A PILOT RANDOMIZED TRIAL TO DETERMINE THE EFFECTS OF A NEW ACTIVE DRESSING ON WOUND HEALING OF VENOUS LEG ULCERS

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Aim: To determine the effect of a new collagen/oxidized regenerated cellulose (ORC)+Silver dressing on healing of non-responsive venous leg ulcers (VLU) and to compare these results with control patients treated with best standard of care.

Methods: 30 VLU patients, 14 males (47%) and 16 females (53%), average age 73±20 years and with a disease duration between 30 days to 20 years, were included in this pilot study and randomized to receive either best standard care treatment (15 patients) or collagen/ORC+Silver dressing therapy (15 patients). Median wound size was 9 cm² in control patients and 6 in collagen/ORC+Silver patients. Study duration was 12 weeks, with dressing changes every week as well as measurements on wound size and assessment of wound appearance. Study endpoints were healing rate at week 12th and rate of area reduction during treatment. Patients showing a reduction of wound size > 50% after 4 weeks therapy were considered to be treatment responders (Margolis Index=MI).

Results: The probability to heal at week 12th was 4 times higher during collagen/ORC+Silver treatment (OR=4.3, 95% CI: 1-17, p<0.04), as well as the reduction in ulcer size was highly significant improved in the treated group versus controls (p=0.00005). MI had a better trend in the collagen/ORC+Silver dressing group, 67% (10/15) than in the control group 47% (7/15) (p=ns). While no difference was observed in infection rates (33% control, 26% collagen/ORC+Silver dressing) this is not surprising due to the fact that the collagen/ORC+Silver dressing was only applied once weekly.

Conclusions: Results of this randomized pilot study confirm the effectiveness of the collagen/ORC+Silver dressing in treatment of hard to heal VLU representing a useful basis for calculating the statistical power of a larger multi-centre randomized control trial.