

In-use Assessment of a Unique, Innovative Compression System

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Introduction

Compression therapy is considered the cornerstone of venous ulcer management¹. Limitations of current products may negatively impact patient quality of life and treatment protocol adherence. These limitations include patient discomfort, product slippage, and overall dissatisfaction with the compression materials^{2,3}. During development of this new compression product, a variety of laboratory tests were conducted to better understand the functional properties and potential benefits provided by the bandage.

This paper presents the results of a pilot study and a follow-up comparative study designed to assess the comfort, length of wear, durability and effects on daily activities of a new, latex-free, two-layer compression bandage.

Pilot Study

Methodology:

A pilot study was conducted with ten healthy, physically active volunteers who had the prototype device randomized to one leg and applied by an experienced 3M CWOCN. Bandage and subject assessments were completed on Days 1, 4, 5, 6, and 7. In an effort to understand the product performance over time, the bandage was left in place even when it had slipped beyond the point at which it would have been removed in a clinical situation. Bandage removal was determined by the subject tolerance, or if it slipped below the calf.

Slippage of the compression system was assessed by measuring the bandage migration from the skin marking made at the top of the bandage at application. Subject assessments were rated on a 0-10 scale, 10 being the highest performance.

Results:

All participants maintained normal activities, had no mobility problems and wore normal footwear. An average wear time of 6.3 days was achieved by the 3M prototype compression system.

- 9 of 10 subjects rated the system as “comfortable or very comfortable”.
- 6 of 10 wore the wrap for the full 7 days, with an average slippage of 3.55 cm.
- 8 of 10 subjects had no sleep interference due to the product.
- The new compression system remained intact, with minimal edge lift (average 0.4 mm).
- Skin was intact and dry upon removal except for one subject with slight maceration.

Conclusions:

The pilot study demonstrated that the new, innovative wrap materials overcame limitations frequently reported with compression systems such as discomfort associated with bandage bunching and wrinkling due to slippage, even when challenged by active volunteers. To gain further experience on how these performance characteristics compare to those of a commercially available compression system, a follow-up comparative study was initiated.

Comparative Study

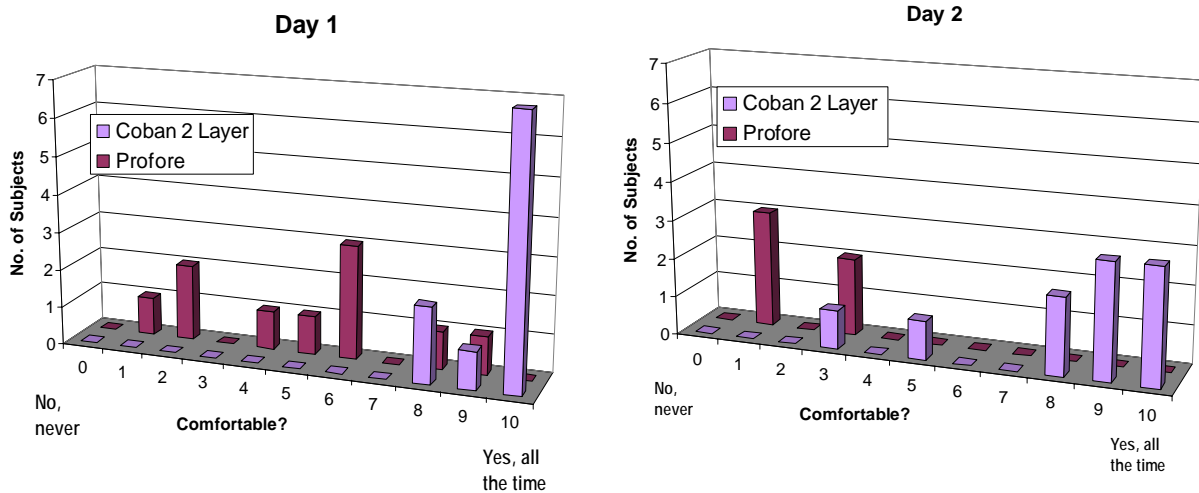
Methodology:

Ten healthy, physically active volunteers were randomized to receive 3M™ Coban™ 2 Layer Compression System on one leg and Profore™ Multi-layer Bandaging System on the other leg, acting as their own control. The Coban 2 Layer Systems were applied by an experienced 3M CWOCN, and the Profore systems were applied by an external clinician experienced in the use of this product. Bandage and subject assessments were completed on Days 1, 2, 3, 6, and 7. Bandage removal was determined using criteria relevant to a clinical situation: the amount of discomfort, migration from the original bandage height and the subjective determination that the bandage was no longer providing compression.

Results of comparative study

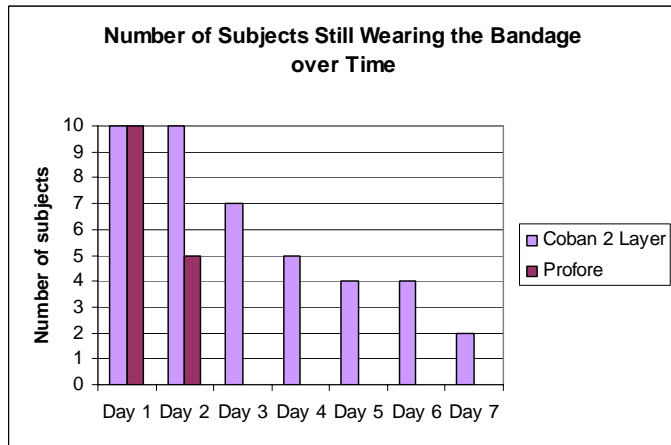
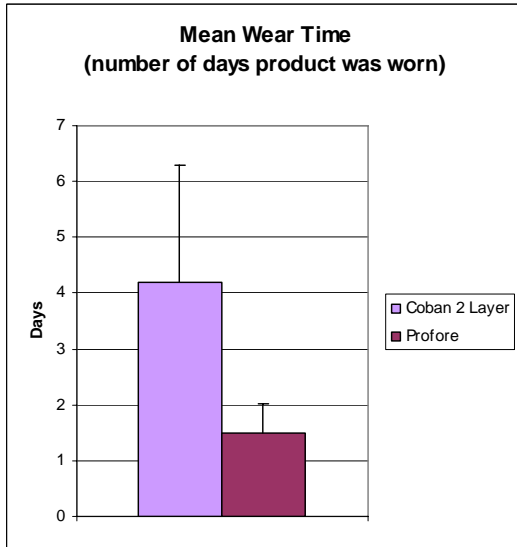
The following graphs summarize the measurements and assessments obtained from all 10 subjects who participated in this comparative study.

Comfort Assessment



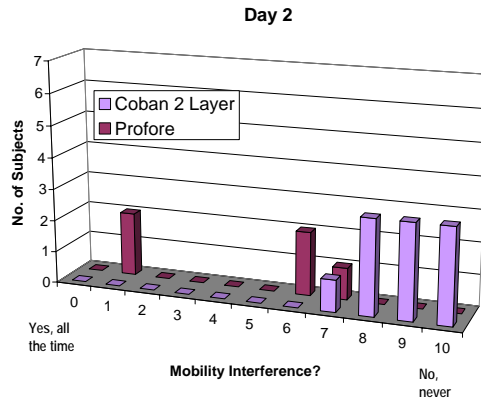
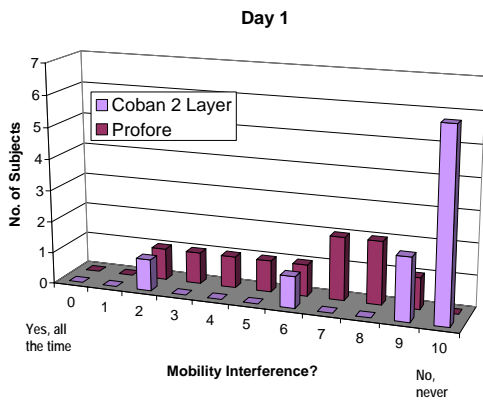
Coban 2 Layer System was rated more comfortable than Profore

Wear Time



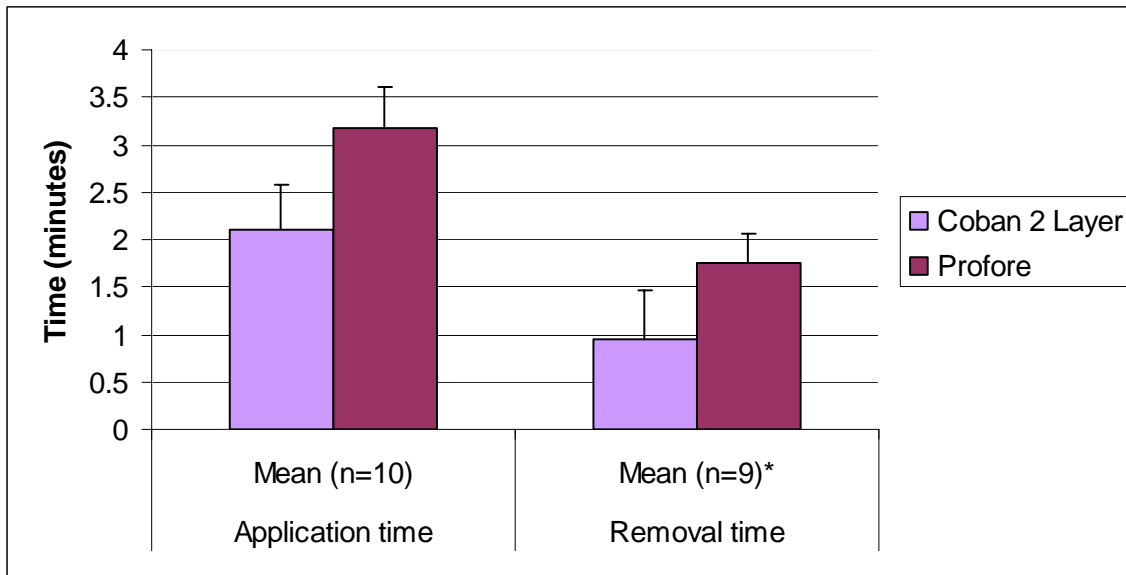
Coban 2 Layer System had an average wear time almost 3 days longer than Profore (4.2 days versus 1.5 days)

Mobility Interference



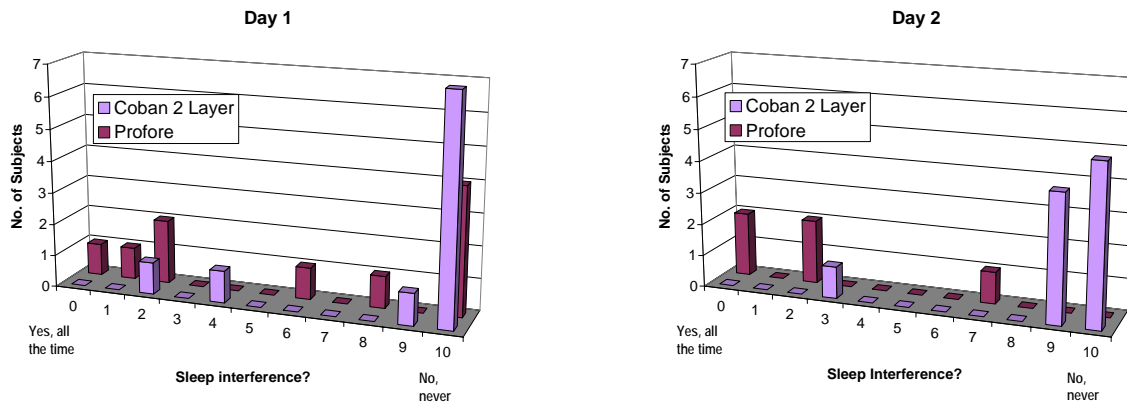
Coban 2 Layer System caused less mobility interference than Profore

Application and Removal Time



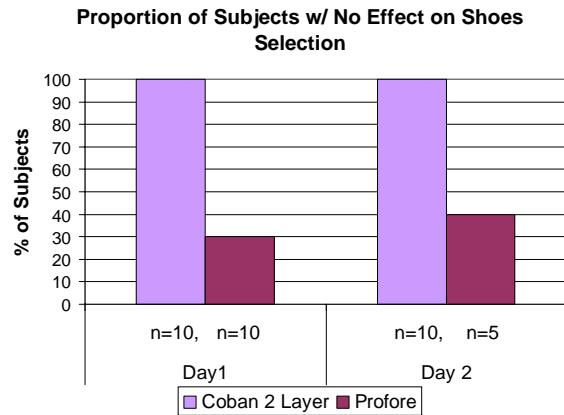
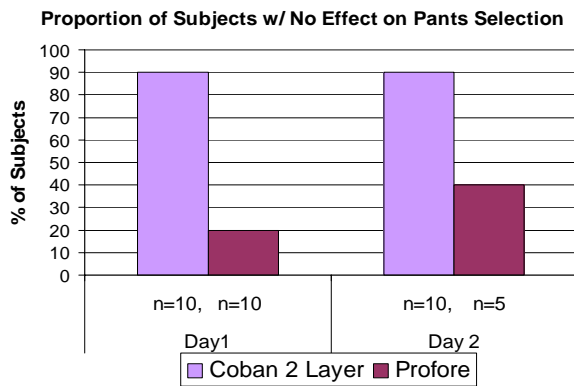
Coban 2 Layer System took less time to apply and remove than Profore

Sleep Interference



Coban 2 Layer System caused less sleep interference than Profore

Effect on Pants and Shoe Selection



Coban 2 Layer System had little effect on pants or shoe selection

Case study:

This subject illustrates the performance characteristics of both compression systems.



Day 0
Application

Active, middle-aged subject enrolled in 7 day trial comparing the performance attributes and wear time of a commercially available compression system (Profore™ Multi-layer Bandaging System) with a new, unique, compression system (Coban™ 2 Layer Compression System). This subject was randomized to receive Coban 2 Layer on the right leg and Profore on the left.



Day 1
24 hour time

After removal of Profore

At the Day 1 assessment, the Coban 2 Layer System had slipped 5 mm and the subject rated it as completely comfortable (score of 10). However, significant changes had occurred in the position of the Profore. It had slipped 68 mm and the subject reported that it was slightly uncomfortable over the articulating aspect of the foot (score of 8). Profore was removed because it had slipped out of position and was no longer providing compression. The skin was intact but deep wrinkles from the bunching of the bandage were evident. Neither bandage system interfered with sleep, and the subject wore the same shoes but had to loosen the shoe over Profore. The subject preferred the Coban 2 Layer System because it was thin and felt like a stocking. Profore felt bulkier and was more noticeable during wear.

Day 3



Day 6



At Day 3, no further slippage had occurred with the Coban 2 Layer System. By Day 6, total slippage was 8 mm. No further migration from the skin marking occurred through Day 7.

Day 7



The Coban 2 Layer System was worn for 7 full days. Subject was completely comfortable (score of 10) throughout the duration of the study. The compression layer remained intact, with minimal linting and no odor. There was no rolling or migration of the bandage at the toe edge.



After removal of Coban 2 Layer System

Throughout the 7 day wear, the subject was able to fully participate in her usual activities with no limitations in her choice of clothing or shoe on the leg treated with the Coban 2 Layer System. Upon removal, the subject's skin was clear and free from maceration and skin wrinkles.

Discussion

Compression bandage efficacy is related to how well the bandage stays in place to provide sustained compression and to patient acceptance of the therapy. The more comfortable the bandage is, the more likely the patients will wear it as prescribed and will obtain the expected benefits in terms of wound healing. The new Coban 2 Layer System showed distinct advantages over Profore. It was faster to apply and remove, more comfortable to wear and could be worn much longer than Profore. Subjects reported that Profore felt uncomfortable, particularly at the instep, which interfered with normal daily activities. Profore had to be removed from all 10 subjects by Day 2 due to considerable discomfort, slippage, or both. This slippage resulted in ineffective compression on the skin and bunching of the bandage layers around the ankle. In addition, all subjects stated an overall preference for the Coban 2 Layer System over Profore.

Conclusions

This study confirmed the positive performance attributes of the new Coban 2 Layer System when compared to Profore:

- Coban 2 Layer System was rated more comfortable than Profore.
- Coban 2 Layer System had an average wear time almost 3 days longer than Profore in healthy, active subjects.
- Coban 2 Layer System caused less mobility interference than Profore.
- Coban 2 Layer System took less time to apply and remove than Profore.
- Coban 2 Layer System affected the choice of pants and shoes less than Profore.

An international clinical study is in progress to validate the efficacy of this product and its effects on quality of life for patients requiring compression.

References

1. Kantor J, Margolis DJ. Management of leg ulcers. *Seminars in Cutaneous Medicine and Surgery* 2003; 22(3): 212-221.
2. Rojas AI, Phillips TJ. Venous ulcers and their management. In: Falanga V, editor. *Cutaneous wound healing*. Martin Dunitz Ltd; 2001. p. 263-86.
3. Cullum N, Nelson EA, Fletcher AW, Sheldon TA. Compression for venous leg ulcers (Review). *The Cochrane Database of Systematic Reviews* 2001;1-34.

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