

AN OPEN, PROSPECTIVE, RANDOMISED, WITHIN VOLUNTEER COMPARISON OF 2 SILICONE FOAM DRESSINGS & A CLINICAL IN MARKET EVALUATION OF A NEW SILICONE FOAM DRESSING

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Aims: Primary objectives were to demonstrate non-inferiority of a new silicone foam dressing to an alternative silicone foam dressing in terms of pain on removal after 1 day wear and overall acceptability of the product.

To demonstrate performance of a new silicone foam dressing within volunteers and patients.

Methods: The volunteer study was an open, prospective, randomised, within volunteer comparison (90 volunteers) of two dressings. All volunteers were aged >50. The Clinical In Market Evaluation will recruit 80 patients from 5 European countries.

Results: For the volunteer study the criteria for demonstrating non-inferiority was met for pain on removal after 1 days wear (the upper limit of the 95% two sided confidence interval was less than 15%).

There was significant evidence of a greater percentage of new silicone foam dressing still in place compared to alternative silicone foam dressing on the upper (8.9% more, $p=0.046$) and lower (6.7% more, $p=0.014$) calves after 1 days wear, lower thighs after 3 days wear (12.5% more, $p=0.012$), upper (20.2% more, $p<0.001$) and lower (11.5% more, $p=0.008$) calves after 3 days wear and on the lower calves after 7 days wear (10.3% more, $p=0.039$). All secondary objectives results will be presented and the patient data from the Clinical In Market Evaluation.

Discussion/Conclusion: The primary objective of the trial was met, as the new silicone foam dressing was demonstrated to be non-inferior to an alternative silicone foam dressing in terms of any pain on removal at 24hrs. There was no evidence of a difference in the level of pain on dressing removal for either dressing at any of the other dressing removal times.

Retention and conformability was better for the for new silicone foam dressing compared to the alternative silicone foam dressing.