CONTINUOUS STREAMING OF THERAPEUTIC SOLUTIONS FOR CHRONIC WOUND DEBRIDEMENT

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Purpose: Demonstrate feasibility, safety and preliminary efficacy of a new modality of chronic wound debridement: Continuous Streaming of Therapeutic solutions (CST), as effective, user-friendly treatment for outpatient and home-care settings.

Methods: Continuous streaming of therapeutic solutions was affected by gravity from a feeding reservoir (IVbag) via tubing connected to ulcers sealed with DermaStream* - an occlusive dressing with inlet/outlet and in-wound solution distribution mechanism –to a collecting bag. On the basis of preclinical results** and previous clinical trial on DermaStream's safety, a multi-centered Phase I/II clinical trial (48 patients) was launched in Israel to test the safety and preliminary efficacy of increasing concentrations of proteolytic enzyme in the streamed solution for venous ulcers debridement. Todate, 16 patients were treated by 5 consecutive 6hrs streaming sessions, followed by standard changes of wet dressings and follow-up for 3 months. Twelve patients were treated with enzyme containing solution and four by streaming of same solution devoid of the enzyme.

Results: Technical feasibility of CST, safety of streaming of proteolytic enzyme solution and pain relief were demonstrated. Wound debridement with exposure of granulation tissue was recorded for 11 patients. Todate, wound closure within 2-7 weeks was observed for six patients.

Conclusions: Our accumulating results clearly indicate that CST provides a safe new modality for wound debridement. These results pave the way to its use as effective home-care treatment aiming at shorter time to heal.

* An FDA approved Israeli product.

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