

## 3M Coban 2 Layer Compression Therapy: Intelligent Compression Dynamics to Suit Different Patient Needs

Jan Schuren,<sup>1</sup> Stéphanie F. Bernatchez,<sup>2,\*</sup> Joseph Tucker,<sup>2</sup> Ellen Schnobrich,<sup>2</sup> and Patrick J. Parks<sup>2</sup>

<sup>1</sup>3M Skin and Wound Care Division, Neuss, Germany.

<sup>2</sup>3M Skin and Wound Care Division, St. Paul, Minnesota.

**Problem:** Chronic venous insufficiency can lead to recalcitrant leg ulcers. Compression has been shown to be effective in healing these ulcers, but most products are difficult to apply and uncomfortable for patients, leading to inconsistent/ineffective clinical application and poor compliance. In addition, compression presents risks for patients with an ankle-brachial pressure index (ABPI) <0.8 because of the possibility of further compromising the arterial circulation. The ABPI is the ratio of systolic leg blood pressure (taken at ankle) to systolic arm blood pressure (taken above elbow, at brachial artery). This is measured to assess a patient's lower extremity arterial perfusion before initiating compression therapy.<sup>1</sup>

**Solution:** Using materials science, two-layer compression systems with controlled compression and a low profile were developed. These materials allow for a more consistent bandage application with better control of the applied compression, and their low profile is compatible with most footwear, increasing patient acceptance and compliance with therapy. The original 3M™ Coban™ 2 Layer Compression System is suited for patients with an ABPI ≥0.8; 3M™ Coban™ 2 Layer Lite Compression System can be used on patients with ABPI ≥0.5.

**New Technology:** Both compression systems are composed of two layers that combine to create an inelastic sleeve conforming to the limb contour to provide a consistent proper pressure profile to reduce edema. In addition, they slip significantly less than other compression products and improve patient daily living activities and physical symptoms.

**Indications for Use:** Both compression systems are indicated for patients with venous leg ulcers, lymphedema, and other conditions where compression therapy is appropriate.

**Caution:** As with any compression system, caution must be used when mixed venous and arterial disease is present to not induce any damage. These products are not indicated when the ABPI is <0.5.

### UNMET NEED

VENOUS INSUFFICIENCY is the underlying condition responsible for 54%–81% of leg ulcers.<sup>2</sup> Compression therapy is considered the most effective treatment for such ulcers.<sup>3,4</sup> Several compression products are available.<sup>2,5</sup> A Cochrane review concluded that multi-layered systems

are more effective than single-layered systems, and that high compression is more effective than low compression.<sup>3</sup> The efficacy of compression systems depends on how well they hold in place to provide continued adequate compression and on patient acceptance. Products that are easier to apply consistently and



Jan Schuren

Submitted for publication March 14, 2011.

\*Correspondence: 3M Skin and Wound Care Division, 3M Center Bldg 270-3N-03, St. Paul, MN 55144-1000 (e-mail: [sfbernatchez@mmm.com](mailto:sfbernatchez@mmm.com)).

### Abbreviations and Acronyms

ABPI = ankle-brachial pressure index

HRQoL = health-related quality of life

mmHg = millimeters of mercury

that are more comfortable are needed for increased patient compliance.

### PRODUCT TECHNOLOGY

The inner comfort layer consists of a latex-free, medical-grade polyurethane foam laminated to a cohesive nonwoven backing. When compressed, the foam grips the skin, and the nonwoven backing provides a cohesive surface for the attachment of the outer compression layer. The outer compression layer consists of a cohesive bandage designed to provide therapeutic compression. The material has been designed to be used at full stretch to ensure an easy and reproducible application. 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. The absence of slippage ensures that sustained therapeutic compression will be achieved throughout the wear of the product. The inelastic sleeve provides the required stiffness to distribute muscle contraction forces equally beneath the bandage, thus supporting the muscle pump and reducing edema.

### INNOVATION

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 improved compression therapy by designing materials engineered with intelligent compression dynamics. The resulting product has the required stiffness to distribute muscle contraction forces equally beneath a bandage that stays in place and is comfortable to wear. The light version provides the same working dynamics, with a 25% reduced resting pressure, making it safe for patients less tolerant of compression. It is unique because it acts as an elastic bandage to allow a sustained pressure profile (up to 1 week) and as an inelastic bandage, giving a high-working pressure during functional activities like weight-bearing or walking. These intelligent compression dynamics support the patient's muscle movements for effective venous return and reduction of edema. The overall profile of the product is thinner than other products available, allowing patients to wear their normal clothes and shoes, which contributes to quality of life and compliance, and potentially leads to more effective therapy.

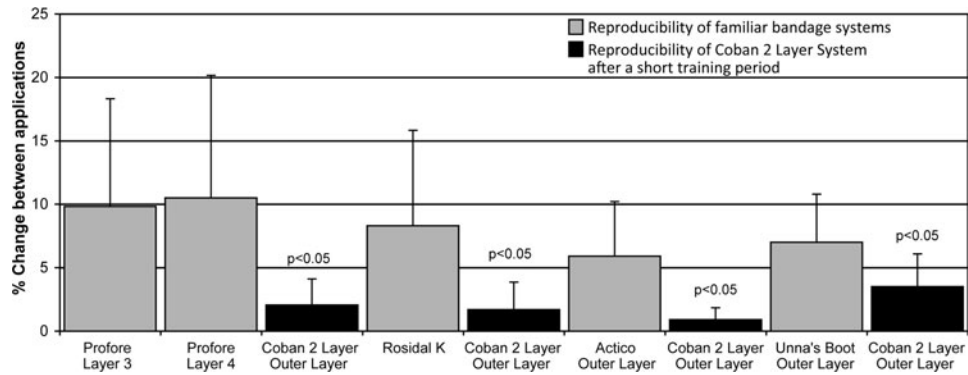
### PEER-REVIEWED DATA

The mechanical properties of Coban 2 Layer Compression System were thoroughly studied and specific pressure measurements were performed to document the performance of the product<sup>6,7</sup> and compare it to the most used brands in the United States and Europe that represent the majority of market shares in each respective market. Our research has found that the widespread belief that correctly applied compression systems provide pressure values graduating from 40 mmHg at the ankle to 17 mmHg below the knee is based solely on theoretical mathematical equations and is not supported by the experimental results.<sup>6</sup> In addition, it could be documented that the dynamics of effective compression therapy are explained by Pascal's Law, which states that when pressure is applied (functional activity) on a fluid (a muscle or muscle group) in a closed container (fascia muscularis and compression bandage), there is an equal increase at every other point in the container.<sup>7</sup>

A randomized, cross-over clinical trial was conducted to compare the Coban 2 Layer Compression System to the Profore<sup>TM</sup> bandage system (Smith & Nephew) for slippage, health-related quality of life, patient preference, and wound healing in 81 venous leg ulcer patients. Slippage was significantly less with the Coban 2 Layer Compression System (2.48 cm) than with Profore (4.17 cm) after 3–7 days ( $p < 0.001$ ), and 72% of patients preferred the Coban 2 Layer Compression System to Profore (6% of patients had no preference). Improvements in health-related quality of life physical symptoms and daily living scores were significantly higher over the first 4 weeks of use for the Coban 2 Layer Compression System than Profore. The study was not powered to detect differences in wound healing.<sup>8</sup>

### NON-PEER-REVIEW OBSERVATION

1. The Coban 2 Layer Compression System was easier to learn and provided more consistent pressure values than Profore, Rosidal<sup>®</sup> K, a short stretch product (Lohmann & Rauscher), and Actico<sup>®</sup> cohesive inelastic bandage (Activa Healthcare Ltd.) in a study involving 32 expert bandagers and an artificial leg model.<sup>9</sup> In addition, the reproducibility of stretch was more consistent with the Coban 2 Layer Compression System than with the other marketed systems (data on file at 3M, publication #70-2009-7377-7, 2006, available at [http://multimedia.3m.com/mws/mediawebservlet?mwsId=66666UuZjcFSLXTtM8T\\_4xf2EVuQEcuZgVs6EVs6E666666-&fn=70-2009-7377-7.pdf](http://multimedia.3m.com/mws/mediawebservlet?mwsId=66666UuZjcFSLXTtM8T_4xf2EVuQEcuZgVs6EVs6E666666-&fn=70-2009-7377-7.pdf); see Fig. 1). A



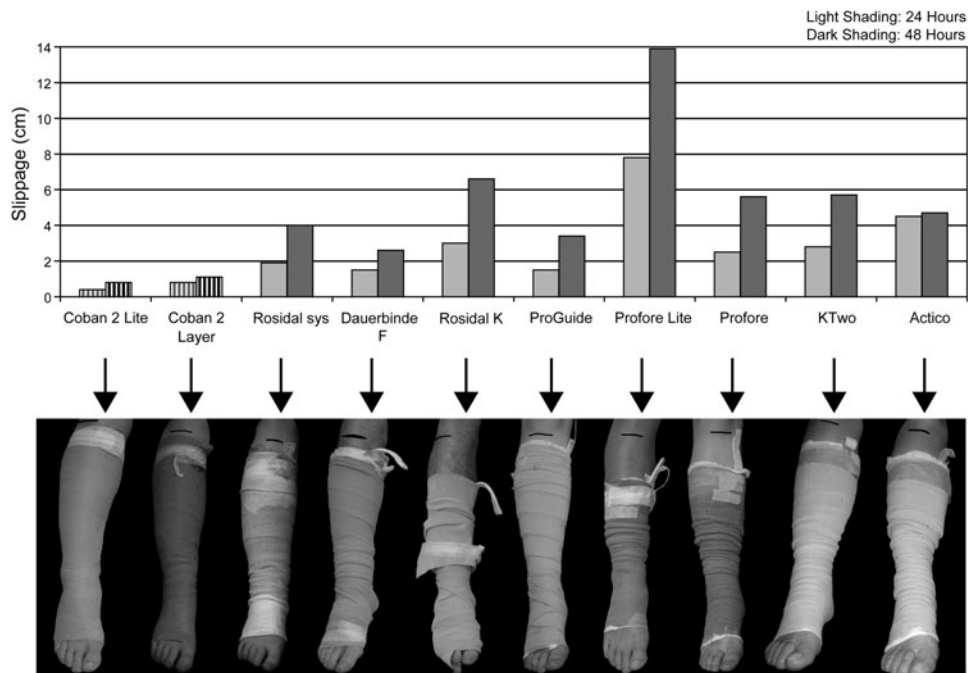
**Figure 1.** Results from an international multi-center comparative evaluation demonstrating reproducibility of applied stretch for various compression systems. Four groups, one for each comparative product (Profore™ [Smith & Nephew], Rosidal® K [Lohmann & Rauscher], Actico® [Activa Healthcare Ltd.], and Unna's Boot [Graham-Field Medicopaste®]), consisting of eight different bandaging experts per group, applied their bandage and the Coban 2 Layer Compression System three times each to an artificial leg. After each application, a 10-cm long line was marked on the applied bandage. The stretch that was produced by the bandage during the application was expressed as an extension ratio obtained by dividing the length of that line by the length of the line after the bandage had been removed from the leg and allowed to relax. For the differences, the percentage change between applications was calculated. Differences were calculated between applications 1 and 2, 1 and 3, and between 2 and 3. A total of 24 values were available to analyze the applicator's consistency in applying stretch during bandaging. A paired *t*-test was used to compare the different products. The Coban 2 Layer Compression System provided the most consistent stretch.

slippage study showed reduced slippage with the Coban 2 Layer Compression System (see Fig. 2).

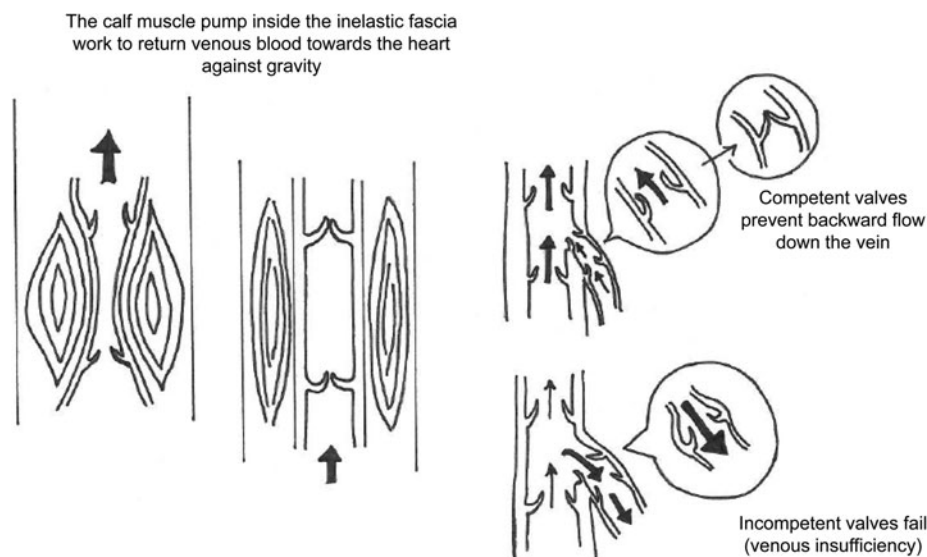
- The product was tested in 30 patients with moderate to severe lymphedema of the leg and compared with inelastic multi-layer compression bandages and was found to be a suitable alternative (data on file at 3M, EU Study No-05-000007, 2009; Identifier: NCT00854516,

available at <http://clinicaltrials.gov/ct2/show/NCT00854516?term=juenger&rank=2>).

- The Coban 2 Lite system was tested in 15 patients with ankle-brachial pressure indexes between 0.5 and 0.8. The product was safe and well tolerated, and results of laser Doppler flowmetry indicated significant improvements of the dermal capillary system



**Figure 2.** Results from a controlled laboratory study demonstrating slippage. Ten different compression systems (Coban 2 Lite system, Coban 2 Layer Compression System [3M]; Rosidal sys, Dauerbinde F, and Rosidal K [all from Lohmann & Rauscher]; ProGuide™, Profore Lite, and Profore [all from Smith & Nephew]; KTwo [Laboratoires Uργο]; and Actico [Activa Healthcare Ltd.]) were applied by 10 different bandaging experts to a total of 120 legs (60 healthy volunteers, both legs wrapped) and worn for 48 h. Average slippage values were calculated for each bandage at 24 and 48 h.



(data on file at 3M, EU Study No-05-000007, 2009; Identifier: NCT00854516, available at <http://clinicaltrials.gov/ct2/show/NCT00854516?term=juenger&rank=2>).

### SUMMARY ILLUSTRATION

Venous leg ulcers are caused by venous insufficiency, which leads to pooling of blood in the lower extremities. Compression therapy supports the patient's muscle movements for effective venous return.

### CAUTION, CRITICAL REMARKS, AND RECOMMENDATIONS

As with any compression system, caution must be used when mixed venous and arterial disease is present to not induce any damage. These products are

not indicated when the ankle-brachial pressure index is  $<0.5$ . Effective compression is intended to reduce edema. The Coban 2 Layer Compression System should be changed if it becomes loose fitting, and when it no longer conforms to the shape of the leg.

### ACKNOWLEDGEMENT AND FUNDING SOURCE

3M Company funded the studies of the Coban 2 Layer Compression System and the Coban 2 Lite system.

### AUTHOR DISCLOSURE AND GHOSTWRITING

All authors are employees of 3M Company. The content of this article was expressly written by the authors listed. No ghostwriters were used to write this article.

### REFERENCES

- Schuren J, Vos A, and Allen JO: Venous leg ulcer patients with low ABPIs: how much pressure is safe and tolerable? *EWMA J* 2010; **10**: 29.
- Rojas AI and Phillips TJ: Venous ulcers and their management. In: *Cutaneous Wound Healing*, edited by Falanga V. London: Martin Dunitz Ltd., 2001, pp. 263–286.
- Cullum N, Nelson EA, Fletcher AW, and Sheldon TA: Compression for venous leg ulcers (Review). *Cochrane Database Syst Rev* 2001; (2 Art. No.:CD000265. DOI: 10.1002/14651858.): 1.
- Kantor J and Margolis DJ: Management of leg ulcers. *Seminars in Cutaneous Medicine and Surgery* 2003; **22**: 212.
- Meyer FJ and Burnand KG: Compression treatment: methods and controversies. In: *Cutaneous Wound Healing*, edited by Falanga V. London: Martin Dunitz Ltd., 2001, pp. 287–305.
- Schuren J and Mohr K: The efficacy of Laplace's equation in calculating bandage pressure in venous leg ulcers. *Wounds UK* 2008; **4**: 38.
- Schuren J and Mohr K: Pascal's law and the dynamics of compression therapy: a study on healthy volunteers. *Int Angiology* 2010; **29**: 431.
- Moffatt C, Edwards L, Collier M, Treadwell T, Miller M, Shafer L, Sibbald RG, Brassard A, McIntosh A, Reyzelman A, Price P, Kraus SM, Walters SA, and Harding K: A randomized controlled 8-week cross-over 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**: 267.
- Collier M and Schuren J: Ease of use and reproducibility of five compression systems. *J Wound Care* 2007; **3M Suppl**: 8.