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PROSPECTIVE, RANDOMIZED, CONTROLLED, MULTI-CENTER CLINICAL TRIAL OF A BIOCELLULOSE WOUND DRESSING FOR THE TREATMENT OF VENOUS ULCERS

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Objectives: To Evaluate the safety and efficacy a biocellulose wound dressing (BWD) produced from microbial cellulose (*Acetobacter Xylinium*) in the treatment of venous ulcers.

Design: Prospective, randomized, controlled study.

Setting: Multicenter Study in the outpatient setting.

Intervention: Each patient with a venous ulcer received either standard care (non-adherent dressing plus compression therapy) or BWD plus compression therapy. Wounds were evaluated for fibrinolysis (autolytic debridement), pain, healing rate, time to 75% complete granulation and time to 50% re-epithelialization.

Outcomes: The study was completed as planned in 48 randomized patients.

Results: Treatment with BWD plus compression was more effective than standard care in fibrinolysis (83% vs. 26%; $p=0.0001$), wound pain (i.e. week-7, 100% of the subjects treated with BWD reported no pain compared to 63% in the standard care group, $p=0<0.05$). Time to 75% granulation was 25 days for the BWD-treated group vs. 36 days for the control-treated group. Time to 50% re-epithelialization was 36 days for the BWD-treated group vs. 50 days for the control-treated group.

Conclusions: Fibrinolysis was significantly greater in the BWD-treated group leading to exposed wound margins and cleaner wound bed. The BWD-treated group reported significantly less wound pain than the group treated with standard care. The time to granulation was 69% less, and the rate of wound healing was 43% greater in the BWD treated group

BWD = Suprasorb X, Lohmann & Rauscher GmbH, Rengsdorf, Germany