Venous leg ulcers affect 400,000 to 600,000 people in the U.S. every year and account for 80-90% of all leg ulcers.
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The Importance of Compression Therapy in Healing Venous Leg Ulcers

The Costs are High
Venous leg ulcers are the most serious complication of venous hypertension. Epidemiological studies suggest that between 1-2% of the population will develop a venous ulcer at some time. These wounds have a high rate of recurrence and are considered to be a major health care problem. The costs for treating venous leg ulcers to the U.S. health care system alone are estimated to be $1 billion per year.²

Venous Leg Ulcers Reduce Patient Quality of Life
Venous leg ulcers significantly reduce patient quality of life. In fact, 81% of patients with venous leg ulcers experience decreased mobility, and 50% report severely limited mobility. As a result, 68% of patients with impaired mobility experience fear, anger, depression and social isolation.²

Compression Therapy is Proven Effective
Compression therapy has been recorded in history from as early as the time of Hippocrates (460–377 BC)³ and is considered the standard of care for treating venous hypertension and venous ulceration. The goal of compression therapy is to reduce edema in the lower extremities by:

• Reducing blood pressure in the superficial venous system
• Aiding venous return of blood to the heart by increasing the velocity of flow in the deep veins
• Reducing the pressure differences between the capillaries and the tissue to prevent backflow

Compression therapy has been shown to improve the lives of patients by significantly reducing edema, increasing mobility and reducing pain.

3M: Advancing the Science of Compression Therapy
3M advanced the science of compression therapy by creating materials engineered to deliver Intelligent Compression Dynamics to provide comfortable, therapeutic compression for the treatment of venous leg ulcers.

Challenges with Current Compression Systems

Clinician-Related Challenges
• Clinicians have varying levels of experience applying compression bandages; training may be informal, inadequate or non-existent
• Application techniques are different for each product
• It can be difficult to attain the appropriate stretch (30-70%) for some elastic bandage systems
• Clinicians may be concerned about potential for injury from bandages, and therefore, may not apply enough compression
• Clinicians know the systems are often poorly tolerated by their patients because they’re bulky, uncomfortable or painful
• Application and removal of zinc paste bandages can be messy; application and removal of four-layer systems can be time consuming
• Some patients require an “unscheduled” clinic visit between regularly scheduled visits, placing additional burden on the clinician and healthcare resources

Patient-Related Challenges
• If a compression system is painful, hot or too bulky to wear with normal shoes, many patients remove the bandages and interrupt therapy
• Some patients wait for their next clinic appointment without wearing any compression bandages
• By removing or not wearing the bandages, patients prolong the healing of the ulcers
Overview of the Venous System

The venous system comprises several components that work together to return blood to the heart:

- veins (superficial, perforator and deep)
- one-way valves
- calf and foot pump mechanisms

The superficial veins act as a collection system returning blood via small perforator veins back to the heart through the deep veins, which lie within muscle and fascia. Veins have thin muscular walls that easily dilate to accommodate venous blood and one-way valves that prevent backflow (reflux). Venous circulation is assisted by the action of foot and calf muscles acting as "pumps" squeezing the blood back to the heart via contraction (muscle systole) and relaxation (muscle diastole).

Normal Venous Pressure

Blood pressure within the veins is usually low and is mainly determined by the weight of the blood column from the foot to the heart. Venous pressure is affected by gravity, body position and movement. When lying down, feet are level with the heart so pressures are low, typically ranging between 0 and 10 mmHg. When sitting, pressures increase to around 40 mmHg. When standing, the pressures are higher, closer to 90 mmHg. Flexing foot or calf muscles propels the blood to the heart and the one-way valves prevent reflux.

Venous Insufficiency

Damage to the veins or valves may lead to unrelieved high venous pressure. Over time, venous hypertension causes an upset in the normal balance that keeps fluids in the vessels, causing pooling of fluid in the lower extremities, which results in edema. If not managed, venous hypertension will ultimately result in venous leg ulcers.

Chronic venous insufficiency is a fairly common condition that affects 2-5% of Americans.
“A rigid sleeve with an anatomical fit around ‘the subject’s’ leg, which stays in place and provides a well tolerated pressure in rest” defines an ideal compression system.

— Jan Schuren, RgN, BN, MSc, inventor of 3M Coban 2 Layer Compression System

Defining the Ideal Compression System

The ideal compression therapy system has been described in the 2003 European Wound Management Association (EWMA) Position Document as one that:

• provides and maintains clinically effective levels of compression
• enhances calf muscle pump function
• is non-allergenic
• is easy to apply
• facilitates ease of training
• is conformable and comfortable
• is durable

The Ideal Physiology: Giraffe Skin

The distance between a giraffe’s heart and feet is twice that of humans, giving it venous blood pressure twice as high as ours. Giraffes also have relatively smaller calf muscles, do not have moving or bending toes and their ankle joint movement is minimal—yet they do not experience venous hypertension.

So why don’t giraffes suffer from edema?

The secret is in the skin. Giraffe skin is extremely tough, fibrous and non-elastic. It creates a rigid sleeve that maximizes the effect of every muscle movement—big and small, moving and resting—to optimize venous return.\(^1\,2\)

3M applied this same principle when developing the 3M™ Coban™ 2 Layer Compression Systems by designing materials that work together to create a rigid sleeve, much like giraffe skin, to consistently provide the right amount of compression to reduce edema.
Measuring the Effects of Compression on Lower Limbs

One instrument used to measure pressures and understand the effects of compression bandages on the anatomy and physiology of the lower limbs is the PicoPress, sold by Microlab Elettronica, Italy.

Figure 1 illustrates pressure values taken from a sensor placed at the B1 site, under a compression bandage, while the subject is resting, standing and flexing the foot. The B1 site is defined as the area at which the Achilles tendon changes into the calf muscles (10–15 cm proximal to the medial malleolus). The wave on the screen reflects the amplitudes generated by normal muscle activity.

Resting Pressure
In the laying or sitting with leg elevated position (LAY), the pressure exerted by the compression bandage against the limb is about 40 mmHg—commonly accepted as the pressure required to counteract the hydrostatic pressure in the veins. This is referred to as resting pressure.

Standing Pressure
In the standing position (STAND), there is a peak in pressure representing the muscle contraction against the bandage. The difference between the standing and resting pressures has been defined as the Static Stiffness Index (SSI). This measurement is used to define the elasticity of a bandage and predict its ability to optimize muscle movements. A bandage with an SSI greater than 10 provides stiffness to keep muscle forces inside the bandage and correlates with optimal peak amplitudes of muscle activity.

Working Pressure
When flexing the foot (EXERCISE), the difference between the high and low pressure points reflect contraction (high) and relaxation (low) of the muscles. These amplitudes are the working pressures required to reduce venous hypertension.
3M™ Coban™ 2 Layer Compression Systems: Designed to Provide Ideal Compression Therapy

3M scientists engineered the Coban 2 Layer Compression Systems with Intelligent Compression Dynamics to deliver ideal compression therapy for patients of all sizes, shapes and lifestyles.

3M™ Coban™ 2 Layer Compression System

The original Coban 2 Layer System is ideal for a majority of patients with venous leg ulcers, lymphedema and other conditions where compression therapy is appropriate.

This proprietary two-layer system is clinically proven to:

• Provide sustained compression for up to 7 days
• Significantly reduce slippage and improve patients’ daily living activities and physical symptoms
• Be preferred by patients for comfort
• Be easy to apply
• Enable patients to wear their own footwear and clothing

3M™ Coban™ 2 Layer Lite Compression System for ABPI ≥ 0.5

Coban 2 Layer Lite System was developed to be more comfortable for patients less tolerant of compression therapy, including those who:

• have mixed etiology with an ABPI greater than or equal to 0.5
• are new to compression, or where tolerance is not known
• are frail
• are less mobile

Coban 2 Layer Lite System reduces the risk of tissue damage and necrosis on patients with an ABPI greater than or equal to 0.5.
Intelligent Compression Dynamics Defined

In compression, dynamics refers to the difference between high and low working pressure points, reflecting intermittent changes in pressure caused by the patient’s own muscle movement. Inelastic or rigid compression systems generate larger dynamics, or amplitudes, and therefore, more effective compression. 3M advanced the science of compression therapy by designing materials engineered with Intelligent Compression Dynamics to create a conformable, inelastic sleeve that stays in place and is comfortable to wear. These Intelligent Compression Dynamics support the patient’s muscle movements for effective venous return and reduction of edema.

Dynamics of Coban 2 Layer Compression Systems

Amplitudes are unique to each person. The following illustrations simulate the amplitudes generated by applying Coban 2 Layer System and Coban 2 Layer Lite System. As illustrated in Figures 2 and 3, Coban 2 Layer Lite System provides working pressures similar to the original, but with a 25% reduced resting pressure, making it a safe, effective, comfortable option for patients less tolerant of compression.

Amplitudes of a Patient with Larger Muscles

![Amplitudes of a Patient with Larger Muscles](image)

Figure 2: This illustration represents the SSI and amplitudes of a patient with well-developed muscle strength. Peak amplitudes are approximately 45 mmHg.

Amplitudes of a Patient with Smaller Muscles

![Amplitudes of a Patient with Smaller Muscles](image)

Figure 3: This illustration represents the SSI and amplitudes of a patient with less muscle tone. At about 25 mmHg, the amplitudes are lower than the original, but still reflect effective compression with an SSI well above 10.
True to 3M’s rich heritage as an innovator and scientific leader, 3M scientists, with extensive research and new laboratory methods, offer new insights into the physics of compression to reduce lower extremity edema.

Contemporary research findings thus led 3M to engineer the unique and proprietary materials of 3M™ Coban™ 2 Layer Compression Systems, clinically proven to comfortably deliver sustained, therapeutic compression. The interlocking materials create an inelastic sleeve with the required stiffness to distribute muscle contraction forces equally beneath the bandage, supporting the muscle pumps to reduce edema.
Designed for Effectiveness

While compression therapy is not new, there is an emerging body of evidence providing a more contemporary understanding of the pathophysiology of compression. Research has identified that the effectiveness of a compression bandage can be predicted by the Static Stiffness Index (SSI). Bandages with an SSI greater than 10 provide enough support to keep the muscle contraction and relaxation forces inside the bandage. Many compression systems require multiple layers to achieve adequate stiffness, but as a result, impede a patient’s mobility and quality of life by creating thick, bulky bandages that slip down.

Breakthrough Research in Materials Science

Historically, Laplace’s Law has been used to explain the effects of compression. However, recent research has shown that the adapted mathematical equation seldom predicts the sub-bandage pressures achieved by compression bandages.

Current breakthrough research has demonstrated that Pascal’s Law provides a better understanding of the effects of compression. Pascal’s Law states that when pressure is applied on a fluid (a muscle or muscle group) in a closed container (fascia and compression bandage), the pressure is transmitted equally and undiminished in all directions throughout the fluid.

Coban 2 Layer Compression Systems Support Pascal’s Law

This principle has been demonstrated in a controlled laboratory study with 12 healthy subjects. Two sensors were placed distally and proximally on the anterior tibias muscle with the third at the B1 position. Coban 2 Layer Compression System was then applied to the limb, providing a rigid sleeve, or closed container. A blood pressure cuff applied over the proximal sensor was inflated in 20 mmHg increments.

Results from a Controlled Laboratory Study Demonstrating Pascal’s Law

![Graph](image)

Figure 4: Percentage change in pressure is similar for all sensors.

Figure 4 illustrates the effects of Pascal’s Law. The sensors not located under the blood pressure cuff show similar pressure changes at each 20 mmHg increase of pressure to the sensor under the cuff.

Coban 2 Layer Compression System materials were designed to provide a thin, comfortable, conforming sleeve with the required stiffness to distribute muscle contraction forces equally beneath the bandage, thus supporting the muscle pump and reducing edema.

Supporting Evidence: See Clinical Evidence Summaries on pages 17, 20, 21 and 22.
Designed to Stay in Place

In laboratory studies, other multi-layer systems can provide effective pressures immediately after application, but when patients become mobile the bandages slip and bunch at the ankle within a short period of time: This slippage is uncomfortable—even painful—often causing patients to remove the bandages, further reducing the potential for healing. 3M™ Coban™ 2 Layer Compression Systems were designed to stay in place to provide sustained compression during wear.

Materials Designed Not to Slip

The inner comfort layer consists of a latex-free medical grade polyurethane foam laminated to a cohesive non-woven backing. When compressed, the foam grips the skin, and the non-woven backing provides a cohesive surface for the attachment of the outer compression layer. The proprietary interlocking materials cohere to each other, creating a rigid sleeve that conforms to the limb and reduces potential for uncomfortable slipping or bunching.

Reduced Slippage Provides Sustained Compression

In a randomized, controlled laboratory study designed to understand the performance characteristics of 10 compression systems, 60 healthy volunteers participated in a 48-hour wear test. Each participant had two systems applied—a different system on each leg—by experts from the United Kingdom, Germany and the Netherlands. 3M™ Coban™ 2 Layer Compression System and 3M™ Coban™ 2 Layer Lite Compression System had the lowest slippage and were the most effective in maintaining resting pressures and amplitudes at values proven to be effective for ulcer healing.

Results from a Controlled Laboratory Study Demonstrating Slippage

Slippage, in cm, after 24 and 48 hours

Coban 2 Layer Compression Systems had the lowest slippage.

Supporting Evidence: See Clinical Evidence Summaries on pages 16 and 17.
Designed for Consistent Application

In practice, sub-bandage pressure is determined by the tension of the materials and the experience of the clinician. Application variability can dramatically affect the efficacy of compression: too little pressure will minimize the therapeutic benefits and too much may cause damage or may not be tolerated by the patient.

Materials Reduce Application Variability

The compression layer of 3M™ Coban™ 2 Layer Compression Systems was designed to be applied at full stretch to eliminate the guesswork of applying at varying extension. The materials reduce application variability to consistently deliver the appropriate pressure for therapeutic compression, regardless of clinician ability. Coban 2 Layer Compression Systems can be applied in half the time of four-layer bandage systems, and are easy to teach and easy to learn.

Proven to be Easy to Apply Consistently

The ease of use and reproducibility of applied pressure for Coban 2 Layer System was demonstrated in an international multi-center comparative evaluation against four currently marketed compression systems. In this study, 32 expert bandagers applied their most familiar bandage system to an artificial limb over pressure sensors three times, and then repeated the process, applying Coban 2 Layer System three times. The applied sub-bandage pressure measurements were recorded for each application. The bandagers were able to apply significantly more consistent pressures with Coban 2 Layer System than with the other systems. The Coban 2 Layer System application technique was easier and faster because of the full stretch application.

Results from an International Multi-Center Comparative Evaluation Demonstrating Reproducibility of Applied Pressures

Supporting Evidence: See Clinical Evidence Summary on page 17.

Coban 2 Layer System provided the most consistent pressures.
Designed for Comfort, Mobility and Daily Living

The materials used in other multi-layer compression systems or zinc paste bandages make them bulky, cumbersome and uncomfortable, often requiring patients to wear special footwear. Painful slippage can further impede patient mobility. Simple tasks like cleaning or walking the dog can become too difficult and patients resign themselves to inactivity to relieve the pressure.

Materials Help Increase Compliance

3M™ Coban™ 2 Layer Compression Systems were designed to get patients “back on their feet.” The materials used in the two-layer systems create a thin, lightweight, breathable sleeve enabling patients to wear their own shoes and clothing, so they can return to their regular daily activities.

The conformable, rigid sleeve generates sustained, therapeutic working pressures and comfortable resting pressures for effective, well-tolerated compression, regardless of activity level. Studies have shown that because Coban 2 Layer Compression Systems are more comfortable, patients are more likely to keep them on, increasing compliance and improving the potential for more effective treatment.

“Standing up all day at work is no longer difficult, and I don’t come home with sore feet anymore.”

– Patrick Murphy, Tampa, FL

“My patients appreciate being able to wear their own shoes.”

– Marcia Hauter, M.D., Wound Healing Center, Normal, IL

Supporting Evidence: See Clinical Evidence Summaries on pages 16, 17, 18, 19, 20, 21 and 22.
Evidence

3M™ Coban™ 2 Layer Compression Systems are supported by a body of evidence from clinicians worldwide, including a randomized controlled clinical trial.

The following summaries demonstrate that Coban 2 Layer Compression Systems have been proven:

- to provide sustained, therapeutic compression for the treatment of venous leg ulcers
- to provide reduced slippage
- to improve health-related quality of life scores
- to be safe, well-tolerated and comfortable
- to be preferred by patients
Evidence

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.


Study Design: Randomized controlled trial

Key Finding: Coban 2 Layer System provided less slippage than Profore™ Compression System.

Purpose
The purpose of this study was to clinically compare two compression bandage systems for slippage, Health Related Quality of Life (HRQoL), patient preference and wound healing with venous leg ulcer patients.

Methodology

- Central and local ethics approvals were obtained and written informed consent obtained. Participants needed to be at least 18 years of age in the UK, be able to understand the questionnaire and have been treated with compression for at least two weeks prior to entry to the study, ABPI < 0.8 excluded.

- Participants were randomized to one of two bandage treatments and followed for 4 weeks. Their treatment was switched to the other compression system for a further 4 weeks and followed for a total of 8 weeks or 9 clinic visits. Participants acted as their own control.

- Primary endpoint of this study was slippage, measured from the top of the bandage to the floor post application and prior to removal. Five secondary endpoints of this study were bandage wear time, wound healing – measured by tracing, HRQoL using the Cardiff Wound Impact Schedule, patient preference and mobility using pedometer.

Results

- Significantly less slippage after three to seven days with Coban 2 Layer System (Mixed ANOVA Model from 697 measurements, p<0.0001).

- No significant differences in percent of wounds that healed (Fisher’s Exact Test, p=0.30) or in wound area reduction (Wilcoxon Rank-Sum Test, p=0.88).

- Improvements in Health Related Quality of Life (HRQoL) Physical Symptoms and Daily Living scores were significantly higher over the first 4 weeks of use for Coban 2 Layer System than Profore™ (pooled 2-sample t-test, p=0.046).

- 72% of patients preferred Coban 2 Layer Compression System over Profore™ (6% had no preference). Patient preference was similar regardless of randomization order (p>0.99).

Bandage slippage for Profore and Coban 2 Layer.
Summary of five case studies on the treatment of venous leg ulcers with a new two layer compression system in a community setting

Sylvie Hampton MA BSc (Hons) DpSN RGN, Andy Kerr RN DipHe, Mike Crossley RN RM, Tissue Viability Consultancy Services, Eastbourne, UK. Data on file at 3M.

Study Design: Five-patient case study series

Key Finding: Coban 2 Layer System successfully provided effective compression therapy.

Purpose
The purpose of this study was to evaluate clinical acceptability and product performance (slippage and wear time) of 3M™ Coban™ 2 Layer Compression System.

Methodology
• Five patients were followed during a six-week evaluation period.
• At each bandage application, the ankle and calf circumference of the patient was measured and recorded.
• The patient adopted a standard stance and the top of the bandage was marked at application and the height from the floor recorded. At removal, the process was repeated and any slippage recorded.
• Digital photographs recorded skin condition, wound and bandage appearance at application and removal.
• Exudate levels were assessed subjectively as “minimal,” “moderate” or “heavy.”

Results
• Coban 2 Layer System was easy to learn and easy to apply.
• Coban 2 Layer system conformed well to a variety of limb shapes.
• Coban 2 Layer System was found to be aesthetically pleasing and demonstrated seven day wear time on the majority of patients (minimum wear time was four days), with minimal occurrences of strikethrough.
• Coban 2 Layer System was never changed due to slippage or sagging.
• The condition of the wound improved in all cases.
• All patients found Coban 2 Layer System comfortable and an improvement over previous compression bandage systems.
Compression therapy in patients with peripheral arterial occlusive disease: A prospective clinical study with the 3M™ Coban™ 2 Layer Lite Compression System for ABPI ≥0.5

Michael Jünger, PhD, MD, Hermann Haase PhD, Andrea Ladwig MD, Linda Schwenke, Jens Bichel, MD, Jan Schuren, RN, BN, MSc.

1University of Greifswald, Fleischmannstrasse 42/43, Greifswald, Germany
23M Deutschland GmbH, Neuss, Germany

Study Design: Fifteen-patient, single-center, open-label study

Key Finding: Coban 2 Layer Lite System was safe for—and well tolerated by—patients with ABPIs between 0.5 and 0.8

Purpose

The purpose of this study was to assess the safety and tolerability of Coban 2 Layer Lite System in patients with an ankle brachial pressure index (ABPI) between 0.5 and 0.8, and to evaluate blood microcirculation during wear.

Methodology

- A single-center, open-label study was performed on 15 patients suffering from peripheral arterial occlusive disease with an ABPI of 0.5-0.8 (five patients with ABPI of ≥0.5 and ≤0.6, four patients with ABPI of >0.6 and ≤0.7 and six patients with >0.7 and ≤0.8).
- Coincident chronic venous disease was allowed but not necessary for recruitment. Six of 15 patients suffered from chronic venous insufficiency.
- All patients received treatment with the Coban 2 Layer Lite System, which stayed in place for one to four days.
- The system was reapplied by study personnel at each clinical visit (days 1, 2, 3, 4, 7, 10 and 14). Study participation stopped after 14 days. Results were summarized from 101 bandage applications.
- At each clinical visit, safety assessments were performed: Measurement of toe pulsation to detect macrocirculation, laser doppler fluxmetry at the forefoot to assess microcirculation of the dermal capillary system, clinical signs of pressure-related skin damage, substantiated by transepidermal water loss (TEWL), painful sensations as potential signs of underperfusion and subbandage pressure was measured at the B1 location. In addition, at baseline and at the end of the study limb volume was measured. A comfort questionnaire was completed at the end of the study.
Results

- Coban 2 Layer Lite System was safe for, and well tolerated by, patients with ABPIs between 0.5 and 0.8.
- An average supine subbandage pressure of approximately 28 mmHg was measured immediately after bandage application.
- Coban 2 Layer Lite System demonstrated beneficial effects on the dermal capillary system.
- No pressure-related skin damage occurred in patients with reduced arterial perfusion.
- No pain related to tissue hypoxia was reported.
- Measurements of limbs indicated reduced volume at the end of the study compared to baseline.
- High wearing comfort, even though most patients currently were not used to wearing compression bandages.
- Results of laser doppler fluxmetry measurements indicate significant improvements of dermal microcirculation under Coban 2 Layer Lite System.
Evidence

Evaluation of new bandage system to improve wound healing outcomes for patients with problematic venous leg ulcers
Gary Bain RN CNC MClEd BN DipApSc, Director Wound Management Services, Sydney Adventist Hospital. Data on file at 3M.

Study Design: Eight-patient case study series

Key Finding: 3M™ Coban™ 2 Layer Compression System obtained faster reduction in edema, pain and exudation.

Purpose
The purpose of this study was to measure wound healing outcomes for patients whose problematic venous leg ulcers had not responded to conventional compression bandaging.

Methodology
Eight patients were enrolled in a four week trial of a new product evaluation. Coban 2 Layer System replaced the previously used compression bandages and patients were followed weekly for wound assessment, care and bandage application.

Results
- Coban 2 Layer System obtained faster reduction in edema, pain and exudation with each clinic assessment than traditional multi-layer compression systems previously utilized.
- Six members of the group reduced their ulcer surface area between 30 - 40% within the four week trial period.
- Minimal bandage bulk allowed patients to wear normal shoes.
- Pain and edema of one patient was eliminated and local erythema was reduced, seven days after initial visit.
- One patient’s ulcer was closed by the sixth weekly visit, after two years of non-healing.
- As a result, Coban 2 Layer System has been added to the clinic’s formulary therapeutic interventions.
Understanding the clinical and patient outcomes of new bandaging system: summary of four case studies

Bill McGuiness and Jan Rice, Co-Convenors “WoW” – World of Wounds Division of Nursing and Midwifery, La Trobe University Melbourne, Victoria. Data on file at 3M.

Study Design: Four-patient case study series

Key Finding: 3M™ Coban™ 2 Layer Compression System delivered comfortable resting pressures, effective working pressures and increased patient comfort.

Purpose
To gain an understanding of the effectiveness of Coban 2 Layer System in terms of clinical and patient outcomes.

Methodology
An evaluation was conducted at two Wound Management Clinics. Four case studies were collected. Coban 2 Layer System replaced previously used bandage systems and patients were followed weekly.

Results
- Coban 2 Layer Compression System was well tolerated and comfortable for all patients.
- Two patients’ persistent leg ulcers healed within the four week evaluation period.
- In all four cases, Coban 2 Layer System achieved considerable edema reduction.
- Coban 2 Layer System delivers a very effective form of compression, addressing the real challenges clinicians and patient currently face.
Evaluating a new and unique 2 Layer Compression System for patients with chronic venous leg ulceration


Study Design: Four-patient case series from a national study

Key Finding: 3M™ Coban™ 2 Layer Compression System provided sustained therapeutic levels of compression that patients could tolerate.

Purpose

The purpose of this study was to evaluate clinical acceptance (bandage slippage and wear time), and quality of life of venous leg ulcer patients treated with Coban 2 Layer System.

Methodology

- Four patients were seen weekly in the clinic of the authors for a period of six weeks.
- At each visit their ulcers were photographed and measured.
- The bandage height from the floor to the top of the bandages was recorded on arrival before bandage change and after every application of this system to assess bandage slippage.
- The patients’ experience of the system and their comments were recorded at week three and week six.
- A lipido-colloid or other simple nonadherent wound contact layer was used beneath the compression system.
- All of the patients included in the study had previously experienced other forms of compression therapy and had not responded successfully to these treatments.

Results

- Coban 2 Layer System provided sustained therapeutic levels of compression that patients could tolerate.
- In all cases, wound dimensions reduced during the six week evaluation period.
- Coban 2 Layer System enabled patients to wear their choice of clothing/footwear and undertake their normal activities of living.
- All patients experienced an increase in comfort levels.
- All four patients were concordant with compression therapy.
References


A Complete Line of Products for Treating Venous Leg Ulcers

3M offers a complete line of products for the management of venous leg ulcers, lymphedema and other conditions where compression therapy is appropriate. These products are compatible and can be worn together with 3M™ Coban™ 2 Layer Compression Systems, for up to seven days.

- 3M™ Wound Cleanser
- 3M™ Cavilon™ No Sting Barrier Film
- 3M™ Tegaderm™ Non-Adherent Contact Layer
- 3M™ Tegaderm™ Ag Mesh Dressing with Silver
- 3M™ Tegaderm™ Alginate Ag Silver Dressing
- 3M™ Tegaderm™ High Integrity Alginate Dressing
- 3M™ Tegaderm™ High Gelling Alginate Dressing
- 3M™ Tegaderm™ Foam Dressing (nonadhesive)

To learn more about 3M™ Coban™ 2 Layer Compression Therapy products, visit us at www.3M.com/coban2layer, contact your 3M Skin and Wound Care representative or call the 3M Health Care Customer Helpline at 1-800-228-3957. Outside of the United States, contact the local 3M subsidiary.

### Ordering Information

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The American Medical Association (AMA) has established a CPT code for the application of multi layer compression systems - CPT Code 29581. Physicians and other healthcare providers treating patients with multi layer compression therapy may be eligible for reimbursement for their services.

Current Procedural Terminology (CPT) is a listing of descriptive terms and identifying codes for reporting medical services and procedures physicians and other medical professionals perform.

HCPCS and CPT codes have been provided to assist you in the preparation of insurance claims. Please note, however, that the reimbursement information provided by 3M Health Care and its representatives is intended to provide general information relevant to coverage and coding for 3M products. Insurers’ reimbursement policies can vary and the use of the codes discussed here does not guarantee that an insurer will cover or pay at any particular level. Health care providers should exercise independent clinical judgment in choosing the codes which most accurately describe the products provided.