EFFICACY OF BROMELAIN-BASED DEBRIDEMENT (BBD) IN DIABETIC FOOT ULCERS - A POST HOC ANALYSIS

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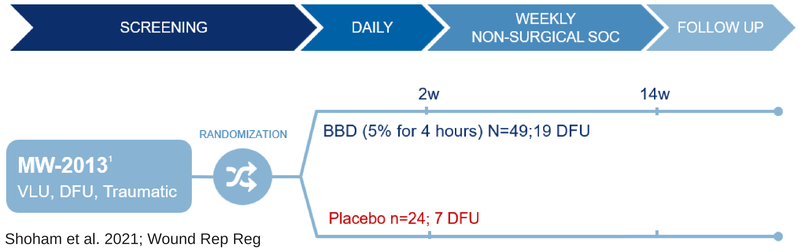
Overview

INTRODUCTION

Chronic wounds affect millions annually in the U.S., incurring significant healthcare costs. Effective debridement is critical for initiating tissue repair. Bromelain-based debridement (BBD) has shown efficacy and safety in various wounds, including burns and venous leg ulcers (VLU). This post hoc analysis evaluates BBD's efficacy in diabetic foot ulcers (DFUs) using data from a multicenter, assessor-blinded, randomized controlled trial.

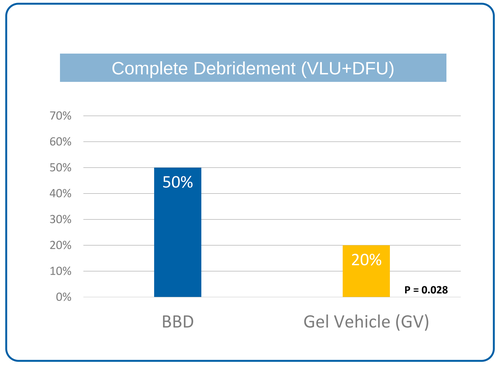
METHODS

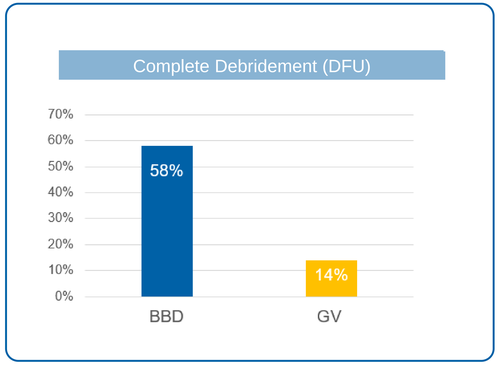
Seventy-three patients with chronic lower extremity ulcers (venous leg ulcers [VLU], diabetic foot ulcers [DFU], or traumatic ulcers) were randomized 2:1 to receive bromelain-based debridement (BBD) 5% (49 patients) or a gel vehicle (GV) control (24 patients). Treatments were applied daily for up to 10 sessions of 4 hours (up to 2 weeks), followed by weekly assessments for 12 weeks.
This post hoc analysis focuses on 19 patients with DFUs (12 BBD, 7 GV). Complete debridement was assessed clinically and defined as ≥90% removal of non-viable tissue within two weeks daily treatment or 100% removal anytime. Granulation tissue was assessed clinically. Wound bed preparation (WBP) was defined as 100% removal of non-viable tissue with ≥75% granulation. Wound closure was defined as complete epithelialization without drainage or dressing use for two weeks.
This subgroup analysis was not powered to detect statistically significant differences.

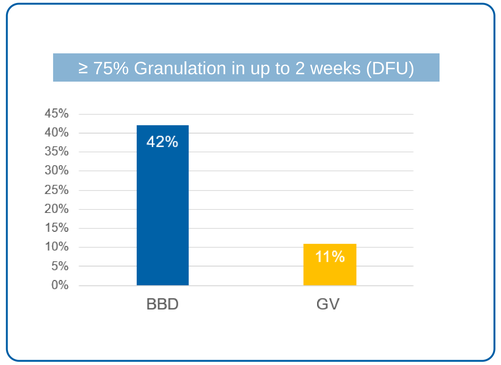


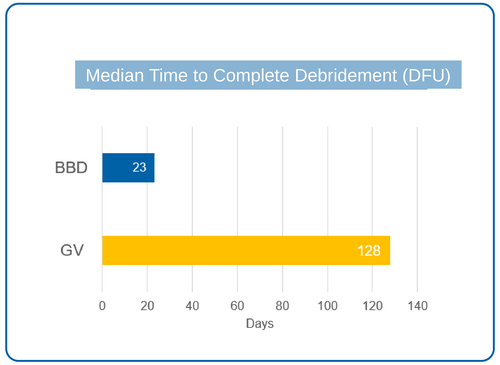
Shoham et al. 2021; Wound Rep Reg

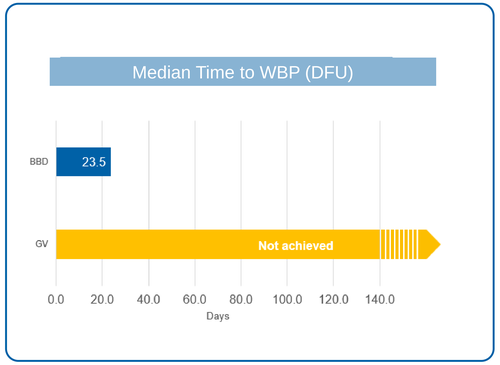
Results











Additional efficacy results

- WBP anytime during the study occurred in 75% (BBD) vs. 43% (GV)
- Wound closure in 57 % (BBD) vs. 25% (GV)

Safety results

- Safety profile of EscharEx in DFU was consistent with the known safety profile in VLU
- In Wagner stages ≥ 2, the safety profile of EscharEx remained consistent with that in VLU, with no new emerging adverse reactions identified

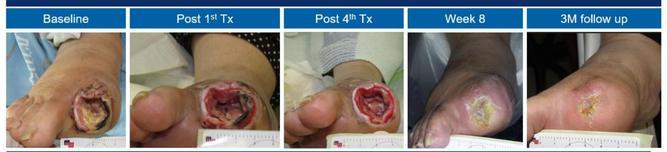
Baseline Characteristics

	BBD (N=12)	GV (N =7)
Demographics		
Age (years, mean (SD))	64.1 (11.15)	61.1 (7.87)
Female gender (n, %)	5 (41.7)	1 (14.3)
Wound size (cm^2, mean (SD)	22 (7.36)	24 (11.11)
Wound duration (weeks, mean (SD)	10.8 (10.9)	23.1 (34.2)
Wagner stage (n, (%))		
Stage 1	4 (33.3)	--
≥ stage 2	8 (66.7)	7 (100%)
Ischemic wounds (n, (%))	4 (33.3)	4 (57.1)
Non-viable tissue (% (SD))	78.2 (19.0)	94.3(6.2)

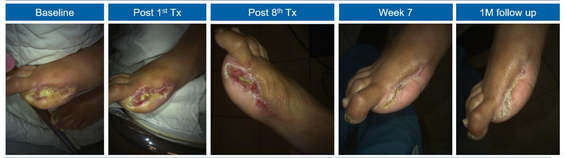
DFU wounds treated with GV had comparable size to those treated with EscharEx, but longer duration, and higher percentage of Wagner stage ≥2 and ischemic wounds

Case studies

Patient: 49-year-old female
Clinical presentation: 6.0cm² DFU(Wagner Grade 2)on the large toe, following amputation
Therapeutic outcome: ≥90% debridement and ≥75% granulation by day 4, and wound healing in 8 weeks.



Patient: 67-year-old male
Clinical presentation: 8.0cm² DFU (Wagner Grade 3),following 1st toe partial ray amputation
Therapeutic outcome: ≥90% debridement by day 11, ≥75% granulation by day 60, and wound healing in 60 days



Conclusions

These results suggest that BBD has clinically meaningful advantages over GV in debridement, granulation tissue promotion, and wound closure for DFUs, achieving WBP faster than GV. The findings support further phase II/III studies to validate BBD for DFU management