

Progression of Wound Healing and Patient Quality of Life with a New, 2 Layer Compression System*

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Background

- Compression therapy is an essential element for managing edema associated with leg ulcers.¹
- Adequate treatment is effective at improving the quality of life of patients with venous ulcers.²
- An ongoing challenge for clinicians is to **meet patient-centered needs** (comfort, ease of use, non-interference of functional activities) while adequately reducing edema to promote venous leg ulcer healing.
- Limitations of current compression devices negatively impact patient quality of life and treatment protocol adherence. These limitations include patient discomfort, product slippage, and overall dissatisfaction with the compression materials.^{3,4}

Study Design

This clinic participated in a randomized, controlled study of crossover design comparing the product performance and patient quality of life with a 2-layer* and a 4-layer** compression system. All patients were in compression prior to enrollment.

- 8 weeks of treatment (4 weeks with each product)
- Performance attributes measured included:
 - Wear time
 - Bandage slippage
 - Mobility
 - Wound area measurements
- Quality of Life Questionnaire (QoL) completed at enrollment, crossover, completion
- Patient preference obtained at study completion
- Crossover study was designed to validate that the new 2-layer system provided effective compression while meeting patient-centered needs.

The following cases demonstrate the progress of wound healing and discuss the differences in QoL scores.

Case Study 1

55 Y/O male. Current ulceration present for 120 weeks, located at previous burn site. ABI 1.01. Patient adherent to compression systems, including Unna boot w/ elastic bandage and/or 4-layer system.** No other medical conditions. 6'-3" tall, 185 lb. Randomized to 4-layer on initiation.



Day 0 -Wound area = 20.6 cm²
 Week 4 - crossover wound area = 16.5 cm²
 Week 8 wound area = 11.8 cm²



Average 4-layer slippage = 4.3 cm/wk
 Average 2-layer slippage = 2.7 cm/wk

Though patient has a resistant, slow to heal ulcer, he rated his overall quality of life a 9/10 at all 3 time points. He reported that the 2 layer system was more comfortable overall, and he experienced less slippage.

** Hartmann-Conco FourPress™ Latex-Free Compression Bandaging System

Case Study 2

50 Y/O male. Wound present for 50 weeks. ABI 1.0. Previous compression systems include Unna boot w/ elastic bandage and 3-layer system. Works as a manager 6 days/wk in a shop and walks a lot. Randomized to 2-layer on initiation.



The first 4 weeks show rapid response in wound area reduction. Patient stated he loved the new 2-layer system. A skin erosion occurred at week 6, possibly due to slippage of 4-layer system.



Average 2-layer slippage = 0.84 cm/wk
 Average 4-layer slippage = 5.6 cm/wk

QoL attributes reported by patient to have improved while wearing the 2-layer system included less sleep disturbance, less pain from the wound site, and improved ability to perform activities of daily living.

Patient very pleased and said that the 2-layer system was by far the most comfortable compression system that he'd ever been in. The wound made excellent progress.

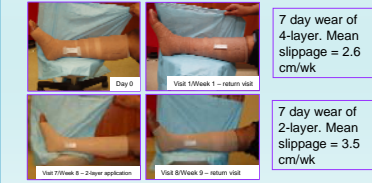
* Hartmann-Conco ThreePress™ Latex-Free Compression Bandaging System

Case Study 3

39 Y/O male. S/P vein surgery 10 years ago. Wound present for 24 weeks with little healing progress, though patient adheres well to compression. Previous compression systems include 3 and 4-layer compression,** and Unna boot with elastic bandage. Works long hours as barber. Walks everywhere. 6' tall, weight 340 lb. ABI = 1.01. Randomized to 4 layer on initiation.



Day 0. Wound size area = 11.8 cm². No maceration.
 Week 4. Wound size area = 6.1 cm².
 Week 9. Wound size area = 5.0 cm². No maceration.



7 day wear of 4-layer. Mean slippage = 2.6 cm/wk
 7 day wear of 2-layer. Mean slippage = 3.5 cm/wk

Discussion: Pt reported that he liked wearing the 2-layer system for its durability and comfort, though he selected the 4-layer as his preferred system for its warmth properties.

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Discussion

- As willing participants in a clinical trial, each subject adhered to the protocol and experienced wound healing progress due to effective, sustained compression.
- The 2 layer system was as effective as the 4 layer system in reducing edema and managing the clinical condition.
- QoL scores were difficult to interpret with only 3 subjects. Interpretation will require analysis of all 80 patient data.
- The 2 layer system provided these patients with comfortable compression and 7 day wear time with minimal slippage.
- Both the patients and clinician reported that the 2 layer system was faster to apply and remove which was appreciated in the busy clinic.

About the QoL Tool

Several validated tools⁵ are available to assist clinicians and researchers in understanding how chronic wounds affect patients' everyday life and their emotional response to these effects.

A quality of life tool, the Cardiff Wound Impact Schedule, has been developed specifically for patients with leg ulcers and diabetic foot ulcers. It measures Health Related Quality of Life as it relates to physical symptoms and everyday living. 3 scales are used: physical symptoms and everyday life, social life (ability to get out and about), and well-being, including anxieties about their outcome.

This tool was selected to learn how product design and performance attributes affect a patients overall response to their condition and treatment. Use of a QoL tool may assist clinicians in evaluating the effectiveness of a new technology

⁵Medical Outcome Short Form - 36 and the Nottingham Health Profile

References:

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