BROMELAIN BASED ENZYMATIC DEBRIDEMENT OF CHRONIC WOUNDS: TOP-LINE RESULTS OF A MULTICENTER PHASE II TRIAL

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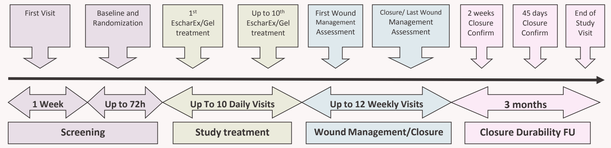
Introduction: Current enzymatic and autolytic wound bed preparation agents used in chronic and hard to heal wounds are slow and/or of limited efficacy, delaying healing in millions of patients worldwide. A fast and effective debridement agent able to complete this process in a few applications is currently an unmet need. Rapid-acting Bromelain based enzymatic debridement has recently been approved for the treatment of deep thermal burns in the EU, Israel and Argentina, after being found to be effective and safe in controlled clinical studies. We present the preliminary late-breaking top line results of a multicenter phase II trial assessing EscharEx®, a new rapid-acting Bromelain-based enzymatic debridement agent in development for chronic wounds.

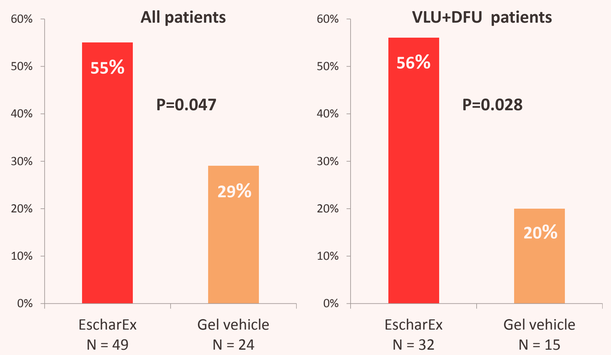
Methods: Seventy-three patients suffering from diabetic (n=23), venous (n=24), and post surgical/traumatic (n=26) chronic ulcers participated in a multicenter, prospective, randomized, assessor-blinded, phase II trial conducted in Europe and Israel, assessing the safety and efficacy of EscharEx versus its gel vehicle (in a 2:1 randomization ratio). Patients received up to 10 daily treatments and were then followed up for 26 weeks. This preliminary report summarizes the results of a pre-planned analysis conducted after all patients completed the 12 week follow up visit.

Study design



Patient and wound characteristics	EscharEx (n=49)	Gel vehicle (n=24)
Gender	22 (44.9%) male 27 (55.1%) female	15 (62.5%) male 9 (37.5%) female
Patient age (years)	65.8 ± 16.1	68.1 ± 13.0
Wound age (weeks)	72.8 ± 163.0	30.8 ± 41.0
Wound size (cm^2)	33.6 ± 29.7	25.8 ± 22.4

Incidence of complete debridement within 10 daily treatments



Results: The primary endpoint, incidence of complete debridement within 10 treatments, was significantly higher in the EscharEx group (55% versus 29%, p=0.047). Additionally, 93% of EscharEx patients achieving complete debridement did so within 7 treatments. The difference in incidence of complete debridement for the combined diabetic and venous ulcers populations was even more significant (56% versus 20%, post hoc analysis, p=0.028), and the time to complete debridement for these populations was significantly shorter for EscharEx (post-hoc analysis, p=0.024). There was no deleterious effect of EscharEx on wound closure, and the overall incidence of adverse events amongst the study groups was comparable, with no EscharEx treatment related serious adverse events reported.

Conclusion: The overall incidence of complete debridement with EscharEx within 10 daily treatments was significantly higher and completed earlier, with even better results in the diabetic and venous ulcers, with no significant safety issues. The complete results of the study are expected in the near future.

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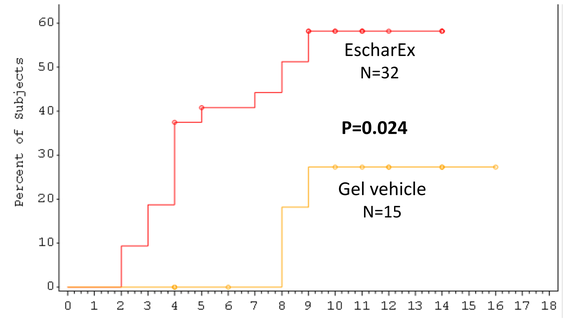
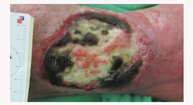
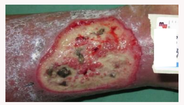
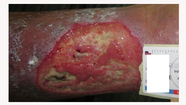
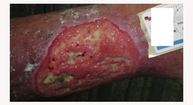
Days to complete debridement, VLU+DFU patients

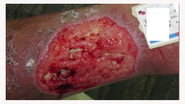


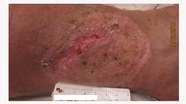

VLU, pre-existing 10 Weeks

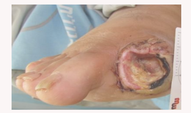

post 1st EscharEx treatment

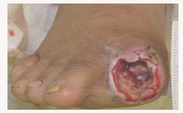

post 3rd EscharEx treatment

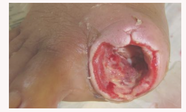

post 5th EscharEx treatment

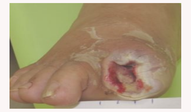

post 7th EscharEx treatment

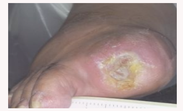

8 weeks post skin-grafting

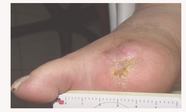

DFU, pre-existing 4 Weeks


post 2nd EscharEx treatment


post 4th EscharEx treatment


1 week post debridements


8 weeks post debridements


5 months post debridements