

Efficacy, safety and acceptability of a new two-layer bandage system for venous leg ulcers

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Message:

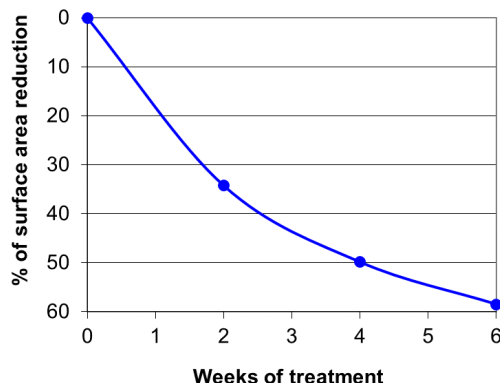
A well-designed multilayered compression system must provide **Consistent** levels of therapeutic compression, **Continuously** (day and night), with a high degree of **Comfort**. When these three elements (the three C's principle) converge in one well designed, easy to apply and wear product, the compression bandage can demonstrate high degree of patient compliance/concordance. The use of a Dual Compression System (DCS) UrgoK2 two layer bandage, which contains two proprietary layers (K Tech and K Press), designed with the 3 C's requirement in mind, led to excellent clinical results and high satisfaction scores from clinicians and patients. The element of **Comfort** associated with this novel Dual Compression is proved strongly in this study. The bandage additionally features printed stretch indicators that allow consistent, continuous application of therapeutic pressure.

Methods:

A clinical trial conducted at 12 sites included a total of 42 patients (268 medical evaluations, 1617 cumulative days of treatment) over a 6 week period. The primary objective was venous ulcer area reduction, the secondary objectives were determination of % wounds healed, leg edema reduction, and patient and nurse satisfaction.

Results:

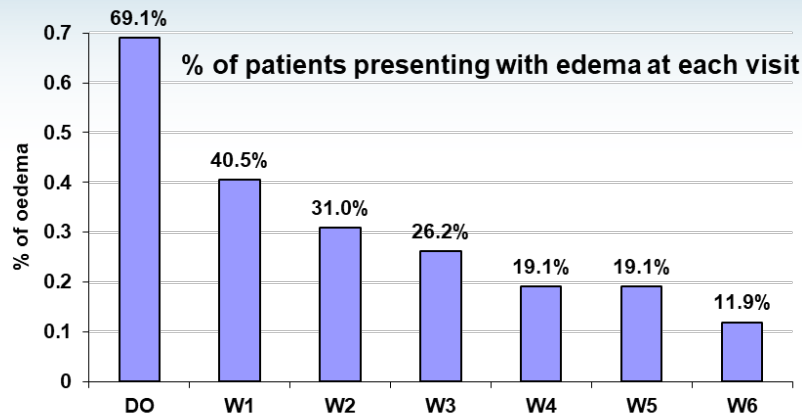
Primary endpoints: Relative reduction of wound surface area. % , compared to Day 0.



The mean surface area reduction at week 6 was 58.5 %, a significant level of wound size reduction with $p < 0.0001$

Secondary endpoints.

1. **Rate of ulcer healing** : 23.8 % of ulcers healed in 6 weeks with a mean healing time of 26 days.
2. **Lower Ankle Edema Reduction**: Increased edema reduction was noted with increased length of compression therapy, with 43% reduction in edema cases seen in one week and 83% reduction seen in 6 weeks.



3. **Other outcomes**: 94.8% of patients reported high levels of comfort during day, and 92.0% at night. 59.3% reported reduction in itchiness, 65.3% reported absence of hot sensation, 83.9% found it easy/very easy to put on footwear, and 89.9% reported good/very good ankle mobility. 99.1% of the bandage applications were deemed to be easy/very easy by the clinicians. 86% of the clinicians reported wound healing improvement with the treatment. Adverse events were very small in number and largely not associated with the treatment regime, with patients continuing with treatment through the six week period.

Conclusion:

This multicentered study showed that the Dual Compression System, UrgoK2 has the ability to significantly reduce venous ulcer wound size (58.6%) with 86% showing improvement in healing over a six week period. Patients reported high levels of comfort and ease in use, and clinicians reported that the application was easy during the hundreds of application episodes. High levels of edema reduction were seen in one week (43%) and over 6 weeks (83% reduction). Consistent and continuous compression led to patient **comfort**, and therefore compliance and excellent clinical results. Comfort and therefore compliance, and clinical results are therefore likely related.



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