

A RANDOMISED, CONTROLLED TRIAL ON SAFETY AND PERFORMANCE OF A NEW FOAM DRESSING ON VENOUS LEG ULCERS

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Aim: The aim of the clinical study was to evaluate a test dressing versus a comparator regarding patient comfort, clinical efficacy and safety. Due to an improved dressing design with softer foam and bevelled edges, focus was on patient comfort and development of pressure marks.

Methods: The study was designed as a prospective, randomised, controlled, open, parallel, multi centre study. 2 x 20 patients with moderately to highly exuding venous or mixed venous and arterial leg ulcers were recruited. Each patient was treated with the test dressing or comparator for 4 weeks.

Results:

- Pressure marks were significantly reduced with the test dressing ($p < 0.0001$).
- The test dressing was perceived as significantly softer ($p = 0.007$) and more flexible ($p < 0.0001$).
- Patient comfort was higher for the test dressing ($p < 0.0001$).
- Exudate handling for the test dressing was at level with the comparator with 98% excellent or good exudate handling, 99% no leakage and 84% no maceration.
- Ulcer area reduction was equal ($p = 0.81$).
- Peri-ulcer skin reactions were low for both study groups, and one device related adverse event was reported for comparator.

Conclusion: Higher patient comfort and lower risk of pressure marks was demonstrated by the test dressing. The test dressing provided same exudate management and ulcer area reduction as the comparator, and was concluded safe to use.