

EVALUATION OF A NOVEL TWO LAYER COMPRESSION STOCKING SYSTEM IN THE TREATMENT OF VENOUS LEG ULCERS

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Objectives: evaluation of the efficacy of a novel two layer compression stocking system in healing rates of venous leg ulcers for a treatment period of 6 weeks.

Method: multicenter, open clinical trial including outpatients with venous leg ulcers characterized by size > 4cm² (planimetry), ABI > 0.8, <1.3, and duration of at least 1 month but less than 1 year. The compression system consisted of two compression stockings: an understocking with no compression on the foot and 18-23 mmHg at ankle (measure point B) worn day and night and an overstocking with open toes and a pressure range between 23-32 mmHg worn during the day only. In combination (understocking and overstocking) a pressure of 40 mmHg was achieved as recommended. Due to the compression level of each stocking component, application is particularly easy for the patients.

Results: 28 patients, 74.7 ± 17.6 years old were included (67.9% women). Ulcer average area was 14.6 ± 20.7 cm² and duration was 5.4 ± 6.6 months. The rate of complete healing reached 4.4% at week 2, 17.4% at week 4, and 39.1% at week 6. A healing rate over 75% was reported for 13.0% of patients at week 2, 43.5% at week 4 and 52.2% at week 6. Moreover, compared with the initial ulcer size, there was a significant (p<0.0001) reduction of 41.7% ± 34.2% at week 2, 61.8% ± 37.7% at week 4, and 68.0% ± 34.2% at week 6. Significance was reached in ITT as well as per protocol analysis.

Conclusion: treatment of venous leg ulcers with the novel stocking system for 6 weeks resulted in complete healing in more than one third of the patients and healing rates of over 75% surface area in more than half of them.