

The Effect of Natural Matrix Biopolymer Membrane on Hard-To-Heal Venous Leg Ulcers: A Pilot Randomised Clinical Trial

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Abstract

Objective: The aim of this study was to evaluate the therapeutic effects of natural matrix biopolymer membrane (NMBM) in the treatment of venous leg ulcers (VLUs).

Method: Patients exhibiting one or more VLU were assigned to a test group receiving NMBM or to a control group receiving conventional treatment. Patients exhibiting venous insufficiency-related ulcers within 0.1-170cm² were included. Efficacy was assessed based on ulcer size and visual analogue scale (VAS) pain scores at baseline and at weeks one, two and four. Ulcer size and pain were compared between groups using a two-way ANOVA.

Results: In this study, 25 patients with 32 VLUs (NMBM group: 14 patients with 17 ulcers; control group: 11 patients with 15 ulcers) were included in the final analysis. At four weeks after baseline measurements, the mean percentage change in VLU area of patients in the NMBM group was 61.6% (95% CI: 40.3-82.9) compared with 84.1% (95% CI: 56.5-111.7) for control group patients. Additionally, the mean percentage change in VLU volume of NMBM group patients was 51.2% (95% CI: 31.8-70.6) compared with 84.0% (95% CI: 57.0-121.0) for control group patients. The NMBM group patients exhibited a mean decrease of 0.38 (95% CI: -0.85-1.61) in VAS pain score over four weeks, compared with a mean decrease of 0.13 (95% CI: -1.32-1.58) for control group patients. No significant differences in VLU area (p=0.210), volume (p=0.122) or VAS pain score (p=0.460) were shown between groups.

Conclusion: NMBM was found to be as effective and safe as the control group treatments. This pilot study suggests NMBM can be used safely to promote ulcer healing.

Keywords: compression therapy; leg ulcer; natural matrix biopolymer membrane; treatment outcomes; venous insufficiency.