data (clinical trials, randomized control trials, case series with at least 5 patients) were included.
- Studies that featured a pediatric population or investigated the use of instillation into the thoracic or abdominal cavity were excluded.
- 6 studies (2 case series, 1 prospective cohort, and 3 retrospective cohorts (2 with controls)) were included.
- NPWTi-d was applied to 86 of 115 patients and 92 of 122 breasts across the studies.
- Data were extracted and analyzed using descriptive statistics.

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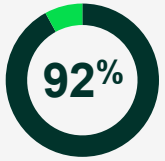
Literature review demonstrated 3M™ Veraflo™ Therapy is associated with high rates of breast pocket salvage and reduced time to implant reinsertion

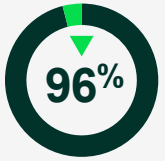
Results

Overall breast pocket salvage rates with NPWTi-d



Rates by prosthesis type & radiation status*
Implants: 97.8% (45/46)
Tissue expanders: 93.8% (15/16)
Nonirradiated: 91.7% (53/58)
Irradiated: 85.7% (12/14)

Time to implant reinsertion



Mean time to reinsertion ranged from 2.3-10.3 days but was significantly shorter in the 1 comparison study that examined this measure.
10.3 days NPWTi-d vs. 247.5 days SOC (p<0.001)

Hospital length of stay

Mean LOS ranged from 4.4-12 days but was significantly shorter in the 1 comparison study that examined this measure.
7.1 days NPWTi-d vs. 11.9 days SOC (p<0.004)

Hospitalizations

The number of hospitalizations were significantly lower in the 2 comparative studies.
2 NPWTi-d vs. 4 SOC (p=0.002)
1 NPWTi-d vs. 2.1 SOC (p<0.001)

* Reported in 5/6 of included studies Statistically significant (p<0.05)

Key points

- Adjunctive use of NPWTi-d along with antibiotic therapy for periprosthetic infections after breast reconstructions was associated with high rates of breast pocket salvage and reduced time to implant reinsertion.
- One study examined impact on bacterial burden and reported a significant reduction in mean bacterial burden for patients receiving NPWTi-d (−1.16 points, p=0.0002), C-reactive protein levels (−39.8 mL/L, p=0.0002), and leukocyte count (−2.33 µL, p=0.0002).
- The 1 study that reported on patient satisfaction found that mean BREAST-Q scores were higher for breast satisfaction (55.0 NPWTi-d vs. 39.7 SOC, p=.032)
- Costs of breast pocket salvage with NPWTi-d are dependent on reconstruction type and salvage protocol. One study estimated a savings of $6,475 per patient with NPWTi-d through reduced office visits and hospitalizations. One study found that costs for NPWTi-d were significantly higher (£14,343 versus £8920, p<0.001) than SOC due to higher numbers of procedures and longer LOS.

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Afzal (2024)

A 10-year study demonstrated that 3M™ Veraflo™ Therapy is associated with higher rates of wound closure in patients with necrotizing soft tissue infection

Study Reference Link

Wound Type
Necrotizing Fasciitis

Specialty
General Surgery

Level of Evidence 3

Afzal H, Dawson E, Fonseca R, Canas M, Diaz L, Filippis A, Mazuski J, Bochicchio KM, Bochicchio GV. Negative Pressure Wound Therapy With and Without Instillation in Necrotizing Soft Tissue Infections. *Surg Infect (Larchmt).* 2024 Feb 28. doi: 10.1089/sur.2023.299. Epub ahead of print. PMID: 38417035.

Study design

Retrospective comparative study

Study purpose

Comparison of necrotizing soft tissue infection wounds in 3 treatment groups, moist wound care dressings (MWC), NPWT, and NPWTi-d

Method

- Medical records, spanning 2008-2018, were reviewed for patients diagnosed with necrotizing fasciitis, Fournier gangrene, or gas gangrene.
- 371 patients were classified into 3 groups, based on treatment with MWC (n=173), NPWTi-d (n=48), or NPWT (n=150). Some patients received NPWT both with and without instillation and were grouped as NPWTi-d.
- Demographic data, pre-existing conditions, laboratory data, microbiologial data, and hospital outcomes were extracted from the registry.
- Multivariable logistic regression models were used to estimate treatment outcomes.

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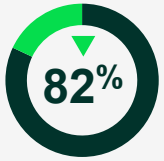
A 10-year study demonstrated that 3M™ Veraflo™ Therapy is associated with higher rates of wound closure in patients with necrotizing soft tissue infection

Results

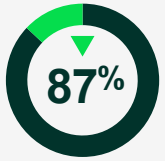
Open wounds at discharge



Fewer open wounds at discharge (p<0.001)*
14.6% (7/48) NPWTi-d
52.7% (79/150) NPWT
81.5% (141/173) MWC

* Note: percent reduction is NPWTi-d vs moist wound dressings

Mortality rates



Lower mortality (p=0.02)*
2.1% (1/48) NPWTi -d
10.7% (16/150) NPWT
16.2% (26/173) MWC

* Note: percent reduction is NPWTi-d vs moist wound dressings

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

Key points

- No significant differences were observed in demographics or complication rates; however intravenous drug use was more common in the NPWTi-d group (20.8%) than the NPWT (6.7%) and MWC groups (4%). Patients receiving NPWTi-d had a longer length of stay and more surgical debridements.
- Multivariable regression showed NPWTi-d was associated with closure rates 5X higher than NPWT (odds ratio [OR], 5.28; 95% confidence interval [CI], 2.40–11.61; p<0.001)
- Although not statistically significant, there was a notable difference in amputation rates in individuals with necrotizing soft tissue infection on the extremities, 6.7% NPWTi-d and 8.6% NPWT vs 17.9% MWC (p=0.12).
- NPWTi-d was associated with increased wound closure, reduced mortality, reduced amputation rates, and reduced tissue loss.

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Collinsworth (2022)

Timing study suggested early initiation of 3M™ Veraflo™ Therapy may improve patient outcomes and reduce care costs

Collinsworth AW, Griffin LP. The effect of timing of instillation therapy on outcomes and costs for patients receiving negative pressure wound therapy. *Wounds*. 2022 Nov;34(11):269-275.

Study Reference Link

Wound Type
Mixed

Specialty
General Wound Care

Level of Evidence 3

Study design

Retrospective, real-world data analysis

Study purpose

The timing of NPWTi-d initiation was evaluated by comparing patient outcomes and care costs.

Method

- This retrospective, matched cohort analysis used deidentified data from the Premier Helathcare Database (PHD) and included patients that were treated with NPWTi-d in 2019 during an inpatient visit.
- 514 patients were divided into two matched cohorts based on when NPWTi-d was initiated, with 257 patients in each group. Patients were categorized as follows:
  - Early - NPWTi-d was the initial negative pressure treatment or if it was initiated within 1 day of NPWT application.
  - Late - NPWTi-d initated within 2 to 7 days of initial negative pressure treatment application.
- For patients with multiple wounds in 2019, only the first documented wound was included in this study.
- Propensity scores were modeled using logistic regression with a binary indicator. Patient matching used the nearest neighbor technique with an exact match on wound type.

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Timing study suggested early initiation of 3M™ Veraflo™ Therapy may improve patient outcomes and reduce care costs

Results

Length of stay

Shorter inpatient stay*

13.4 days Early vs 16.3 days Late (p<0.0001)*

OR visits during NPWT

Fewer trips to the operating room while receiving NPWT:

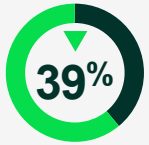
1.7 early vs 2.9 late (p<0.0001)*

OR visits during hospitalization

Fewer trips to the operating room*

During hospitalization:
3.1 early vs 4.1 late (p=0.0002)*

Length of NPWT



Shorter NPWT duration*

7.0 days Early vs 11.4 Late (p<0.0001)*

Time to final operating room procedure

Reduced time to final operating room procedure*

9.6 days Early vs 12.2 days Late (p=0.0008)*

Number of debridements

Reduced number of debridements*

1.3 early vs 1.7 late (p=0.0221)

Wound-related Readmissions

Reduced number of readmissions (60 days)

3.9% (10/257) patients early vs 9.3% (24/257) patients late (p=0.0130)

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

Key points

- There were no significant differences between groups in terms of the hospital day when first debridement was received or discharge status.
- Patients with early NPWTi-d initiation had a $10,877 lower mean cost of index admission (p<0.0001), which included lower NPWT costs.
- This study provides evidence that early NPWTi-d initiation may help improve patient outcomes and reduce care costs.

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Gabriel (2021)

Literature review and meta-analysis demonstrated 3M™ Veraflo™ Therapy can have a positive effect on clinical outcomes compared to standard of care

Gabriel A, Camardo M, O'Rorke E, Gold R, Kim PJ. Effects of Negative-Pressure Wound Therapy With Instillation versus Standard of Care in Multiple Wound Types: Systematic Literature Review and Meta-Analysis. *Plastic and Reconstructive Surgery*. 2021 Jan 1;147(1S-1):68S-76S.

Study Reference Link

Wound Type **Surgical**

Specialty **Mixed**

Level of Evidence 2

Study design

Systematic Review and meta-analysis

Study purpose

The goal is to determine the outcomes of NPWTi-d versus control in multiple wound types through the synthesis of existing data from both randomized controlled studies and observational studies.

Method

- A comprehensive and systematic literature search was used to identify peer-reviewed clinical studies published prior to December 31 2019. Only studies comparing NPWTi-d (Veraflo Therapy) to another treatment (control) and with >10 patients were included. Clinical studies of pediatric or thoracic/abdominal cavity instillation were excluded.
- 13 studies were analyzed, including 720 patients
- Data from these clinical studies was extracted by one reviewer and checked by a second reviewer
- Random-effects models were used to pool results in each publication and evaluate outcomes of NPWTi-d vs Control groups.

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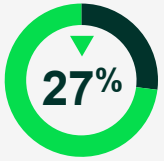
Literature review and meta-analysis demonstrated 3M™ Veraflo™ Therapy can have a positive effect on clinical outcomes compared to standard of care

Results

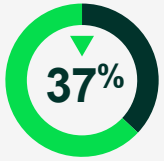
Number of surgical debridements



Fewer surgical debridements *

2.23 NPWTi-d vs 3.07 Control (p=0.01)*

Time to final surgical procedure



Shorter time to closure*

3.02 days NPWTi-d vs 4.16 days Control (p=0.03)*

Length of therapy

Reduced length of therapy*

1.52 days NPWTi-d vs 3.49 days Control (p<0.03)*

2.39x

Wounds treated with instillation were 2.39 times more likely to close than SOC (p=0.01)

4.4x

Subject wounds undergoing instillation had 4.4 times higher odds of bacterial count reduction than SOC (p=0.003).

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

Key points

- Control treatments included NPWT without instillation (n=9), wet-to-moist gauze dressings (n=3), or gentamicin polymethylmethacrylate beads (n=1).
- Instilled topical solutions included polyhexamethylene biguanide solution (PHMB, n = 6), saline (n=4), Dakin's solution (n=3), or silver nitrate (n=1).
- This meta-analysis shows NPWTi-d use has positive effect in various wound types.

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Kim (2022)

An economic model demonstrated that the use of 3M™ Veraflo™ Therapy can provide potential cost savings compared to standard of care therapies

Kim PJ, Lookess S, Bongards C, Griffin LP, Gabriel A. Economic model to estimate cost of negative pressure wound therapy with instillation vs control therapies for hospitalized patients in the United States, Germany, and United Kingdom. *International Wound Journal*. 2022 May;19(4):888-89

Study Reference Link

Wound Type
Trauma Surgery

Specialty
Multidisciplinary

Level of Evidence 5

Study design

Health Economic Model

Study purpose

Estimate of the cost of using NPWTi-d compared to Control in wound management.

Method

- An economic model was developed to compare cost differences betwen NPWTi-d and control therapies.
- Wound types included in this model were contaminated, infected, non-infected, acute, and chronic.
- Total cost was evaluated as the sum of three main components, cost of wound related therapy days, cost of therapy, and cost of operating room associated with excisional debridement.
- Data inputs were derived from a published Meta-Analysis that included 13 clinical trials (Gabriel, et al. 2021), and from hospital cost data.
- Control treatments included NPWT without instillation (n=9), wet-to-moist gauze dressings (n=3), or gentamicin polymethylmethacrylate beads (n=1)

Note: SOC included wounds managed with wet-to-moist dressings, NPWT without instillation, and antibiotics.

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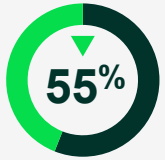
An economic model demonstrated that the use of 3M™ Veraflo™ Therapy can provide potential cost savings compared to standard of care therapies

Results

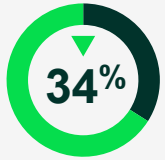
Wound-related therapy days



Fewer wound-related therapy days*

9.88 days NPWTi-d vs 21.80 days Control (p=0.02)*

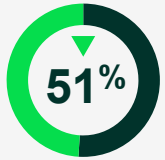
Number of operating room visits



Fewer operating room visits*

1.77 days NPWTi-d vs 2.69 days Control (p=0.008)*

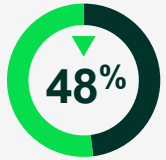
Total savings per patient USA



Reduced total per patient estimated costs for NWTi-d vs control, $32,584 vs $65,922.

Saving $33,338

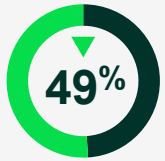
Total savings per patient Germany



Reduced total per estimated costs for NWTi-d vs control, €9,103 vs €17,570.

Saving €8,467

Total savings per patient UK



Reduced total per patient estimated costs for NWTi-d vs control, £5,973 vs £11,599.

Saving £5,626

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

Key points

- Gabriel et al., 2021 showed fewer operating room visits, lower overall product cost, and shorter length of therapy for NPWTi-d treated wounds compared to control wounds.
- An economic model based on these assumptions demonstrates a potential cost-savings with use of NPWTi-d compared to control.

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Kim (2020)

NPWTi-d with saline demonstrated that 3M™ Veraflo™ Therapy led to favorable outcomes compared to NPWT without instillation in infected wounds

Kim PJ, Silverman R, Attinger CE, Griffin L. Comparison of Negative Pressure Wound Therapy With and Without Instillation of Saline in the Management of Infected Wounds. *Cureus*. 2020 Jul 7;12(7):e9047.

Study Reference Link

Wound Type
Mixed, Infected

Specialty
Plastic Surgery

Level of Evidence 3

Study design

Retrospective analysis of two previous studies

Study purpose

Comparison of NPWT and NPWTi-d using saline in infected wounds.

Method

- A retrospective control cohort study of two independent, previously published studies from a single investigator in one hospital (Kim et al., 2014 and Kim et al., 2015).
- Patient characteristics and clinical outcomes of infected wounds were evaluated for the NPWT (n=74) control group (Kim et al., 2014) and NPWTi-d (n=42) treatment group (Kim et al., 2015). All patients underwent excisional surgical debridement and received parenteral or oral antibiotics.
- Continuous -125 mmHg was used in both groups.
- Additionally, NPWTi-d included instillation of 0.9% saline and dwell time of 20 minutes at 2 hour intervals.

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NPWTi-d with saline demonstrated that 3M™ Veraflo™ Therapy led to favorable outcomes compared to NPWT without instillation in infected wounds

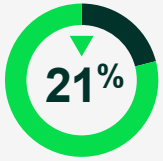
Results

Number of operations

Fewer operations*

2.5 ± 0.9 NPWTi-d vs 3.0 ± 0.9 NPWT (p=0. 0048)*

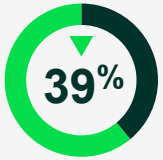
Length of hospital stay



Shorter hospital stay*

11.7 ± 6.0 days NPWTi-d vs 14.9 ± 9.2 days NPWT (p=0.0443)*

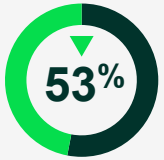
Time to final procedure



Reduced time to final procedure*

5.6 ± 3.6 days NPWTi-d vs. 9.2 ± 5.2 days (p=0.0001)*

Wound closure



Higher wound closure/coverage*

92.9% NPWTi-d vs 62% NPWT (p=0.0004)*

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

Key points

- More wounds remained closed at one month with NPWTi-d (82.1%) compared to NPWT (37.8%) (p=0.0001)
- There were no significant differences in demographics, comorbidities, wound etiologies or anatomical locations of wounds but the NPWT group had a higher percentage of patients with end-stage renal disease (p=0.0119).
- This study adds to published evidence on the use of NPWTi-d as adjunctive therapy in the management of infected wounds.
- Results indicate that compared to NPWT, NPWTi-d with saline to manage infected wounds can lead to favorable outcomes.

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Cole (2020)

Compared to alginate and collagen dressings, 3M™ Veraflo™ Therapy with 3M™ Veraflo™ Cleanse Choice™ Dressing demonstrated fewer complications in the management of lower limb wounds

Cole W. Early-stage Management of Complex Lower Extremity Wounds Using Negative Pressure Wound Therapy with Instillation and a reticulated open cell foam with through holes. *Wounds*. 2020;32:159-163.

Study Reference Link

Wound Type
Mixed/chronic lower extremity

Specialty
Vascular Surgery

Level of Evidence 3

Study design

Small retrospective comparative study

Study purpose

Assessment of clinical outcomes of NPWTi-d with ROCF-CC dressings versus advanced wound dressings.

Method

- Retrospective assesment of complex lower extremity wounds treated with NPWTi-d (n=5) or advanced wound dressings (n=5).
- Patients were treated by one investigator, at a single institution, between June 2015 and October 2017. Patients in both groups underwent initial surgical debridement.
- The Control group was treated with alginate or collagen advanced wound dressings that were changed 1 to 3 times per week according to manufacturers' instructions.
- The NPWTi-d group used ROCF-CC dressings that were changed every 2 to 3 days. Normal saline was instilled every 2 hours and dwelled for 20 minutes followed by application of continous negative pressure (-125 mmHg).

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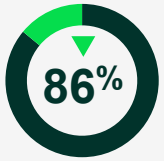
Compared to alginate and collagen dressings, 3M™ Veraflo™ Therapy with 3M™ Veraflo™ Cleanse Choice™ Dressing demonstrated fewer complications in the management of lower limb wounds

Results

Surgical Debridements



Fewer surgical debridements*
1 ± 0.0 NPWTi-d vs 7 ± 10.1 Control (p=0.004)*

Wound Complications

Fewer wound complications*
0 NPWTi-d vs 0.8 Control (p=0.024)*

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

Key points

- This assessment included diabetic foot ulcers (n=4), venous leg ulcers (n=2), pressure ulcers (n=2), a trauma wound (n=1), and a wound resulting from a hematoma (n=1).
- More wounds healed in the NPWTi-d group (5/5, 100%) compared to the Control group (2/5, 40%).
- Complications in the Control group included continued infection, return for surgery, toe amputation, and wound open for longer than 2 years. 1 patient from the Control group underwent below the knee amputation and another was lost to follow-up after 2 years.
- All wounds in the NPWTi-d treatment group healed within 1.5 to 5 months without readmission to hospital and no complications.
- The outcomes in these patients, supports the use of NPWTi-d with ROCF-CC for the management of lower limb wounds.

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Chowdhry (2019)

A regimen of adjunctive 3M™ Veraflo™ Therapy with 3M™ Veraflo™ Cleanse Choice™ Dressing followed by 3M™ Prevena™ Therapy shown to help manage sternal surgical wounds that previously failed to close

Chowdhry SA, Wilhelmi BJ. Comparing Negative Pressure Wound Therapy with Instillation and Conventional Dressings for Sternal Wound Reconstructions. Plastic and Reconstructive Surgery. *Global Open*. 2019 Jan 4;7(1):e2087.

Study Reference Link

Wound Type
Sternal

Specialty
Cardiothoracic Surgery

Level of Evidence 3

Study design

Retrospective comparative study

Study purpose

Comparison of NPWTi-d followed by ciNPT vs wet-to-moist dressings and wound closure strips to manage sternal wounds that failed to close.

Method

- Included 30 consecutive patients who had undergone muscle flap reconstruction for preexisting sternal wounds that had failed to close after CABG with left internal mammary artery harvested.
- The NPWTi-d (n=15) group was treated with ciNPT after primary closure, while the Control group was treated with Wet-to-moist dressings followed by wound closure strips.
- In the Control group (n=15), wet-to-moist dressings were soaked in 1/8 strength Dakin's solution. Dressings in the control group were changed every 6 hours.
- Adjunctive NPWTi-d treatment used reticulated open cell foam dressings with through holes (ROCF-CC) that were changed every 72 hours. Instillation of 1/8 strength Dakin's solution every 2 hours with a dwell time of 20 minutes followed by application of negative pressure at -125 mmHg.

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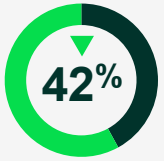
A regimen of adjunctive 3M™ Veraflo™ Therapy with 3M™ Veraflo™ Cleanse Choice™ Dressing followed by 3M™ Prevena™ Therapy shown to help manage sternal surgical wounds that previously failed to close

Results

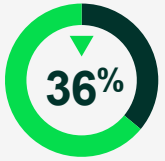
Debridements/Dressing changes



Fewer debridements/dressing changes were performed at the time of surgical debridement*

1.8 ± 0.7 NPWTi-d vs 3.1 ± 1.0 Control (p=0.0011)*

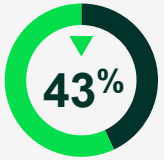
Therapy days



Reduction in average length of therapy*

5.4 ± 2.1 days NPWTi-d vs. 8.4 ± 2.9 days Control (p=0.0041)*

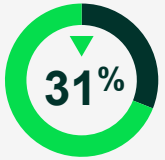
Time to wound closure



Reduced time to primary closure*

7.9 ± 2.3 days NPWTi-d vs. 13.9 ± 3.2 days Control (p<0.0001)*

Drain duration after ciNPT



Shorter mean drain duration after ciNPT was applied to closed incisions*

15.0 ± 2.0 days NPWTi-d vs. 21.7 ± 3.9 days Control (p=0.0004)*

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

Key points

- 75% of wounds in the NPWTi-d treatment group closed within 9 days, and the remainder closed within 12 days.
- 75% of wounds in the control group closed by 16 days and the remainder closed within 20 days.
- The regimen evaluated in this study coupled adjunctive NPWTi-d followed by muscle flap reconstruction and application of ciNPT to manage the closed incisions. In these patient outcomes, NPWTi-d and ciNPT helped manage preexisting sternal surgical wounds that had previously failed to close.

solventum

Kim (2015)

Study of 3M™ Veraflo™ Therapy with instillation of saline may be as effective as instillation with an antiseptic solution

Kim PJ, Attinger CE, Oliver N, Garwood C, Evans KK, Steinberg JS, Lavery LA. Comparison of Outcomes for Normal Saline and an Antiseptic Solution for Negative-Pressure Wound Therapy with Instillation. *Plastic and Reconstructive Surgery*. 2015 Nov;136(5):657e-64e.

Study Reference Link

Wound Type
Infected wounds requiring surgical debridement

Specialty
Plastic Surgery

Level of Evidence 1b

Study design

Prospective randomized comparative study

Study purpose

Comparison of NPWTi-d outcomes using normal saline or PHMB.

Method

- This single center study compared outcomes of NPWTi-d with instillation of 0.9% normal saline vs 0.1% polyhexanide plus 0.1% betaine (PHMB) on infected wounds that required hospital admission and operative debridement.
- After initial debridement, all patients received oral antibiotics and subsequent debridements performed every 2 to 4 days.
- 100 patients were included
- Intention to treat analysis: NPWTi-d + normal saline (n=49); NPWTi-d + PHMB (n=51).
- Per protocol analysis: NPWTi-d + normal saline (n=42); NPWTi-d + PHMB (n=41).

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Study of 3M™ Veraflo™ Therapy with instillation of saline may be as effective as instillation with an antiseptic solution

Results

Time to final surgical procedure

Shorter time until ready for final surgical procedure (per protocol analysis)*

5.6 days NPWTi-d + normal saline vs 7.5 days NPWTi-d + PHMB (p=0.04)*

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

Key points

- As a variety of instillation solutions have been used with NPWTi-d, the primary objective of this study was to compare the effects of two of these solutions (normal saline and PHMB) with NPWTi-d in infected wounds.
- No significant differences were observed in the number of operating room visits, length of hospital stay, proportion of wounds closed/covered, or proportion of wounds that remained closed at the 30-day follow-up.
- However, a statistically significant reduction (p=0.04) in time to final surgical procedure was reported when normal saline was used at the instillation solution.
- In this group of patients, results showed that NPWTi-d with instillation of 0.9% normal saline may be as effective as the PHMB antiseptic for the adjunctive inpatient management of infected wounds.

solventum

Gabriel (2014)

NPWTi-d use in management of extremity and trunk wounds demonstrated 3M™ Veraflo™ Therapy can improve clinical outcomes and lower costs

Gabriel A, Kahn K, Karmy-Jones R. Use of negative pressure wound therapy with automated, volumetric instillation for the treatment of extremity and trunk wounds: clinical outcomes and potential cost-effectiveness. *Eplasty*. 2014 Nov 3;14:e41.

Study Reference Link

Wound Type
Mixed complex or infected upper or lower extremity or trunk wounds

Specialty
Plastic Surgery

Level of Evidence 3

Study design

Retrospective comparative study

Study purpose

Comparison of clinical outcomes and estimate of cost-differences of wounds treated with NPWTi-d versus NPWT.

Method

- Medical records were reviewed for patients ages 21 to 80 with infected or critically colonized wounds, treated with NPWTi-d (n=48) or NPWT (n=34) between January 1, 2010 and May 31, 2013. Patients with pressure ulcers or infected hardware or implants were excluded.
- Patients were treated by one investigator using similar protocols that included debridement and systemic antibiotics. Dressings were changed every 2 to 3 days for both groups.
- NPWT used reticulated open cell foam (ROCF) dressings with or without micro-bonded silver.
- NPWTi-d used a specialty ROCF dressing for enhanced distribution of the solution on the wound bed. Saline or polyhexanide topical solution was instilled every 1 to 2 hours with a dwell time of 1 to 60 seconds followed by application of negative pressure at -125 mmHg.

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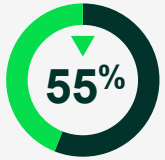
NPWTi-d use in management of extremity and trunk wounds demonstrated 3M™ Veraflo™ Therapy can improve clinical outcomes and lower costs

Results

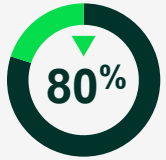
Operating room debridements



Fewer operating room debridements*

2 NPWTi-d vs 4.4 NPWT (p<0.0001)*

Length of therapy



Reduction in length of therapy*

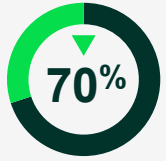
8.1 days NPWTi-d vs. 20.9 days NPWT (p<0.0001)*

Time to wound closure

Reduction in time to wound closure

4.1 days NPWTi-d vs. 20.9 days NPWT (p<0.0001)*

Hospital Stay



Shorter hospital stay*

8.1 days NPWTi-d vs. 27.4 days NPWT (p<0.0001)*

Therapy cost (hypothetical model)

▼ $1,418

In a hypothetical model, the average therapy cost was $1,418 lower for the NPWTi-d group ($799) compared to the NPWT group ($2,217).

OR debridement cost (hypothetical model)

▼ $8,143

The hypothetical model showed an average OR debridement cost reduction of $8,143 with NPWTi-d ($6,786) and NPWT ($14,929).

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

Key points

- The use of NPWTi-d resulted in fewer trips to the operating room for debridements, faster time to closure, shorter length of therapy, and shorter hospital stay compared to patients receiving NPWT.
- Compared to NPWT, the NPWTi-d group experienced easier and less painful dressing changes.
- Less odor was reported during dressing changes of the NPWTi-d group, possibly due to periodic instillation and removal of instilled solutions and wound exudate. The solutions did not cause the odor. removal of a wound solution.
- Earlier wound closure occurred in the NPWTi-d group, possibly due to repetitive wound cleansing and exudate removal.
- NPWTi-d resulted in positive clinical outcomes and potential cost savings compared to NPWT.

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Kim (2014)

Retrospective study demonstrated that 3M™ Veraflo™ Therapy may be more beneficial for adjunctive treatment of infected wounds than NPWT

Kim PJ, Attinger CE, Steinberg JS, Evans KK, Powers KA, Hung RW, Smith JR, Rocha ZM, Lavery L. The impact of negative-pressure wound therapy with instillation compared with standard negative-pressure wound therapy: a retrospective, historical, cohort, controlled study. *Plastic and Reconstructive Surgery*. 2014 Mar;133(3):709-16.

Study Reference Link

Wound Type
Mixed, Infected

Specialty
Plastic and reconstructive

Level of Evidence 3

Study design

Retrospective comparative study

Study purpose

Compared outcomes of NPWT with and without instillation using two dwell times.

Method

- Medical records from a single institution, MedStar Georgetown Univeristy Hospital, were evaluated.
- Included patients required readmission for infected wounds, had at least two operative debridements and received NPWT or NPWTi at intial operation.
- 142 patients were included. NPWT (n=74) was compared to two NPWTi groups of 6-minute (NPWTi-6; n=34) and 20-minute dwell times (NPWTi-20; n=34)
- InfoV.A.C. Therapy System was used for NPWT and V.A.C. Ulta with Veraflo Instillation Therapy was used for NPWTi. -125 mmHg was used for all groups.
- Prontosan solution was instilled for both NPWTi groups at intervals of 3.5 hour for NPWTi-6 and 2 hours for NPWTi-20.

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Retrospective study demonstrated that 3M™ Veraflo™ Therapy may be more beneficial for adjunctive treatment of infected wounds than NPWT

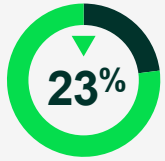
Results

Number of operating room visits

Fewer operating room visits*

3.0 ± 0.9 NPWT vs 2.4 ± 0.9 (p=0.04)* NPWTi-6 and 2.6 ± 0.9 (p=0.003)* NPWTi-20

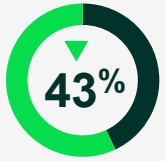
Length of hospital stay



Shorter hospital stay*

11.4 ± 5.1 days NPWTi-20 (p=0.03)* vs 14.9 ± 9.2 days NPWT

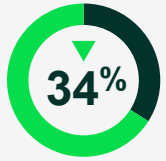
Time to final procedure



Shorter time to final surgical procedure*

9.23 ± 5.2 days NPWT vs 7.8 ± 5.2 days NPWTi-6 (p=0.04) 7.5 ± 3.1 days NPWTi-20 (p=0.002)*

% of wounds closed



Higher % of wounds closed before discharge*

94% NPWTi-6 vs 62% NPWT (p=0.0004)*

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

Key points

- There was no significant difference in age, sex, BMI, smoking status and comorbidities between treatment groups.
- There was no statistically significant improvement in overall wound cultures; however, there was a significant improvement in Gram-positive cultures the 6-minute dwell time group.
- Length of hospital stay was also shorter for NPWTi-6 (11.9 ± 7.8 days) compared to NPWT, but the difference was not statistically significant (p=0.10).
- A higher percentage of wounds in NPWTi-20 group were closed compared to the NPWT group (80% vs. 62%), but the difference was not statistically significant (p=0.08).
- These results show that NPWT with instillation (6- or 20- minute dwell time) may be more beneficial than NPWT for adjunctive treatment of infected wounds that require hospital admission.

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