

A Clinical Comparison of a Two-layer and a Four-layer Compression Bandage System in the Treatment of Venous Leg Ulcers

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Objective

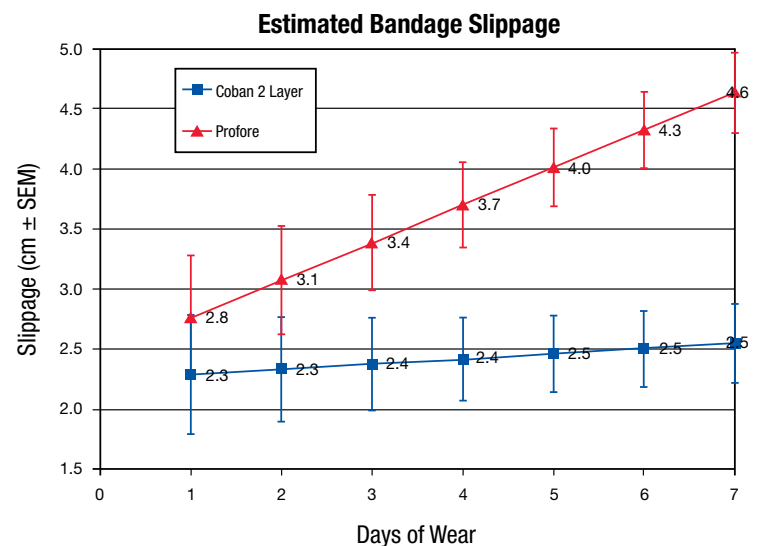
To clinically compare two compression bandage systems for slippage, Health Related Quality of Life (HRQoL), patient preference and wound healing with venous leg ulcer patients.

Methodology

- 3M™ Coban™ 2 Layer Compression System was compared to Profore™ Multi-Layer Compression Bandage System.
- Eight-week, ten-center, prospective, open-label, clinical trial.
- Participants (n=81) were randomized to one of the two compression systems for 4 weeks and then crossed over to the other system for an additional 4 weeks, or until the ulcer healed.
- 3M™ Tegaderm™ Foam Dressing was used as the primary wound dressing for all ulcers.
- All other ulcer treatments were per standard procedure at each location.
- The primary endpoint was bandage slippage measured at each dressing change.
- Secondary endpoints included HRQoL (Cardiff Wound Impact Schedule), patient preference, and wound healing.

Results

- There was significantly less slippage after 3 to 7 days with Coban 2 Layer (Mixed ANOVA Model from 697 measurements, $p < 0.0001$).
- Improvements in HRQoL Physical Symptoms and Daily Living scores were significantly higher over the first 4 weeks of use for Coban 2 Layer than Profore (pooled 2-sample t-test, $p = 0.046$).
- 72% of patients preferred Coban 2 Layer over Profore (6% had no preference). Patient preference was similar regardless of randomization order ($p > 0.99$).
- There were 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, $p = 0.88$).



Conclusion

There was significantly less bandage slippage with Coban 2 Layer than with Profore. While less bandage slippage did not appear to impact wound healing, it may have influenced patient preference in favor of Coban 2 Layer and potentially impacted patients' HRQoL.



Aspects of this study were presented at the following conferences:

Symposium on Advanced Wound Care and Wound Healing Society

April 24 – 27, 2008

San Diego, CA

European Wound Management Association

May 14-16, 2008

Lisbon, Portugal

World Union Wound Healing Society

June 6 – 8, 2008

Toronto, Canada

Wound Ostomy and Continence Nurses Society

June 21 – 25, 2008

Orlando, FL

Canadian Dermatology Association

June 27 – July 2, 2008

Montreal, Canada



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