

CONTINUOUS STREAMING OF PAPAİN SOLUTIONS FOR THE DEBRIDEMENT OF VENOUS LEG ULCERS

Amihay Freeman¹, Tali Yaakobi¹, Noa Hadar¹, Amir Shiner², Sam Nitezki³, Jonathan Lorber⁴, Arie Bass⁴.

¹*Tel Aviv University (Tel Aviv, Israel)*

²*EnzySurge Ltd (Rosh Haayin, Israel)*

³*Rambam Hospital (Haifa, Israel)*

⁴*Asaf Harofeh Hospital (Zrifin, Israel)*

Aim: The growing numbers of chronic ulcers present huge challenge to currently employed treatments. There is an urgent need in a new effective, user-friendly treatment modality for the home-care settings. Here we report results demonstrating feasibility, safety and preliminary efficacy of a new modality of chronic wound debridement: continuous streaming of proteolytic enzyme solution.

Methods: Continuous streaming of solutions was affected by gravity from a feeding reservoir onto ulcers occluded within disposable device, simultaneously affecting mild negative pressure. Used solutions were collected in disposable collecting-bag. A multi-centered, double-blinded, Phase I/II randomised controlled trial was launched to test the safety and preliminary efficacy of increasing concentrations of papain in the streamed solutions for venous ulcers debridement. Patients were treated with 5-consecutive daily 6hrs-streaming sessions, followed by standard changes of wet dressings throughout a 3months follow-up period. Streaming of same solution devoid of enzyme served as control.

Results: 48 patients were enrolled, 36 were treated with enzyme containing solutions and 12 with solutions devoid of enzyme. Patients treated with enzyme containing solutions experienced debridement with exposure of 50-70% of wound area as granulation tissue vs exposure of 30% for the control group. 50% of enzyme debrided wounds exhibited spontaneous wound-closure or >75% wound size reduction within 2-7 weeks post treatment.

Conclusions: Our results indicate that continuous streaming of proteolytic enzyme solution is a safe and effective modality for wound debridement, applicable at the outpatient clinic, nursing-home and homecare settings.