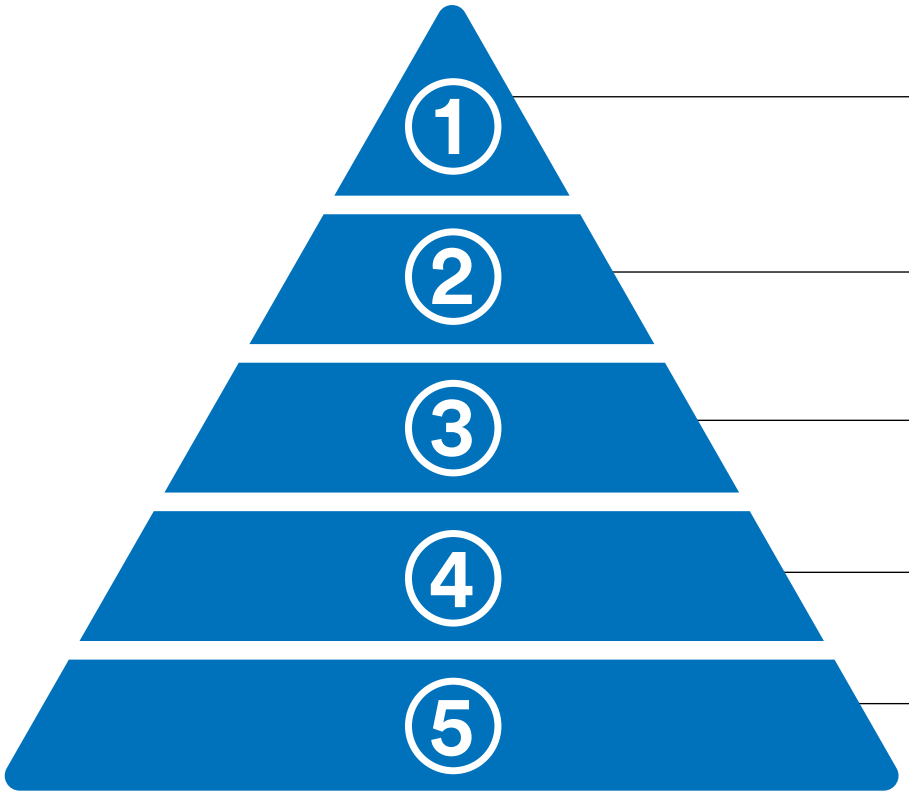
3M Science. Applied to Life.™

Solutions for Diabetic Foot Ulcer Care

Clinical Evidence Summaries

Table of Contents

Levels of Evidence Key



1. Randomized controlled prospective studies (RCTs) or meta-analyses of RCTs.
2. Prospective studies. May be controlled or have more than one cohort. Will not be randomized.
3. Retrospective studies that have a comparison or control. Sometimes referred to as case control or comparative retrospective studies.
4. Case series or retrospective studies. Two or more cases are considered a case series.
5. Expert opinion, consensus documents, single case reports, economic models and literature reviews.

DFU and Advanced Wound Dressings

Contents

Case series evaluation of a silver non-adherent dressing.

Bradbury S, Ivins N, Harding K. Case series evaluation of a silver non-adherent dressing. *Wounds UK.* 2011;7(2):12-19.

Design

Case series evaluation of a silver non-adherent dressing

Background/Objectives

To evaluate the efficacy of 3M™ Silvercel™ Non-Adherent Antimicrobial Alginate Dressing on various wound types.

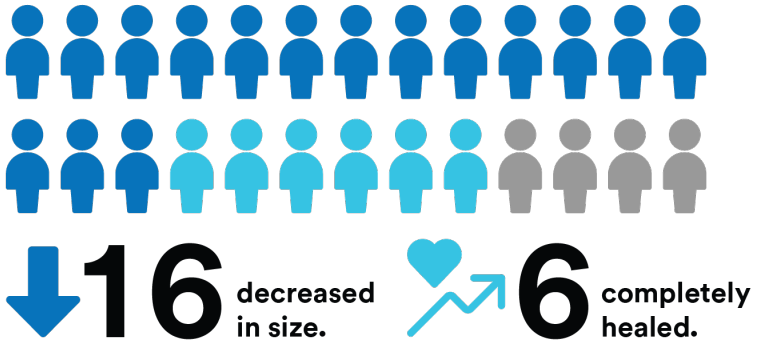
Methods

Silvercel Non-Adherent Dressing was applied to 26 patients with either systemic or locally infected wounds, critically colonized wounds or wounds at high risk of developing infection, i.e. those with a history of recurrent infection or known associated comorbidities. The dressing was applied for up to 12 weeks or until clinically indicated. It was applied with appropriate standard of care treatment for the wound type. Comprehensive wound assessment was performed every one to two weeks.

Results

Sixteen patients' wounds decreased in size, with six achieving complete healing during or within two weeks of completing the evaluation. 16 patients remained free of infection. The majority of patients experienced no pain or decreased pain. There were no reports of (visible) fiber shedding and only two patients experienced an episode of dressing adherence.

Out of 26 infected wounds



Sixteen patients progressed towards healing, which was evident by a decrease in wound size. Three went on to heal completely a week after stopping the dressing and achieved complete wound closure. In six patients, the wound size increased.

Key Findings

Silvercel Non-Adherent Dressings have the potential to affect positively the outcome of infected, critically colonized or high risk wounds of various aetiologies when used in conjunction with standard of care, and to minimize pain at and between dressing changes.

DFU and 3M™ Cavilon™ No Sting Barrier Film

Contents

A liquid film-forming acrylate for periwound protection: a systematic review and meta-analysis.

Schuren J. et al. A liquid film-forming acrylate for periwound protection: a systematic review and meta-analysis. *Int Wound J.* 2005;2(3): 230-238.

Design

Meta-Analysis

Background/Objectives

To complete a systematic review of reliable evaluations for the cost-effectiveness and clinical performance of a film-forming liquid acrylate that's used to protect chronic ulcer periwound skin.

Methods

Two reviewers analyzed search results to identify randomized controlled trials and obtain their full reports. The reviewers extracted and summarized details from eligible studies with a data extraction sheet. In cases where the interventions and outcome measures were similar, trial results were combined using a meta-analysis.

Results

Nine studies were identified as eligible. The review showed that, when used as a barrier to protect the periwound area of chronic ulcers, a liquid-film forming acrylate (3M™ Cavilon™ No Sting Barrier Film) is safe and effective. No difference was found between the protective properties of different barrier methods (i.e., petrolatum, zinc oxide paste, and windowed adhesive dressings) used to protect the peri-wound skin around chronic ulcers.

A review of nine eligible case studies showed that when used as a barrier to protect the periwound area of chronic ulcers, a liquid-film forming acrylate (3M™ Cavilon™ No Sting Barrier Film) is **safe and effective.**

Key Findings

The liquid, film-forming, terpolymer-based, alcohol-free barrier film significantly impacted periwound skin integrity in comparison to no treatment or a placebo. It also may have reduced nursing time, provided pain control and enhanced patient comfort.

Reducing skin maceration in exudative diabetic foot ulcers.

Lázaro-Martínez JL, García-Morales EA, Aragón-Sánchez FJ, et al. Reducing skin maceration in exudative diabetic foot ulcers. *Revista de Enfermería (Barcelona, Spain).* 2010 Mar;33(3):9-14.

Design

Prospective Cohort

Background/Objectives

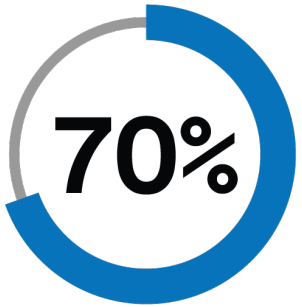
Demonstrate the effectiveness in the periwound skin maceration reduction with the use of no-sting barrier film (NSBF) 3M™ Cavilon™ No Sting Barrier Film.

Methods

Study included 40 patients of both sexes, age 18 and older, with foot ulcers. Patients demonstrated moderate to high exudate. Grades varied, with grade III in the plantar area being the most common. All patients used Cavilion NSBF for 30 days. Visits were at 0, 15 and 30 days using exudate and level maceration as the variables. SPSS® Software v15.0 generated data for statistic analysis. The “t-student” test was used as the media comparison of the qualitative variables. The “chi-squared” test determined variables of qualitative associations. Significant differences were assumed in values of α of 5% ($p < 0.05$) for a confidence interval of 95% y β values that established the potential of the study of 80%.

Results

- After 30 treatment days, 70% of the ulcers had healthy edge or lower exudates (Day zero n = 8 vs. Day 30 n = 28 $p < 0.05$)
- There were 17 cases with fibrin tissues in the upper 60% of the ulcer at day zero and two cases at day 30 ($p < 0.001$)
- At day zero, granulation tissue was present in 13 cases with upper 50% in wound bed, compared to 25 cases at the conclusion of the study ($p < 0.001$)



of the ulcers showed healthy edge or lower exudates after 30 days of treatment.

Key Findings

Cavilon No Sting Barrier Film was shown to be effective in managing the maceration of high exudate diabetic foot ulcers.

DFU, 3M™ Promogran Prisma™ Collagen Matrix with ORC and Silver

Contents

Randomized comparative trial of a collagen/oxidized regenerated cellulose dressing in the treatment of neuropathic diabetic foot ulcers.

Lázaro-Martínez JL, García-Morales E, Beneit-Montesinos JV, Martínez-de-Jesús FR, Aragón-Sánchez FJ. Randomized comparative trial of a collagen/oxidized regenerated cellulose dressing in the treatment of neuropathic diabetic foot ulcers. *Cir Esp.* 2007 Jul;82(1):27-31.

Design

Randomized Controlled Trial

Background/Objectives

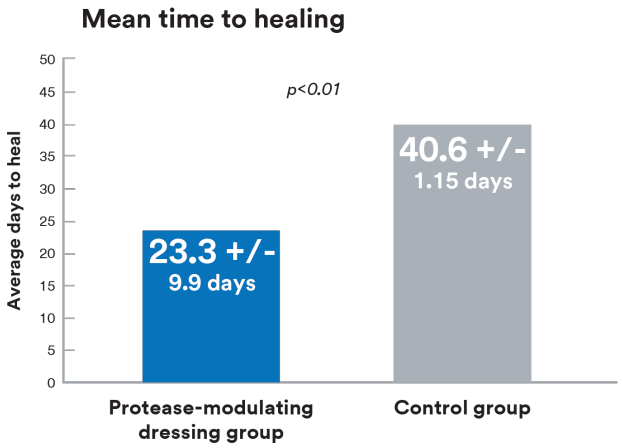
The objective of this study was to assess protease-modulating dressing efficacy in the management of neuropathic diabetic foot ulcers (DFU).

Methods

RCT included 40 patients that presented with DFU for six weeks or longer. Patients were randomized to an intervention group using protease-modulating dressing (oxidized regenerated cellulose (ORC)/collagen; n = 20) and an intervention group using a control dressing/treatment (n = 20) as specified within the standardized good wound care protocol. Patients were followed up after six weeks.

Results

After six weeks, 12 of 19 patients (63%) receiving protease-modulating dressing achieved healing relative to three of 19 patients (15%) receiving the control therapy ($p < 0.03$). Patients receiving protease-modulating dressing also demonstrated a significantly shorter mean time to healing relative to the control group (23.3 ± 9.9 days versus 40.6 ± 1.15 days; $p < 0.01$).



Key Findings

Protease-modulating dressing group demonstrated a higher rate of wound healing and a shorter average healing time in comparison to the control group.

Efficacy of oxidized regenerated cellulose/collagen dressing for management of skin wounds: a systematic review and meta-analysis.

Zhang L, Wang S, Tan M, Zhou H, Tang Y, Zou Y. Efficacy of oxidized regenerated cellulose/collagen dressing for management of skin wounds: a systematic review and meta-analysis. *Evid Based Complement Alternat Med.* 2021 Aug 4;2021:1058671.

Design

Systematic Review and Meta-Analysis

Background/Objectives

Assess wound healing efficacy of ORC/collagen dressings and ORC/collagen/silver-ORC dressings relative to standard of care (SOC) or control dressings in managing chronic wounds (diabetic foot ulcers, venous leg ulcers and pressure injuries. The majority were DFU (7/11)).

Methods

A systematic review was performed by searching PubMed, Scopus, Embase, and CENTRAL for potential studies. Studies had a minimum of 10 participants (five/group or cohort). Cochrane risk of bias tool was employed to analyze potential risk bias. Meta-analysis was performed using RevMan 5.3v. Heterogeneity was calculated using I2 statistics. The I2 value (> 40%, moderate to considerable heterogeneity) was used as basis for a random or fixed effect model.

Results

- Wound Healing Rates: Overall OR 1.79 [1.09, 2.94] was found to be significantly favoring ORC/collagen-treated group (p = 0.02). Heterogeneity among the studies was found to be moderate (i2 = 57%)
- Time to Achieve Complete Wound Healing: Overall MD −2.25 [−22.95, 18.46] between both groups was found nonsignificant (p = 0.83). Heterogeneity among the studies was also found to be high (i2 = 97%)
- Percentage Wound Relative Reduction: Overall MD 18.15 [6.09, 30.21] was found to be significantly favoring ORC/collagen-treated group (p = 0.003). Heterogeneity among the studies was also found to be low (i2 = 29%)

Patients treated with ORC/collagen dressings [or ORC/collagen treated group] saw superior wound relative reduction.

Key Findings

Dressings containing ORC/collagen were demonstrated to be beneficial via treatment group's improved wound healing rates and percentage of wound relative reduction compared with standard of care interventions that do not inhibit MMP activity.

Use of oxidised regenerated cellulose/collagen dressings versus standard of care over multiple wound types: a systematic review and meta-analysis.

Chowdhry SA, Nieves-Malloure Y, Camardo M, et al. Use of oxidised regenerated cellulose/collagen dressings versus standard of care over multiple wound types: a systematic review and meta-analysis. *Int Wound J.* 2021. Epub ahead of print.

Design

Systematic Review and Meta-Analysis

Background/Objectives

Performance of oxidized regenerated cellulose (ORC)/collagen dressings compared with standard dressings was assessed.

Methods

A systematic literature search was conducted using PubMed, EMBASE, and QUOSA for comparative studies published between 1996 and 2020. Random effects meta-analyses were conducted. Differences in wound closure rates, percent wound area reduction, wound area reduction, time to complete healing, days of therapy, number of dressing applications, pain, and concentrations of matrix metalloproteinase-2 (MMP-2), elastase, plasmin and gelatinase were examined.

Results

- Patients in the ORC/collagen group showed a greater percent area reduction compared with the control group (effect estimate of standard mean difference = 1.11, 95% CI [0.32, 1.90], p = 0.006)
- Patients receiving ORC/collagen showed increased area reduction compared with patients receiving control dressings (effect estimate of standard mean difference = 0.61, 95% CI [0.11, 1.11], p = 0.017)

Wounds treated with ORC/collagen dressings

3.4x **more likely to close than those receiving control dressings.**

Key Findings

In these analyses, ORC/collagen dressings use was associated with increased wound closure rates and wound area reduction.

Use of oxidized regenerated cellulose (ORC)/collagen/ silver-ORC dressings alone or subsequent to advanced wound therapies in complex wounds.

Klein RJ. Use of oxidized regenerated cellulose (ORC)/collagen/silver-ORC dressings alone or subsequent to advanced wound therapies in complex wounds. *Wounds.* 2020 Feb;32(2):37-43.

Design

Retrospective Study

Background/Objectives

Examines the use of ORC/collagen/silver-ORC dressings alone or subsequent to advanced wound therapies.

Methods

Wounds were assessed upon presentation. If necessary, oral and/or intravenous antibiotics were administered. Each wound underwent sharp debridement. Patients received either ORC/collagen/silver-ORC dressings with a secondary dressing alone or following NPWT. Skin substitutes and epidermal grafting also were utilized to promote wound healing and wound size reduction.

Results

- Twenty-four patients with an average age of 66.8 +/- 12.7 years were treated
- The most prevalent comorbidities were hypertension, diabetes, obesity, peripheral neuropathy, hyperlipidemia, coronary heart disease and tobacco use
- Wound types (n = 27) included diabetic foot ulcers, surgical wounds, traumatic wounds, an ulcer (secondary to chronic gout with tophi) and thermal burns
- All 27 wounds fully closed, with an average time to heal of 65.5 +/- 41.5 days

65.5 days
+/- 41.5 days for average time to heal.

Key Findings

Use of advanced treatment modalities including NPWT, epidermal grafting and ORC/collagen/silver-ORC dressings contributed to wound healing in these patients with complex and/or chronic wounds.

A retrospective analysis of the cost-effectiveness of a collagen/oxidized regenerated cellulose dressing in the treatment of neuropathic diabetic foot ulcers.

Làzaro-Martìnez JL, Aragòn-Sànchez FJ, Garcìa-Morales E, Beneit-Montesinos JV, Gonzàlez-Jurado M. A retrospective analysis of the cost-effectiveness of a collagen/oxidized regenerated cellulose dressing in the treatment of neuropathic diabetic foot ulcers. *Ostomy Wound Management.* 2010 Nov 1;56(11A):4-8.

Design

Retrospective Analysis/Study

Background/Objectives

Analyze cost-effectiveness in the treatment of neuropathic diabetic foot ulcers (DFUs).

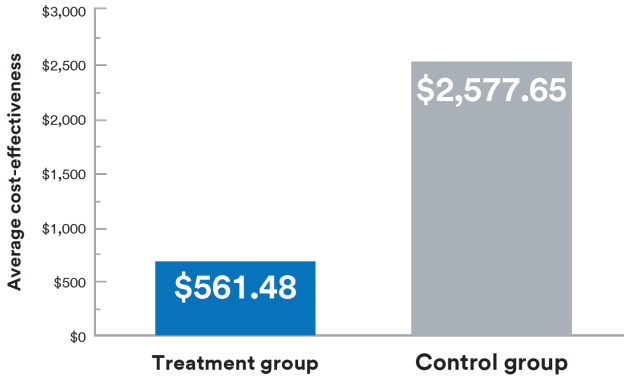
Methods

The cost-effectiveness study was conducted using data from a previously published RCT (Lazaro-Martinez 2007) of 40 patients in Spain with neuropathic DFU. Patients received either oxidized regenerated cellulose (ORC)/collagen dressings (n = 20) or standard care (n = 20). The costs of direct healthcare services included staff, ancillary supplies, dressings and patient transport costs.

Results

The total cost of treatment was $35,373.63 in the treatment group and $41,242.63 in the control group. For both treatment groups combined, the average cost of treatment for patients with ulcer healed was lower than those whose ulcers did not heal ($1,611.52 vs. $22,280.13; $p < 0.001$). The average cost-effectiveness in the treatment group was $561.48 compared to $2,577.65 in the control group.

Cost-effectiveness in the treatment of neuropathic diabetic foot ulcers



Key Findings

Managing neuropathic DFUs with ORC/collagen dressings were shown to have a significant cost-benefit ratio over the standard of care.

DFU and Negative Pressure Wound Therapy (NPWT)

Contents

Negative pressure wound therapy after partial diabetic foot amputation: a multicentre, randomised controlled trial.

Armstrong DG, Lavery LA; Diabetic Foot Study Consortium. Negative pressure wound therapy after partial diabetic foot amputation: a multicentre, randomised controlled trial. *Lancet*. 2005;366(9498):1704-10.

Design

Randomized Controlled Trial

Background/Objectives

Investigate whether negative pressure wound therapy (NPWT) delivered by the 3M™ V.A.C.® Therapy System improves the proportion and rate of wound healing after partial foot amputation in patients with diabetes.

Methods

Enrolled 162 patients into a 16-week, 18-centre, randomized clinical trial in the USA. Patients who were randomly assigned to NPWT (n = 77) received treatment with dressing changes every 48 hours. Control patients (n = 85) received standard moist wound care according to consensus guidelines. The primary endpoint was to determine if NPWT use could increase rates of wounds with complete closure. Secondary endpoints assessed the rates of wound healing or surgical closure, foot salvage and treatment-related complications.

Results

Primary Endpoint
The NPWT group showed a greater number of healed wounds (43 [56%] vs. 33 [39%], p = 0.04).

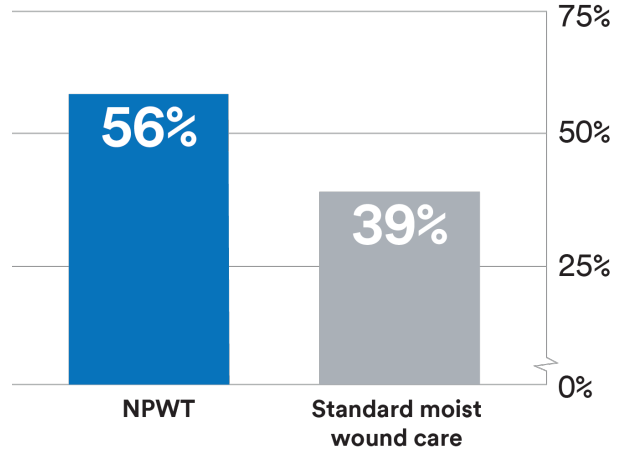
Secondary Endpoint

- Rate of wound healing was significantly increased in the NPWT group (p = 0.005)
- Rates of a second amputation were similar between the groups (two [3%] vs. nine [11%], p = 0.06)
- Fewer days to reach 76–100% granulation tissue for patients receiving NPWT (median time to event 42 days [IQR 40–56]) than that for controls (84 days [57–112]; p = 0.002)
- In total, 52% of the NPWT group (40 patients) and 54% of the control group (46 patients) experienced one or more adverse events (p = 0.875)

Key Findings

NPWT seems to be safe and effective for complex diabetic foot wounds, resulting in increased rates of wound closure, shorter time to wound closure, and a smaller proportion of patients experiencing re-amputations than standard of care.

Healed wounds within 16 weeks



p=0.04

Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers—a multicenter randomized controlled trial.

Blume PA, Walters J, Payne W, Ayala J, Lantis J. Comparison of negative pressure wound therapy using vacuum-assisted closure with advanced moist wound therapy in the treatment of diabetic foot ulcers—a multicenter randomized controlled trial. *Diabetes Care*. 2008;31(4):631-6.

Design

Randomized Controlled Trial

Background/Objectives

The purpose of this study was to evaluate safety and clinical efficacy of negative pressure wound therapy (NPWT) compared with advanced moist wound therapy (AMWT) to treat foot ulcers in diabetic patients.

Methods

Multicenter randomized controlled trial enrolled 342 patients. Patients were randomly assigned to either NPWT (3M™ V.A.C.® Therapy System) or AMWT (predominately hydrogels and alginates) and received standard off-loading therapy as needed. The trial evaluated treatment until day 112 or ulcer closure by any means. Patients whose wounds achieved ulcer closure were followed at three and nine months.

Results

Primary Endpoint
A higher rate of wound closure was observed in the NPWT group (73 [43.2%] vs. 48 [28.9%], p = 0.007).

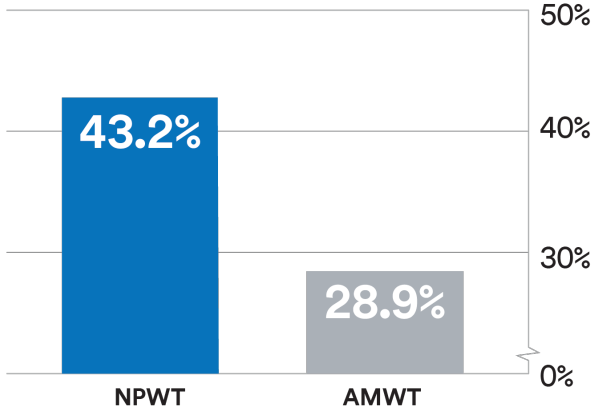
Secondary Endpoints

- Increased wound surface area reduction was observed in the NPWT group (-4.32-cm^2 vs. -2.53-cm^2, p = 0.021)
- Time to wound closure was shorter in the NPWT group (96 days [95% CI 75.0, 114.0] vs. undeterminable, p = 0.001)
- NPWT patients had significantly fewer secondary amputations (p = 0.035)
- Rates of treatment-related complications were similar between the two groups

Key Findings

NPWT appears to be as safe as and more efficacious than AMWT for use in the treatment of diabetic foot ulcers.

Wounds closure rate at 112 days



p=0.007

Use of vacuum-assisted closure therapy in the treatment of diabetic foot wounds.

Dalla Paola L, Carone A, Ricci S, Russo A, Ceccacci T, Ninkovic S. Use of vacuum-assisted closure therapy in the treatment of diabetic foot wounds. *J Diabetic Foot Complications*. 2010;2(2):33-44.

Design

Randomized Controlled Trial

Background/Objectives

Evaluate the effectiveness of 3M™ V.A.C.® Therapy in enhancing skin-graft take of diabetic foot wounds (Study I) and its effectiveness when used in the treatment of infected open minor amputations (Study II).

Methods

Two parallel randomized controlled trials were conducted. In Study I, 70 patients were randomly assigned to either V.A.C.® Therapy (V1 group) or coverage of the grafts with non-adherent gauze (C1 group). The primary endpoint for Study I was the evaluation of skin graft take. In Study II, 130 diabetic subjects were randomized to either surgical debridement and V.A.C.® Therapy (V2 group) or surgical debridement and semi-occlusive silver dressing (C2 group).

Results

Study I
The percentage of patients with complete graft take was significantly higher in the V1 group (80% vs. 68%, p = 0.05).

Study II
Primary Endpoint

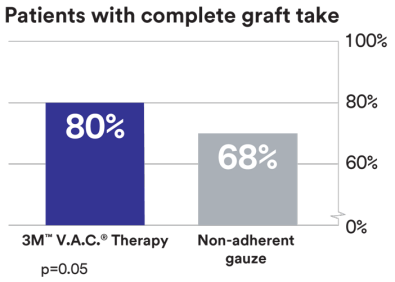
- Shorter time to granulation development over bone observed in V2 group (41 ± 8 vs. 59 ± 18 days, p = 0.03)

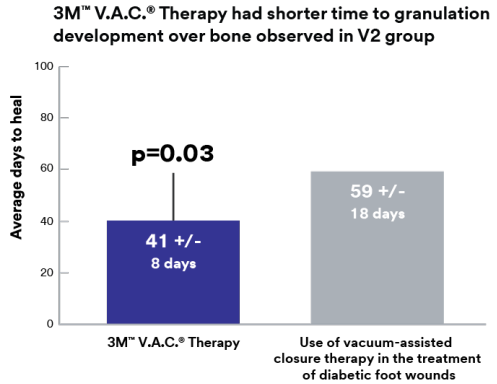
Secondary Endpoints

- Fewer days for infection control in V2 group (10 ± 8 vs. 19 ± 13 days, p = 0.05)
- Shorter time to complete closure was observed in the V2 group (65 ± 16 vs. 98 ± 45 days, p = 0.005)
- Similar rates of amputation after the follow up period were observed in both groups V2 (n = 3) and C2 (n = 5)
- Reduced time required for surgical procedures observed in V2 group (2.5 vs. 6 hours, p = 0.02)

Key Findings

This study demonstrates that the use of V.A.C.® Therapy in the treatment of diabetic foot wounds can be associated with reduced wound bed preparation time, shorter wound closure time and a better graft take rate when compared to standard wound care.





Vacuum-assisted closure improves the quality of life in patients with diabetic foot.

Karatepe O, Eken I, Acet E, Unal O, Mert M, Koc B, Karahan S, Filizcan U, Ugurlucan M, Aksoy M. Vacuum-assisted closure improves the quality of life in patients with diabetic foot. *Acta Chir Belg.* 2011;111(5):298-302.

Design

Randomized Controlled Trial

Background/Objectives

To determine 3M™ V.A.C.® Therapy effects on quality of life when used in the treatment of diabetic foot ulcers in comparison to standard wound care.

Methods

Consecutive diabetic foot ulcer patients (n = 67) were randomly split into two groups. One received V.A.C.® Therapy (Group 1, n = 30) while the other received standard wound care (Group 2, n = 37). The day before the study, and in the month following wound healing, an SF-36 questionnaire was administered. The researchers completed two comprehensive indexes of SF-36, Physical Component Summary (PCS) and Mental Component Summary (MCS). They also performed global analyses of the eight domains. Standard antidiabetic treatment, debridement, daily wound care including antiseptic bath, necessary toe removal for gangrene and wound care with conventional methods or V.A.C.® Therapy were used as clinical measures. The time from hospital admission to the time of re-epithelization was used to determine healing time.

Results

Baseline demographics were similar in both groups. For patients in the V.A.C.® Therapy group, there was a significant reduction in healing times. Following V.A.C.® Therapy, all eight domains of SF-36, PCS, and MCS scores were improved.

There was a significant reduction in healing times.
Following 3M™ V.A.C.® Therapy, all eight domains of SF-36, PCS, and MCS scores were improved.

Key Findings

The use of V.A.C.® Therapy in the treatment of chronic diabetic ulcers was shown to be effective and have positive effects on patient quality of life.

Comparing calcium alginate dressings to vacuum-assisted closure: a clinical trial.

Vassallo IM, Formosa C. Comparing calcium alginate dressings to vacuum-assisted closure: a clinical trial. *Wounds.* 2015 Jul;27(7):180-90.

Design

Prospective Cohort

Background/Objectives

A comparison and evaluation of vacuum-assisted closure wound therapy to calcium alginate dressings used in the treatment of neuroischemic diabetic foot ulceration.

Methods

Thirty subjects living with type 2 diabetes and presenting with a newly diagnosed neuroischemic foot ulceration participated in a single-center quasi-experimental matched subject clinical trial. There were two subject groups. Group A (n = 15) received negative pressure wound therapy and group B (n = 15) received calcium alginate dressings treatment. Throughout the trial, ulcer area and depth were measured.

Results

Negative pressure therapy was 3.2 times more effective in reducing ulcer surface area and 3.78 times more effective in reducing ulcer depth in comparison to calcium alginate ($p = 0.0001$).

Key Findings

For neuroischemic ulceration, negative pressure therapy should be considered the choice for wound management due to its ability to reduce ulcer surface area and depth in comparison to calcium alginate dressings. Improved health outcomes, improved quality of life and fewer diabetes-related foot complications could result from this type of therapy.

Vacuum-assisted closure versus moist dressings in the treatment of diabetic wound ulcers after partial foot amputation: a retrospective analysis in 65 patients.

Sukur E, Akar A, Uyar AC, Cicekli O, Kochai A, Turker M, Topcu HN. Vacuum-assisted closure versus moist dressings in the treatment of diabetic wound ulcers after partial foot amputation: a retrospective analysis in 65 patients. *J Orthop Surg (Hong Kong).* 2018 May-Aug;26(3):2309499018799769.

Design

Comparative Retrospective Study

Background/Objectives

A comparison in the effectiveness of 3M™ V.A.C.® Therapy with conventional moist wound dressings for diabetic wound ulcer treatment after partial foot amputations.

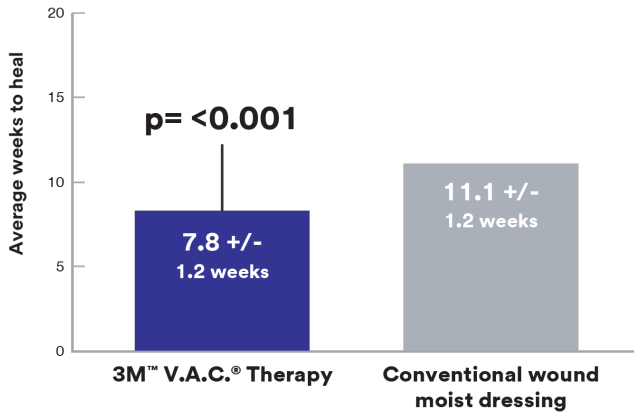
Methods

Sixty-five DFU patients who previously had partial foot amputation surgeries received either V.A.C.® Therapy (group A: 31 patients) or conventional wound moist dressing (group B: 34 patients) treatment.

Results

If a reamputation was required, the final result was considered a failure. A successful result included the patients who reached 90% of wound granulation. Group A reached 90% granulation tissue in significantly less time (7.8 +/- 1.2 weeks vs. 11.1 +/- 1.2 weeks; p < 0.001). Reamputation requirements showed no significant difference; 38.7% (12 patients) in group A and 41.2% (14 patients) in group B, (p = 0.839).

3M™ V.A.C.® Therapy reached 90% granulation quicker



Key Findings

For patients with complex DFUs who had previously received partial foot amputation surgery, a V.A.C.® Therapy system appears to provide effective treatment.

A retrospective cohort study evaluating efficacy in high-risk patients with chronic lower extremity ulcers treated with negative pressure wound therapy.

Yao M, Fabbi M, Hayashi H, Park N, Attala K, Gu G, French MA, Driver VR. A retrospective cohort study evaluating efficacy in high-risk patients with chronic lower extremity ulcers treated with negative pressure wound therapy. *Int Wound J.* 2014 Oct;11(5):483-8. Epub 2012 Nov 19.

Design

Retrospective Cohort Study

Background/Objectives

Analyze negative pressure wound therapy (NPWT) efficacy in comparison to the standard of care on wound healing for high-risk patients with multiple significant comorbidities and chronic lower extremity ulcers. Evaluate across the continuum of care settings.

Methods

Using Boston University Medical Center electronic medical records, along with chart abstraction to identify detailed medical history, comorbidities, healing outcomes and ulcer characteristics, researchers conducted a retrospective cohort study of high-risk patients. From 2002 to 2010, 258 diabetic ulcer patients (140 NPWT and 118 non-NPWT patients) were included in the cohort.

Results

Wound closures for NPWT (3M™ V.A.C.® Therapy System) patients increased in diabetic ulcers (HR = 3.26, 95% CI = 2.21-4.83).

Wound closures for NPWT (3M™ V.A.C.® Therapy System) patients increased in diabetic ulcers.

Key Findings

NPWT patients demonstrated shorter time to wound closure than non-NPWT patients, despite greater significant comorbidities. Early use of NPWT resulted in greater benefits than late intervention. There is a higher correlation with poor outcomes for longer intervals before NPWT interventions.

NPWT in diabetic foot wounds – a systematic review and meta-analysis of observational studies.

Rys P, Borys S, Hohendorff J, Zapala A, Witek P, Monica M, Frankfurter C, Ludwig-Slomczynska A, Kiec-Wilk B, Malecki MT. NPWT in diabetic foot wounds – a systematic review and meta-analysis of observational studies. *Endocrine.* 2020 Apr;68(1):44-55.

Design

Systematic Review and Meta-Analysis

Background/Objectives

A systematic review of observational non-RCTs analyzing NPWT safety and efficacy for DFU patients.

Methods

An electronic database search was conducted for NPWT observational studies. Single-arm study results were presented as percentages of patients with the relevant outcome. Point estimates of outcomes were calculated using a meta-analysis of comparative studies. Dichotomous data were reported as relative risks (RR), while continuous outcomes were reported as either weighted or standardized mean differences.

Results

Sixteen observational studies (12 single-arm and four comparative) were identified. In total, this included 18,449 patients with DFU (1,882 managed with NPWT). Among NPWT patients, ulcers were larger (average size range 6.6-27.9 cm^2) in comparison to controls (≤ 3 cm^2). For NPWT patients, 15% showed healing and 5% had major amputations.

The meta-analysis revealed a reduced risk of major amputations [RR = 0.23 (0.07; 0.80)] for patients receiving NPWT. Due to between-study heterogeneity, healing rate and any amputation risk were inconclusive. Six deaths out of 158 patients were reported in four publications, but none of them were considered to be related to NPWT. In 6% of NPWT patients, serious adverse events occurred.

NPWT patients experienced reduced risk of major amputations [RR=0.23 (0.07;0.80)].

Key Findings

There is supportive evidence in this systematic review of observational studies supporting the safety and efficacy of using NPWT as an adjunct therapy in DFU management.

DFU and 3M™ Snap™ Therapy System

Contents

Comparative effectiveness of mechanically and electrically powered negative pressure wound therapy devices: a multicenter randomized controlled trial.

Armstrong DG, Marston WA, Reyzelman AM, Kirsner RS. Comparative effectiveness of mechanically and electrically powered negative pressure wound therapy devices: a multicenter randomized controlled trial. *Wound Repair Regen*. 2012 May-Jun;20(3):332-41.

Design

Randomized Controlled Trial

Background/Objectives

This prospective, multicenter, comparative efficacy, noninferiority-powered, randomized controlled study was designed to compare 3M™ Snap™ Therapy System with 3M™ V.A.C.® Therapy in the treatment of noninfected, nonischemic, nonplantar lower extremity diabetic and venous wounds.

Methods

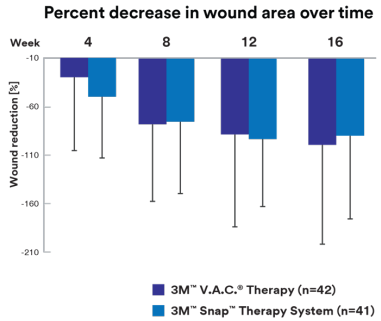
From 17 sites in the US, a total of 132 patients suffering from noninfected, nonischemic, nonplantar lower extremity diabetic and venous wounds were enrolled. Wounds that exhibited > 30% wound surface reduction during the first week after enrollment were excluded from the study. Dressing changes were performed according to the IFUs (2x/week for Snap Therapy, 3x/week for V.A.C.® Therapy, or more). Inclusion criteria included patients aged ≥ 18 years; lower extremity venous ulcer or diabetic ulcer with a surface area < 100 cm^2 but > 1 cm^2, and < 10 cm in widest diameter. Wounds were to have been present for > 30 days before admission.

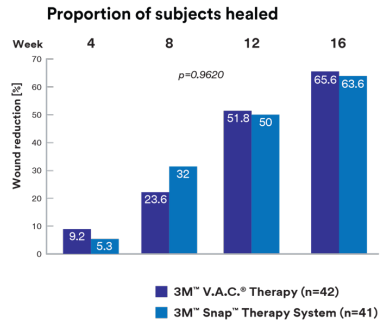
Results

Eighty-three patients (41 Snap Therapy, 42 V.A.C.® Therapy) completed the study with either healing or 16 weeks of therapy. Between 12 and 16 weeks of therapy, the Snap Therapy -group reported 63.6% wound healing and the V.A.C.® Therapy group reported 65.6% wound healing. At 4, 8, 12, and 16 weeks, there were no statistical differences identified between groups, either Snap Therapy (patients having a reduction of 73.8%, SD ± 78.35), or V.A.C.® Therapy (patients having a reduction of 75.0%, SD ± 85.28). However, the baseline wound surface area in the V.A.C.® Therapy group was significantly larger. There was no significant difference (p = 0.3449) in the proportion of subjects with wounds healed over time.

Key Findings

This study provides prospective, randomized, controlled trial evidence that wounds managed with Snap Therapy result in a similar wound size reduction to those managed with V.A.C.® Therapy.





Evaluation of chronic wound treatment with the 3M™ Snap™ Therapy System versus modern dressing protocols.

Lerman B, Oldenbrook L, Eichstadt SL, Ryu J, Fong KD, Schubart PJ. Evaluation of chronic wound treatment with the 3M™ Snap™ Therapy System versus modern dressing protocols. *Plast Reconstr Surg*. 2010 Oct;126(4):1253-1261.

Design

Prospective Observational and Retrospective Comparative

Background/Objectives

To evaluate the use of 3M™ Snap™ Therapy System in the treatment of more difficult chronic wounds of the lower extremity.

Methods

Twenty-one outpatient wound care clinic patients with chronic, lower extremity wounds received wound management with Snap Therapy and were observed for the lesser of up to four months or wound closure. The retrospective phase of the study compared these outcomes to a matched control group at the same clinic that received standard modern dressings.

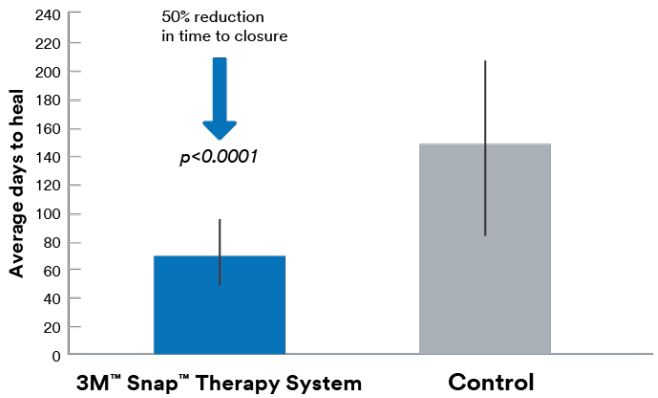
Results

All of the patients in the Snap Therapy group that tolerated treatment demonstrated wound size improvement and 86% displayed a significant healing trend toward wound closure ($p < 0.05$). Snap Therapy-treated subjects healed in an average of 74.25 ± 20.1 days, whereas the matched controls healed in an average of 148.73 ± 63.1 days. This significantly shorter time to closure represents a 50% absolute reduction in time ($p < 0.0001$) for Snap Therapy subjects.

Key Findings

Snap Therapy may be a helpful wound management tool, providing benefits for both patients and clinicians.

3M™ Snap™ Therapy System patient population shows a reduced time to closure



Comparative effectiveness of the 3M™ Snap™ Therapy System.

Hutton DW, Sheehan P. Comparative effectiveness of the 3M™ Snap™ Therapy System. *Int Wound J*. 2011 Apr;8(2):196-205.

Design

Health Economic Model

Background/Objectives

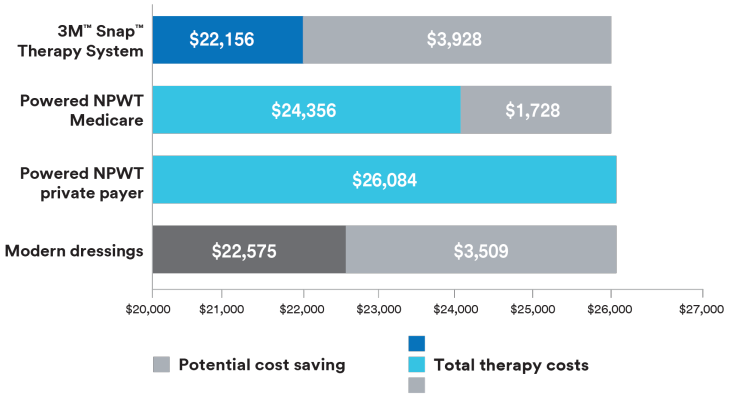
To compare the costs and the effectiveness of 3M™ Snap™ Therapy System versus 3M™ V.A.C.® Therapy and standard modern wound dressings.

Methods

Three wound care therapies were analyzed (modern wound care dressings, powered negative pressure wound therapy and Snap Therapy) for costs-effectiveness in the care of diabetic lower extremity wounds. The analysis design accounted for all healthcare costs and took a decision analytical modeling approach, using data available on each therapy to predict outcomes. Costs are based on the literature comparing NPWT to modern dressings and from USA Medicare reimbursement rates.

Results

The base case assumed that Snap Therapy has better effectiveness than modern dressings and equal effectiveness to powered negative pressure wound therapy. Based on this assumption, Snap Therapy was shown to save $9,699 (42%) over modern dressings, $2,774 (17%) over powered NPWT for a private payor and $2,296 (15%) over powered NPWT for Medicare.



Key Findings

Snap Therapy can lead to cost savings compared to modern wound dressings due to its potential to reduce wound closure time, avoiding the costs of longer treatment durations.

The 3M™ Snap™ Therapy System: biomechanical and animal model testing of a novel ultraportable negative-pressure wound therapy system.

Fong KD, Hu D, Eichstadt S, Gupta DM, Pinto M, Gurtner GC, Longaker MT, Lorenz HP. The 3M™ Snap™ Therapy System: biomechanical and animal model testing of a novel ultraportable negative-pressure wound therapy system. *Plast Reconstr Surg*. 2010 May;125(5):1362-1371.

Design

Animal Model

Background/Objectives

To evaluate potential differences between 3M™ Snap™ Therapy System and a wound vacuum-assisted closure advanced-therapy system device.

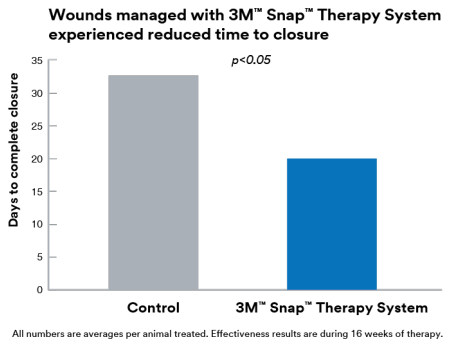
Methods

The study compared Snap Therapy with a wound vacuum-assisted closure advanced-therapy system. In vitro testing used a bench-top pressure sensor, pressure-sensitive film and microtomographic scan analysis. In addition, 10 rats with open wounds received a miniaturized Snap Therapy (mSNAP) device. A randomized system activation group (~ -125 mmHg) and control group (atmospheric pressure) were assembled. Wound measurements and histologic data were analyzed.

Results

Mechanical testing data:
Similar pressure was delivered by the Snap Therapy and the vacuum-assisted closure device in both conditions: in absence, as well as in presence of exudate. Both systems produced similar contact stress profiles for equivalent pressure levels.

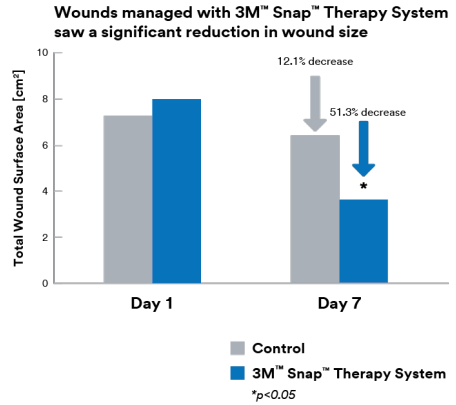
Animal testing data:
Animals treated with mSNAP had a 51% reduction in wound size compared to a 12% reduction in control subjects at post-op day 7. Fewer days to reepithelialization than in control subjects (21 days vs. 32 days; $p < 0.05$).



All numbers are averages per animal treated. Effectiveness results are during 16 weeks of therapy.

Key Findings

This analysis suggests that Snap Therapy and an electrically powered negative-pressure wound therapy system showed similar biomechanical properties and functional wound-closure benefits. Compared to control subjects, Snap Therapy demonstrated fewer days to complete wound closure.



All numbers are averages per animal treated. Effectiveness results are during 16 weeks of therapy. Percent decrease is relative to day 1.

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