RANDOMIZED, CROSS-OVER, CLINICAL TRIAL TO COMPARE THE IMPACT OF TWO-LAYER VERSUS A FOUR-LAYER COMPRESSION BANDAGE SYSTEM IN THE TREATMENT OF VENOUS LEG ULCER

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Aim: To compare bandage slippage, Health Related Quality of Life (HRQoL) and patient preference during the treatment of venous leg ulcers with a two-layer versus a four-layer compression bandage system.

Methods: The trial was conducted at 10 centres in UK(3), US(5), Canada(2). Subjects (n=81) were randomized to one of the 2 compression systems. Subjects were followed for a total of 8 weeks, which included a minimum of 9 clinic visits. Treatment cross-over occurred at week 4. All ulcers were covered with the same primary dressing. The primary endpoint was bandage slippage measured at each dressing change. Secondary endpoints included HRQoL (Cardiff Wound Impact Schedule), wound healing/wound area reduction both assessed at baseline, at the time-point of treatment cross-over and end of study. Patient preference was inquired by questionnaire.

Results: Mean slippage estimated from a mixed ANOVA model (701 measurements) was 2.48 cm for the 2-layer system and 4.17 cm for the 4-layer system (p<0.0001). Positive changes in HRQoL Physical Symptoms and Daily Living Scores during Period 1 were significantly higher with the two-layer system (pooled 2-sample t-test, p=0.046). There were no significant differences in percent of wounds that healed (Fisher’s Test, p=0.47) or in wound area reduction (Wilcoxon Test, p=0.87). Subjects had a strong preference for the 2-layer system (72%) vs. the 4-layer system (22%), with 6% having no preference. Preference was similar regardless of randomization order (p>0.99).

Discussion: This study reveals that there is significantly less bandage slippage with the cohesive 2-layer system compared to the 4-layer system. Less bandage slippage may have influenced patient preference in favour of the 2-layer system and positively impacted patients’ Physical Symptoms and Daily Living Score.