3M Science. Applied to Life.™

Solutions for Venous Leg Ulcer Care

Clinical Evidence Summaries

Published on: October, 2021

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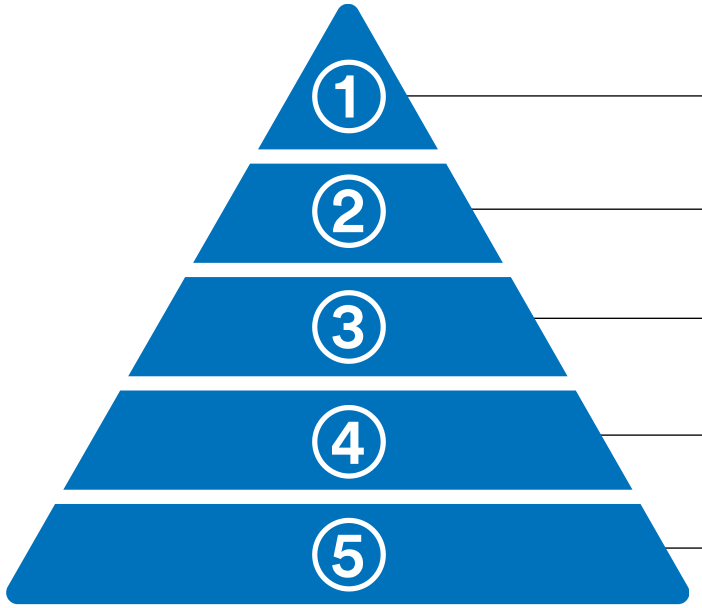
Levels of Evidence Key



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 is considered a case series.
5. Expert opinion, consensus documents, single case reports, economic models and literature reviews.

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VLU and Compression Studies

Contents

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3M™ Coban™ 2 Two-Layer Compression System delivered comfortable, skin friendly, sustained compression supporting edema reduction and venous leg ulcer healing.

Mosti G, Crespi A, Mattaliano V. Comparison Between a New, Two-component Compression System With Zinc Paste Bandages for Leg Ulcer Healing: A Prospective, Multicenter, Randomized, Controlled Trial Monitoring Sub-bandage Pressures. *Wounds* 2011;23(5):126-34.

Design

Randomized Controlled Study

Background/Objectives

Compare the effectiveness and tolerability of Unna Boot (UB), a multi-component, stiff, high-pressure bandage, to a new, two-component bandage.

Methods

100 patients with venous leg ulcers were randomized equally into two groups who either received zinc paste bandages or Coban 2 Compression System. Patients were observed on a weekly basis for 3 months; then monthly until completely healed. Primary outcomes included ulcer healing/area reduction, pain and exudate control. Secondary outcomes assessed ease of bandage application and removal, pressure after application and bandage comfort.

Results

Primary Outcomes within 3 Months

Coban 2 Layer Compression System patients were healed.

zinc paste patients were healed.

Median healing time, pain control, and reduction of leg edema and limb circumference were similar in both groups.

Secondary Outcomes

- Minimal bandage slippage (11/50 vs 5/50) and mild skin scaling (21/50 vs 7/50) occurred significantly more in the Coban group ($p<0.001$)
- Coban 2 Compression System was reported as easier to apply and remove and was well tolerated
- Upon removal, supine pressures were higher in the Coban group and standing pressures were higher in the zinc paste group, though not significant
- Static stiffness index was higher in the zinc paste group ($p<0.001$); however both groups had observed values associated with high stiffness

Key Findings

Coban 2 Compression System proved to be **effective in providing compression therapy in the treatment of venous ulcers due to its stiffness in delivering compression therapy** similar to zinc paste bandages, which are seen as gold standard treatment in some markets.

Equivalence in comfort, skin friendliness and ulcer pain reduction were seen in both compression systems.

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Crossover study showed 3M™ Coban™ 2 Two-Layer Compression System improved symptoms and daily living for patients with VLU.

Moffatt CJ, Edwards L, Collier M, et al. A randomised controlled 8-week crossover clinical evaluation of the 3M™ Coban™ 2 Layer Compression System versus Profore™ to evaluate the product performance in patients with venous leg ulcers. *Int Wound J.* 2008; 5(2):267-79. doi: 10.1111/j.1742-481X.2008.00487.x.

Design

Randomized Controlled Trial

Background/Objectives

Compare a two-layer compression system (Coban 2 Two-Layer Compression System) to a four-layer system (Profore™ Multi-Layer Compression Bandage System) in patients with venous leg ulcers.

Methods

81 participants (Coban n=39, Profore n=42) were enrolled in the 8-week study. Patients were randomized to the compression system used first. After 4 weeks, treatment was switched to the other compression system and used for another 4 weeks. The primary endpoint was bandage slippage measured at each dressing change. Secondary endpoints included wound healing, health-related quality of life (HRQoL) and patient preference.

Results

Primary Outcomes

Significantly less bandage slippage was observed for the 2-layer system between days 3-7 ($p<0.001$).

Secondary Outcomes

- Percent of wounds healed, wound area reduction, and healing rate was similar between the two groups
- HRQoL scores were significantly higher in the 2-layer system patients ($p<0.05$) the before treatment switch
- Patients had a strong preference for the 2-layer system
- Adverse events (n=135) were reported in 41 patients, though 67 with 4-layer system, 68 with a 2-layer system, 68% of events were unrelated to the compression bandages
- Adverse events included redness, eczema, folliculitis, wound infection, and pain at wound site, which are consistent with compression bandage use, a majority of which were unrelated to treatment
- Patients using Coban 2 reported significant improvement ($\rho = 0.046$) in their physical symptoms and daily living (e.g., sleep, comfort, mobility, ability to perform everyday tasks, etc.) compared to a 4-layer compression bandage, prior to treatment change

Key Findings

Coban 2 Compression System had **significantly less slippage** than Profore Compression Bandage.

While reduced bandage slippage did not impact wound healing, it may have influenced patient preference in favour of the the Coban 2 Compression System and potentially impacted patient's HRQoL.

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3M™ Coban™ 2 Lite Two-Layer Compression System shown safe for use on patients with mixed aetiology leg ulcers.

Ivins N, Jones N. Two-layer reduced compression system for lower limb wounds: a non-comparative evaluation. *Br J Community Nurs.* 2020; 25(Sup4):S10-S16. doi: 10.12968/bjcn.2020.25.Sup4.S10.

Design

Prospective Cohort

Background/Objectives

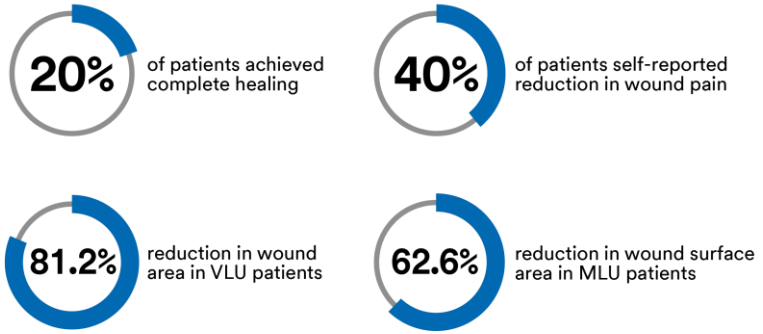
Evaluate the initial clinical experiences with Coban 2 Lite Compression System and evaluate the performance of the compression system in providing therapeutic compression for the treatment of chronic venous leg ulcers (VLU) and mixed aetiology leg ulcers (MLU).

Methods

Patients (n=30, 12 men, 18 women; mean age=68.5 years) were enrolled for evaluation. Patients with an ankle-brachial pressure index (ABPI) >= 0.5 and <=0.8 and patients with normal arterial perfusion (ABPI>0.8) who could not tolerate bandaging were included. Patients were followed for 16 weeks or until the ulcer was healed.

Results

Primary Outcomes



- Decreased volume of wound exudate was observed 16 patients (53%)
- Minimal periwound maceration was recorded in 20% of patients

Adverse Events

- Adverse events were reported in nine patients; events included wound infection (n=3), bandage discomfort (n=1), unable to tolerate compression (n=2), and increased pain (n=1)
- The remaining two patients withdrew from the study due to non-bandage related events

Key Findings

Patients suggested Coban 2 Lite Compression System was **comfortable to wear** with minimal slippage.

Coban 2 Lite Compression System was **safe and effective** for providing compression therapy in the treatment of venous leg ulcers and mixed etiology ulcers in **patients unable to tolerate high-strength compression.**

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3M™ Coban™ 2 Lite Two-Layer Layer Compression System shown safe for use on patients with moderate peripheral arterial occlusive disease.

Ladwig A, Haase H, Bichel J, Schuren J, Junger M. Compression therapy of leg ulcers with PAOD. *Phlebology.* 2014, 29(1 suppl):7-12. doi: 10.1177/0268355514529507. Epub 2014 May 19.

Design

Prospective Cohort

Background/Objectives

Assess the safety of Coban 2 Lite Compression System (a short-stretch, 2-layer compression system) for use on subjects with peripheral arterial occlusive disease (PAOD).

Methods

Subjects (n=15, 7 females, 8 males) with moderate PAOD (ankle-bracial pressure index [ABPI] of 0.5-0.8) had the compression system applied on days 1, 2, 3, 4, 7, 10, 14 of the study with sub-bandage pressure post-application, pressure-related skin damage, hypoxia-related pain, and adverse events recorded. Subject comfort was assessed through a questionnaire at the final visit.

Results

- After bandage application, the average sub-bandage pressure (while standing) was between 31.20 +/- 7.85 mmHg at visit 0 and 29.54 +/- 6.96 mmHg at visit 6
- Leg volume assessment revealed a significant reduction in average volume (p=0.03) at the end of the study

Adverse Events

- Adverse events (n=22) were reported in 12 patients
- Adverse events included: skin dryness, contraction, sweating, tightness, itching, pain, and erysipelas
- One adverse event (cardiac arrhythmia) was classified as serious, but was not related to treatment
- No clinical signs of skin damage occurred with use of Coban 2 Lite Compression System

Key Findings

Coban 2 Lite Compression System was **safe for patients with ABPI of 0.5-0.8.**

Coban 2 Lite Compression System was **well tolerated by patients.**

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3M™ Coban™ 2 Two-Layer Compression System improved clinical outcomes and cost-effectiveness in newly diagnosed venous ulcers.

Guest JF, Fuller GW, Vowden P. Clinical outcomes and cost-effectiveness of three different compression systems in newly-diagnosed venous leg ulcers in the UK. *J Wound Care*. 2017; 26(5):244-254. doi: 10.12968/jowc.2017.26.5.244.

Design

Comparative Retrospective Study

Background/Objectives

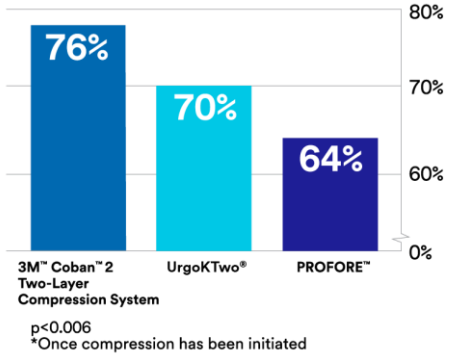
Assess in clinical practice in the United Kingdom the clinical outcomes and cost-effectiveness of using Coban 2 Compression System (two-layer compression system) in the treatment of patients newly-diagnosed with a venous leg ulcer (VLU) compared with two other systems: KTwo (two-layer); and Profore™ Multi-Layer Compression Bandage System (four-layer).

Methods

A retrospective cohort analysis of data from patients newly diagnosed with a VLU, randomly extracted from a database shown to contain patient data representative of the UK population (The Health Improvement Network database). Patients were treated with one of three compression bandaging systems (Coban 2, n=200; KTwo, n=200; Profore, n=200). Clinical outcomes and cost-effectiveness of the alternative compression systems were estimated over six months after starting treatment.

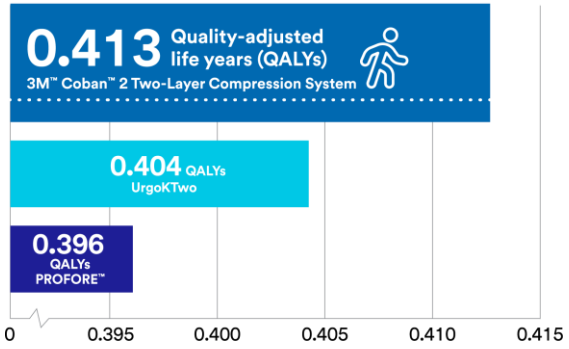
Results

VLU Healing Rate within 6 months*



p<0.006
*Once compression has been initiated

Mean number of quality of life after 6 months per patient



Key Findings

Initiating compression therapy with the Coban 2 Compression System was associated with **increased healing rate** and significantly **less time to heal.**

Coban 2 Compression System provided **better health-related quality of life** and **decreased management costs.**

Patient management costs were lower with 3M™ Coban™ 2 Layer Compression System

47% ↑ PROFORE™

26% ↑ UrgoKTwo™

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VLU and Negative Pressure Wound Therapy (NPWT)

Contents

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Negative pressure wound therapy shown to be effective for patients with VLU wounds present for more than 30 days.

Marston WA, Armstrong DG, Reyzelman AM, Kirsner RS. A multicentre randomized controlled trial comparing treatment of venous leg ulcers using mechanically versus electrically powered negative pressure wound therapy. *Advances in Wound Care*. 2015; 4(2):75-82.

Design

Multicenter Randomized Controlled Trial

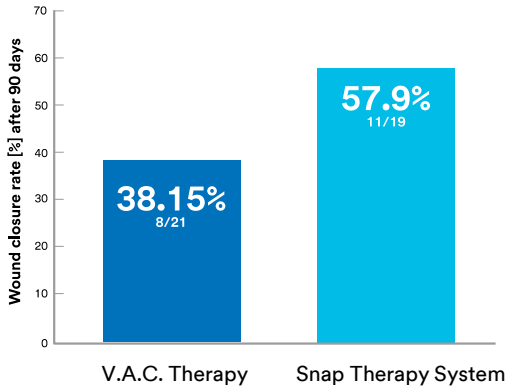
Background/Objectives

This study is a sub-analysis of a previously published RCT and compares two different negative pressure wound therapy (NPWT) modalities in the treatment of venous leg ulcers (VLUs), the mechanically powered 3M™ Snap™ Therapy System (MP NPWT) to the electrically powered vacuum-assisted 3M™ V.A.C.® Therapy System (EP NPWT).

Methods

132 patients with lower extremity wounds, including a large number of VLUs, from 13 sites participated in this study. Patients were randomly assigned either MP NPWT or EP NPWT and evaluated for 16 weeks or until complete wound closure was observed. Patients with lower extremity VLUs present for > 30 days with surface area <100 cm^2 and >1 cm^2 were included in the study. This sub-analysis included 40 patients (19 MP NPWT, 21 EP NPWT). The primary outcomes assessed wound size reduction and rates of wound healing. Secondary outcomes included serious adverse events, device-related adverse events, and complications.

Results



Primary Endpoint

- Analysis of wound size reduction* found wounds treated with MP NPWT had significantly greater wound size reduction at 4, 8, 12, and 16 weeks (p-value <0.05)
- At 90 days, a higher number of MP NPWT patients showed complete wound closure compared to EP NPWT patients

Secondary Endpoint

Serious adverse events, device-related adverse events, and complications were similar between the treatment groups (p>0.05).

Key Findings

An average wound size reduction of 38.4% decrease in wound area at 8 weeks and 49.5% decrease at 16 weeks was found for all 40 sub-analysis patients.

Adverse events, device-related adverse events, and complications reported were similar to the previously reported larger study population.

These results support the use of MP-NPWT for the treatment of VLUs.

*The MP NPWT patients had a mean initial wound size smaller than the EP NPWT patients (4.85 +/- 4.49 cm^2 vs 11.60 +/- 12.12 cm^2)

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The 3M™ Snap™ Therapy System showed a 50% reduction in time to healing for highly challenging lower extremity wounds.

Lerman B, Oldenbrook L, Eichstadt SL, Ryu J, Fong KD, Schubart PJ . Evaluation of Chronic Wound Treatment with the SNAP Wound Care System versus Modern Dressing. Protocols. Plast Reconstr Surg. 2010;126(4):1253-1

Design

Prospective Observational Study with Retrospective Control

Background/Objectives

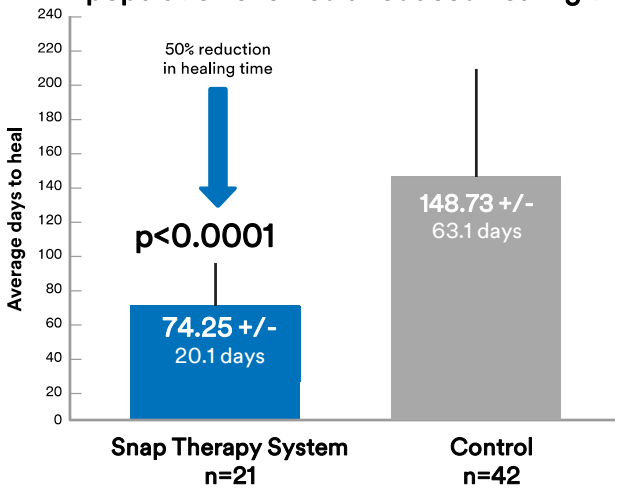
Evaluate the Snap Therapy System for the treatment of more difficult chronic wounds of the lower extremity.

Methods

63 patients (Snap Therapy n=21, matched controls n=42) at an outpatient wound care clinic with difficult-to-treat lower extremity ulcers were included in this study. Inclusion criteria were chronic wounds on the lower extremity <10 cm in greatest diameter and > 1.5 cm in narrowest diameter, and surrounded by 2 cm or more of intact epithelium around the wound edges. In addition, the wound must not have healed following > 14 days of use of traditional treatments. Two unique historical control patients treated with standard wound dressings (control group) were matched to each Snap Therapy System patient. Time required for healing was assessed.

Results

Snap Therapy System-treated patient population showed a reduced healing time:



- Snap Therapy System group patients had significantly higher history of osteomyelitis than the control group (p=0.036)
- Snap Therapy System group patients showed wound size reduction and 86% (18/21) exhibited a significant trend (p<0.05) toward wound healing over the 4-month study period
- Snap Therapy System group showed a 47.4% improvement in the percentage of wounds healed over the study period compared to the control group
- When the individual patient was compared to their matched controls, time to healing was reduced in the Snap Therapy System patient (p<0.0001)

Key Findings

Subjects treated with Snap Therapy System had **significantly reduced healing times.** Snap Therapy System may be useful for the **treatment of difficult lower extremity wounds.**

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VLU and 3M™ Promogran™ Matrix Family

Contents

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Twice as many VLU wounds healed at week 4 in those patients that received 3M™ Promogran Prisma™ Wound Balancing Matrix vs. Standard of Care.

Cullen BM, Serena TE, Gibson MC, Snyder RJ, Hanft JR, Yaakov RA. Randomized Controlled Trial Comparing Collagen/Oxidized Regenerated Cellulose/Silver to Standard of Care in the Management of Venous Leg Ulcers. Adv Skin Wound Care. 2017 Oct;30(10):464-468. doi: 10.1097/01.ASW.0000524452.80170.d8.

Design

Randomized Controlled Trial

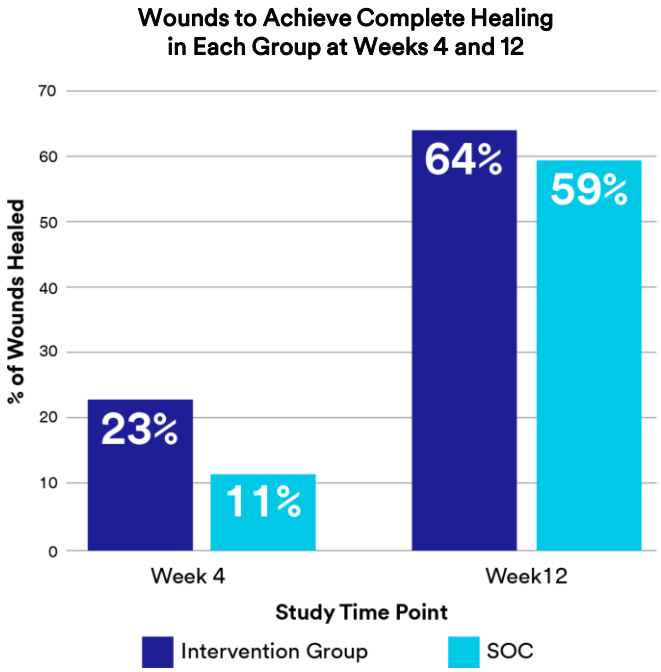
Background/Objectives

Evaluate healing outcomes in venous leg ulcers (VLUs) treated with Promogran Prisma Matrix, a combination of collagen, oxidized regenerated cellulose and silver, in conjunction with standard of care (SOC) which included multilayer compression and 3M™ Adaptic™ Non-Adhering Dressing, (collectively the intervention group) compared with SOC alone (control group).

Methods

49 subjects were randomized on a 1:1 basis to either an intervention group (n=22) or control group (n=27). The primary endpoint was percentage of wound area reduction at 12 weeks. Secondary endpoints included proportion of wound closure (100%) and pain assessment.

Results



A mean wound area reduction of 85.6% was observed for the collagen/ORC/silver group compared to 72.5% in the SOC group; this was not statistically significant.

Key Findings

Trend toward improved healing rate in the intervention group versus control group. Collagen/oxidized regenerated cellulose/silver is a **suitable and safe adjunctive intervention** for use with SOC to manage VLUs.

This study is limited by a lack of run-in period to exclude wounds on a healing trajectory and a lower number of included patients.

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3M™ Promogran™ Protease Modulating Matrix Wound Dressing helped achieve significant reduction in VLU wound area.

Vin F, Teot L, Meaume S.The healing properties of Promogran in venous leg ulcers. J Wound Care. 2002 Oct;11(9):335-41. doi: 10.12968/jowc.2002.11.9.26438.

Design

Randomized Controlled Trial

Background/Objectives

Compare healing rates of venous leg ulcers (VLUs) treated with Promogran Matrix and compression therapy with those treated with a non-adherent dressing and compression therapy.

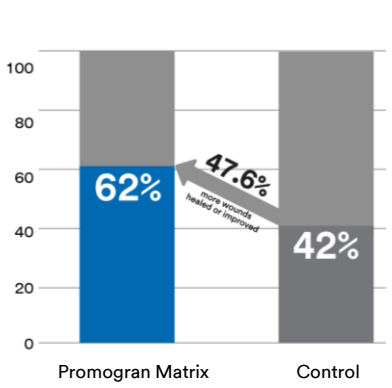
Methods

73 patients with stagnating VLUs, from 14 centres in France were included in the study. Target wounds were >2cm but <10cm in any one dimension. Subjects were randomly provided either Promogran Matrix (n=37) or a non-adherent dressing (3M™ Adaptic™ Non-Adherent Dressing) (n=36) with a secondary dressing of gauze followed by short-stress compression (Biflex). Wounds were assessed weekly over 12 weeks and dressings were changed at least twice weekly by either study participating nurses or the investigator. Independent clinicians reviewed and assessed wound tracings and imagery and performed an intent-to treat analysis.

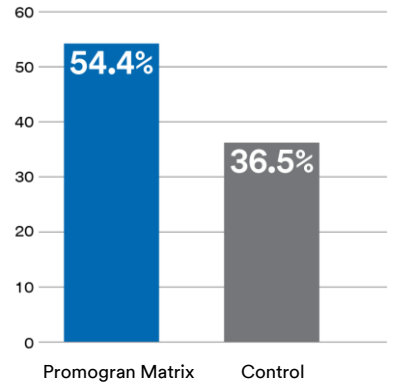
Results

- 25 patients healed prior to week 12
- Wound surface area decreased significantly more in patients treated with Promogran Matrix p<0.0001
- No severe local adverse events were reported in either group; poor dressing tolerance was noted as the reason to switch treatment in five control patients and three Promogran Matrix patients

A 12-week multicentre RCT involving VLU patients (n=73) showed:



Wounds Healed or Improved (p=0.0797)



Reduction in Wound Area (p=0.0001)

Key Findings

A trend toward increased rates of healing (or reduction in time to heal) was seen in patients that were allocated the Promogran Matrix dressing compared to those allocated the non-adherent control dressing.

Promogran Matrix promoted a significant reduction in wound surface area compared to the non-adherent control dressing.

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3M™ Promogran Prisma™ Wound Balancing Matrix helped maintain an environment that allowed for optimal healing of donor site wounds.

Konstantinow A, Fischer TV, Ring J. Effectiveness of collagen/oxidized regenerated cellulose/silver-containing composite wound dressing for the treatment of medium-depth split-thickness skin graft donor site wounds in multi-morbid patients: a prospective, non-comparative, single-centre study. Int Wound J. 2017 Oct;14(5):791-800. doi: 10.1111/iwj.12698. Epub 2016 Dec 1.

Design

Prospective, Non-Comparative, Single-Centre Study

Background/Objectives

Evaluate the performance of a composite wound dressing containing collagen/oxidized regenerated cellulose (Promogran Prisma Matrix) in the treatment of medium-depth (0·4 mm) donor site wounds (DSWs) in multi-morbid patients diagnosed with chronic leg ulcers (chronic non-diabetic or venous leg ulcers (VLU) that required split-thickness skin grafting (STSG).

Methods

25 patients (mean age 71.6 years) with multiple comorbidities were included in the study. DSW (mean 78-cm^2) were covered with: non-adhesive silicone mesh, Promogran Prisma Matrix, absorbent foam dressing, cotton gauze pads, and long-stretch bandaging. Dressings were left in place for 10 days, except in the case of heavy bleeding. The primary objective was to determine the DSW time to heal; the secondary objective evaluated the postoperative DSW bleeding and patient reported pain (using a 6 item scale).

Results

Primary Endpoint

Complete DSW epithelialization was observed between postoperative day (POD) 10 and 34 (mean 17.2 days)

Secondary Endpoints

- Postoperative medium to strong DSW bleeding was observed in five patients within the first two postoperative days (PODs). However, only two of these required superficial dressing change.
- Postoperative DSW pain levels were moderate (mean 0.5, range 0-1.5) on POD 1
- While clinical signs of DSW infection were seen in two patients after the first dressing change, neither needed antibiotic treatment

Key Findings

The composite dressing used helped maintain an environment that allowed for epithelization resulting in fast wound healing of 0·4 mm donor site wounds with **minimal or no pain** and bleeding even in patients under anticoagulation.

Because of longer dressing change intervals and a low DSW morbidity, the composite dressing used has the **potential to reduce treatment costs.**

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3M™ Promogran™ Protease Modulating Matrix Wound Dressing reduces gelatinase and elastase in wound exudates of patients with VLU.

Smeets R, Ulrich D, Unglaub F, Woltje M, Pallua N.Effect of oxidized regenerated cellulose/collagen matrix on proteases in wound exudate of patients with chronic venous ulceration. Int Wound J. 2008 Jun;5(2):195-203. doi: 10.1111/j.1742-481X.2007.00367.x.

Design

Prospective Controlled Cohort Study

Background/Objectives

Oxidized regenerated cellulose/collagen matrix (ORC/collagen matrix) has been reported to modify wound microenvironments by binding and inactivating excess levels of proteases such as elastase, plasmin and gelatinases in wound exudates. Study sought to compare levels of the gelatinases matrix metalloproteinase 2 (MMP-2), elastase and plasmin in wound exudates collected from chronic venous insufficiency patients with venous leg ulcers treated with either an ORC/collagen matrix or a standard control therapy.

Methods

27 patients, during a 12-week treatment period, wound exudate samples were obtained from a control group of 10 patients treated with a hydrocolloid dressing and a treatment group of 17 patients treated with a combination of ORC/collagen matrix and hydrocolloid dressing.

On admission and days 5, 14 and every subsequent 14th day, ulcers were photographed to determine healing rate and changes in ulcer appearance, and MMP-2 concentration and the gelatinase, elastase and plasmin activities were analyzed from wound exudates.

Results

- Wound healing rates, MMP-2 concentrations, and plasmin activity were similar between the two groups
- Gelatinase activity was significantly reduced in ORC/collagen matrix treated patients on days 5, 14, 28, and 42 compared to day 0 ($p<0.05$)
- Reduced elastase activity was observed in wound exudates from ORC/collagen matrix patients at all time points ($p<0.05$)

Key Findings

ORC/collagen matrix reduces elastase and gelatinase activity in patients with chronic venous ulcers wound exudates of in vitro.

ORC/collagen matrix treatment reduces gelatinase and elastase activity in wound exudates of patients with chronic venous insufficiency (CVI). Thereby, rebalancing the hostile chronic wound microenvironment and facilitating wound repair.

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Early use of 3M™ Promogran Prisma™ Wound Balancing Matrix may improve clinical outcomes.

Cullen B, Gibson M, Nisbet L. Early adoption of collagen/ORC therapies improves clinical outcomes. Poster presented at the 4th Congress of the World Union of Wound Healing Societies, September 2-6, 2012; Yokohama, Japan

Design

Prospective Multi-centre Cohort Study

Background/Objectives

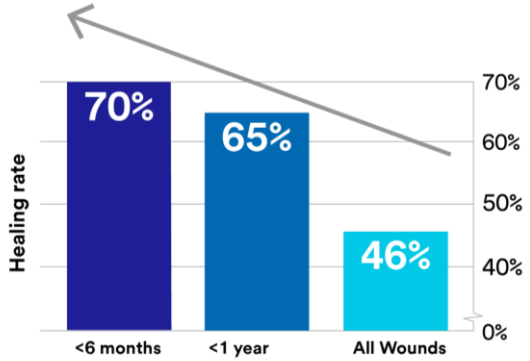
Determine prognostic factors predictive of response to Collagen/ORC and Collagen/ORC/Silver therapies.

Methods

Patients with VLUs (n=56) were randomized on a 1:1 basis to receive either C/ORC or C/ORC/Silver therapy. Wound area was measured every two weeks for up to 12 weeks. Clinical endpoints included 50% reduction in wound area by week 12 and VLU healing by week 12.

Results

- Early treatment with Collagen/ORC or Collagen/ORC/Silver increased the rate of wounds healed and improved within 12 weeks ($p<0.0005$)
- The improvement rate was 88% in wounds <1 year



Key Findings

VLUs of <6 months' duration showed **improved healing or were healed in 12 weeks .**

Early Usage of Promogran Prisma Matrix in wound management may lead to **improved success rates.**

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VLU and Other Advanced Wound Care Solutions

Contents

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A large-scale evaluation of managing moderate and highly exuding wounds in the community.

Hughes M.A., Jones J. A large-scale evaluation of managing moderate and highly exuding wounds in the community. Wounds UK. 2017; 13(3):78-85.

Design

Product Evaluation Survey/Questionnaires n=101

Background/Objectives

This article reports findings from a large-scale NHS evaluation (101 patient evaluations) that looked at the clinical performance of 3M™ Kerramax Care™ Super-Absorbent Dressing in exudate management, and patient satisfaction with it as a primary dressing.

Methods

District nurses completed one evaluation form per patient documenting their experiences of using Kerramax Care Dressing in their wound management practice.

A total of 101 patient evaluations were completed. All wounds were moderate to heavily exuding wounds.

Results

Figure 1. Effectiveness of care: exudate control

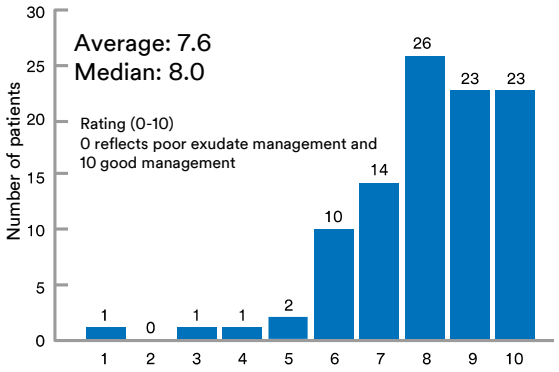


Figure 2. Patient safety: surrounding skin

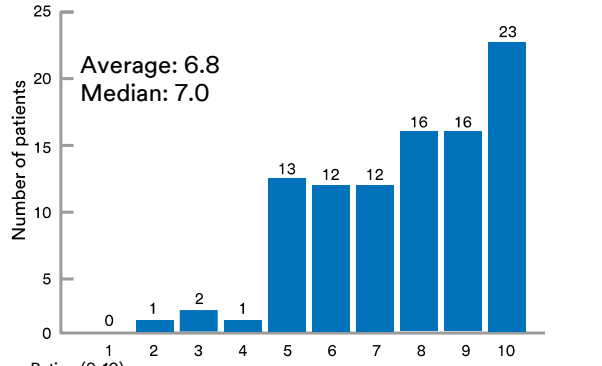
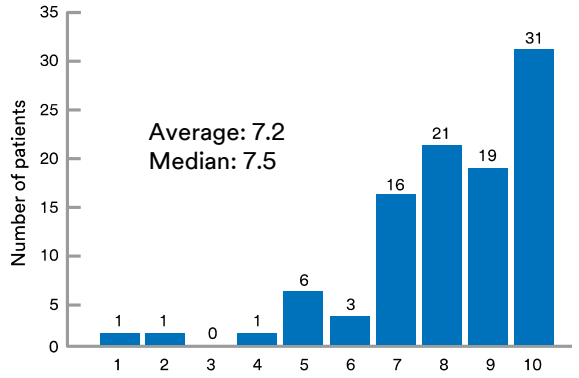


Figure 3. Patient experience: patient comfort



Key Findings

32% of nurses stated that Kerramax Care Dressing exceeded expectations.

98% of clinicians would be happy to continue using Kerramax Care Dressing as their superabsorbent of choice.

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VLU and 3M™ Cavilon™ No Sting Barrier Film

Contents

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3M™ Cavilon™ No Sting Barrier Film shown to be more cost effective than zinc paste in venous leg ulcer treatment.

Cameron J, Hoffman D, Wilson J, Cherry G. Comparison of two peri-wound skin protectants in venous leg ulcers: a randomized controlled trial. *J Wound Care*. 2005;14(5):233-6. doi: 10.12968/jowc.2005.14.5.26779.

Design

Randomized Controlled Trial

Background/Objectives

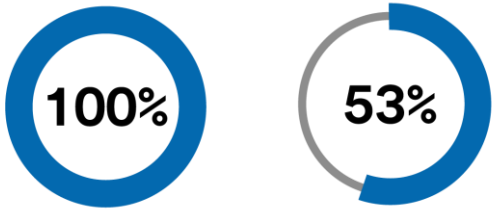
A randomized controlled trial was designed to determine whether or not early intervention with a suitable skin barrier preparation could prevent skin breakdown. This study was conducted to compare the efficacy and cost-effectiveness of two skin protectants, Cavilon No Sting Barrier Film (NSBF) and zinc paste compound, in the management of maceration and irritation of the peri-wound area of venous leg ulcers.

Methods

The study assessed 35 patients with venous leg ulcers and surrounding skin problems treated with either Cavilon No Sting Barrier Film or zinc paste compound. Treatments were reapplied at each dressing change for 12 weeks.

Results

Skin comfort level responses of "good" or "very good"



The mean total costs over 12 weeks **was significantly higher for the zinc oxide group (p<0.0001).**

Average removal and reapplication time

Cavilon No Sting Barrier Film	Zinc Paste
0.19 minutes	**5.53** minutes
p<0.0001	

Key Findings

The **wound area** of venous leg ulcers treated with Cavilon No Sting Barrier Film **reduced by 55.5%** after 12 weeks.

Time for removal and reapplication was **significantly shorter** with Cavilon No Sting Barrier Film than zinc paste.

Patients treated with Cavilon No Sting Barrier Film reported **lower pain and higher comfort** of periwound skin.

Despite having higher product cost, 12 weeks of treatment with Cavilon No Sting Barrier Film was significantly more cost effective than zinc oxide paste.

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Venous leg ulcer patients treated with 3M™ Cavilon™ No Sting Barrier Film used in combination with a multilayer compression system saw a greater reduction of ulcer size.

Serra N, Palomar F, Fornes B, Capillas R, Berenguer M, Aranda J, Sanchez J, Ruiz P, Reina T, Marinel.lo J. Effectiveness of the association of multilayer compression therapy and periwound protection with Cavilon (no sting barrier film) in the treatment of venous leg ulcers. *Gerokomos*. 2010;21(3):124-130.

Design

Randomized Controlled Trial

Background/Objectives

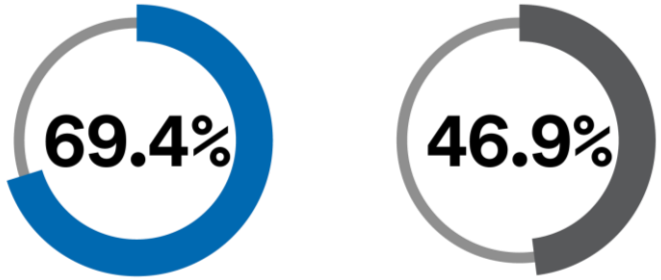
Evaluate the clinical effectiveness of a multi-layer compression bandage and the impact of Cavilon No Sting Barrier Film use on the periwound skin of venous leg ulcers.

Methods

All patients were treated with compression therapy with the same multilayer bandages and randomized to the intervention group (n=49), treated with Cavilon No Sting Barrier Film, or to the control group (n=49). Up to 13 weekly visits were performed over the span of 12 weeks. The study was reviewed and approved by the institutional research board of the seven participating centers. The primary endpoint was ulcer size reduction.

Results

Percentage of patients with ulcer reduction over 50% at 4 weeks.



- At the conclusion of 4 weeks, 69.4% of Cavilon group patients showed over 50% ulcer size reduction ($p<0.01$)
- After 12 weeks, 83.4% of patient in the Cavilon group and 71.6% of patients in the control group had ulcer size reductions greater than 50% ($p=0.046$)

Key Findings

Within the first 4 weeks of treatment, ulcers treated with Cavilon No Sting Barrier Film, in combination with compression therapy, **decreased in size by at least half.**

In addition to receiving compression therapy, patients treated with Cavilon No Sting Barrier Film had **greater reduction of ulcer size** at 12 weeks than the control group.

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3M™ Cavilon™ No Sting Barrier Film demonstrated rapid and substantial reduction in periwound erythema compared to placebo.

Neander KD, Hesse F. The protective effects of a new preparation on wound edges. *J Wound Care* 2003; 12(10): 369-371.

Design

Randomized Controlled Trial

Background/Objectives

This study investigated the effect of Cavilon No Sting Barrier Film (NSBF) versus control (water) on erythema on the edges of highly exuding wounds in patients with venous stasis ulcers.

Methods

An intra-individual double-blind randomized test was completed in 227 patients. The two sides of each wound on each patient were treated, with NSBF applied to one side of the wound edge and the control applied to the other side. Periwound erythema was assessed daily using a chromameter.

Results

Day 2: NSBF treated side **erythema had reduced to 1%** versus 97% on the control side.

Day 3: **Erythema had completely disappeared in 88.1%** of the periwound skin treated with NSBF.

Day 4: periwound skin treated with NSBF achieved **total erythema clearance**.

vs

99% erythema intensity for control-treated skin.

Key Findings

The study showed the protective effects of Cavilon No Sting Barrier Film in helping to control erythema. In 97.3% of the wound edges treated with NSBF, the erythema noticeably decreased within two days.

Erythema reduction of the periwound skin was shown to be superior in those wound edges treated with NSBF in each of the 4 days of treatment.

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3M™ Cavilon™ No Sting Barrier Film shown to be easier to apply and remove in diabetic foot ulcer and venous leg ulcer treatment.

Dini V, Salibra F, Brilli C, Romanelli M. Instrumental evaluation of the protective effects of a barrier film on surrounding skin in chronic wounds. *Wounds*. 2008;20(9):254-7.

Design

Prospective Cohort Study

Background/Objectives

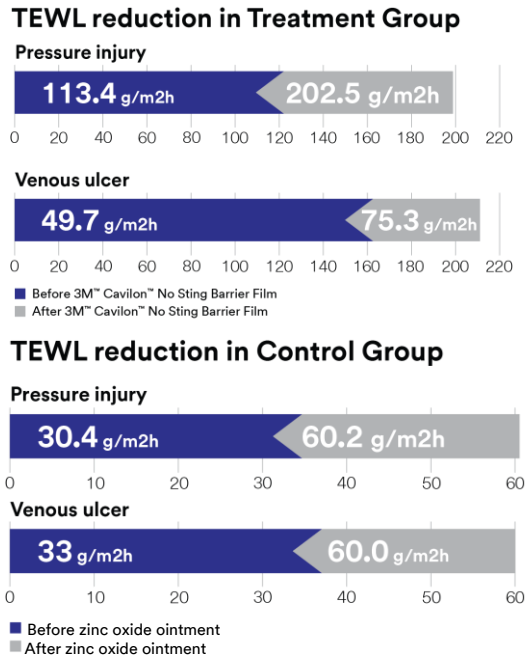
This randomized, observational study investigated the effects of Cavilon No Sting Barrier Film on skin surrounding chronic wounds monitoring its transepidermal water loss (TEWL).

Methods

The study evaluated 20 patients with pressure injuries and 20 patients with venous ulcers. Primary endpoint was TEWL, indicative of skin integrity. Patients were treated with either Cavilon No Sting Barrier Film (treatment group) or zinc oxide ointment (control group).

Results

By week 4, there was a 45% overall reduction in TEWL values in both the treatment group and control group compared to baseline (p<0.01)



Clinicians found that Cavilon NSBF was easier to apply and remove than zinc oxide ointment, which could cause trauma to the periwound skin

Key Findings

Patients treated with Cavilon No Sting Barrier Film showed a **45% reduction in transepidermal water loss.**

Cavilon No Sting Barrier Film was found to be **easier to apply and remove** than zinc oxide ointment.

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Skin protected with 3M™ Cavilon™ No Sting Barrier Film or 3M™ Cavilon™ Durable Barrier Cream showed a greater reduction in venous leg ulcer size.

Guest JF, Taylor RR, Vowden K, Vowden P. Relative cost-effectiveness of a skin protectant in managing venous leg ulcers in the UK. *J Wound Care*. 2012;21(8):389-94, 396-8. doi: 10.12968/jowc.2012.21.8.389

Design

Retrospective Analysis of Historic Cohort

Background/Objectives

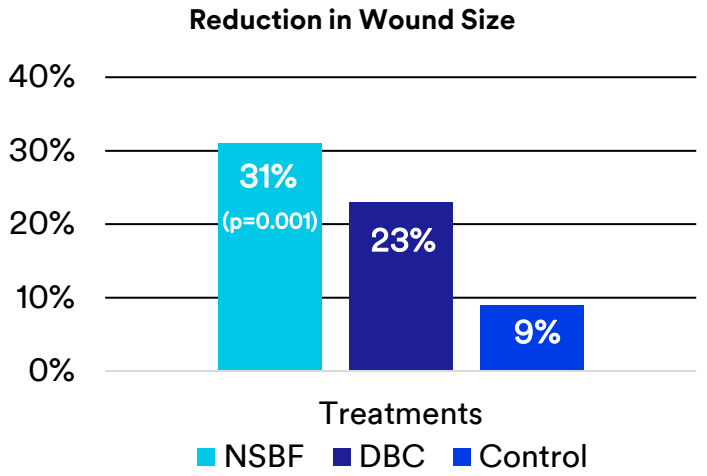
Estimate the clinical and cost-effectiveness of using a skin protectant — Cavilon No Sting Barrier Film (NSBF) or Cavilon Durable Barrier Cream (DBC) — versus not using one in venous leg ulcer (VLU) management.

Methods

Patients with VLUs between 2008 and 2009 were treated with Cavilon skin protectant — NSBF (n=166) and DBC (n=89) — matched to control patients (n=255) from The Health Improvement Network (THIN) database. Used Cavilon skin protectants significantly more ($p<0.05$) in patients with larger wound size and high exudate levels. Estimated costs and outcomes of patient management over six months.

Results

- At 6 months, there was no difference in percent of ulcers fully healed or time to full healing between the three groups
- Resource use was similar between the three groups



Key Findings

Significantly greater wound size reduction was observed in the group treated with NSBF compared to the other two groups. NSBF can offer protection to larger wounds, to help promote wound healing, without increasing costs.

Clinicians were more likely to use Cavilon skin protectant in large, highly exudating wounds.

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