

OP5

LeucoPatch™ seems to improve healing of diabetic foot ulcers - outcome from an open multicenter clinical study

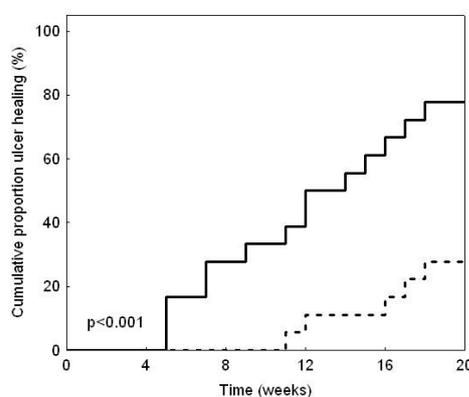
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Background and Aim: LeucoPatch™ is a biologically active dressing, produced from 18 mL of autologous blood using a Leucopatch™ device. The final product appears as a membrane containing a high concentration of growth factors, platelets and leucocytes. The aim of this pilot study was to evaluate effectiveness of LeucoPatch™ on healing of diabetic foot ulcers.

Methods: The study setting was multidisciplinary Diabetes Foot Units in Denmark and Sweden. Patients with non-ischemic, diabetic Wagner grade 1 or 2 foot ulcers without clinical signs of infection and with a duration >6 weeks were included. Patients, with >40% ulcer area reduction during a two week run-in period were excluded. LeucoPatch™ was applied once weekly for 18 weeks or until ulcer healing. Time to healing was compared to a matched (Wagner grade, ulcer duration and size) control group. Data are given as median and quartiles. Ulcer healing rates are given as a Kaplan-Maier curve analysis (Cox-Mantels test). A $p < 0.05$ was considered as statistical significant. **Results:** 18 patients (4 females, Wagner

grade 1=4, grade 2=14) with ulcer duration of 28 (14-46) weeks and ulcer area of 1.0 (0.5-1.7) cm² were included. 78% of these



patients healed their foot ulcers within the follow-up period of 20 weeks, as compared to 28% in the control group.

Conclusion: This pilot-study indicates that LeucoPatch™ might improve healing of diabetic foot ulcers. A randomised controlled trial is designed to further evaluate this issue