EscharEx® for DFU

Post-hoc analyses from phase 2 (MW2013)

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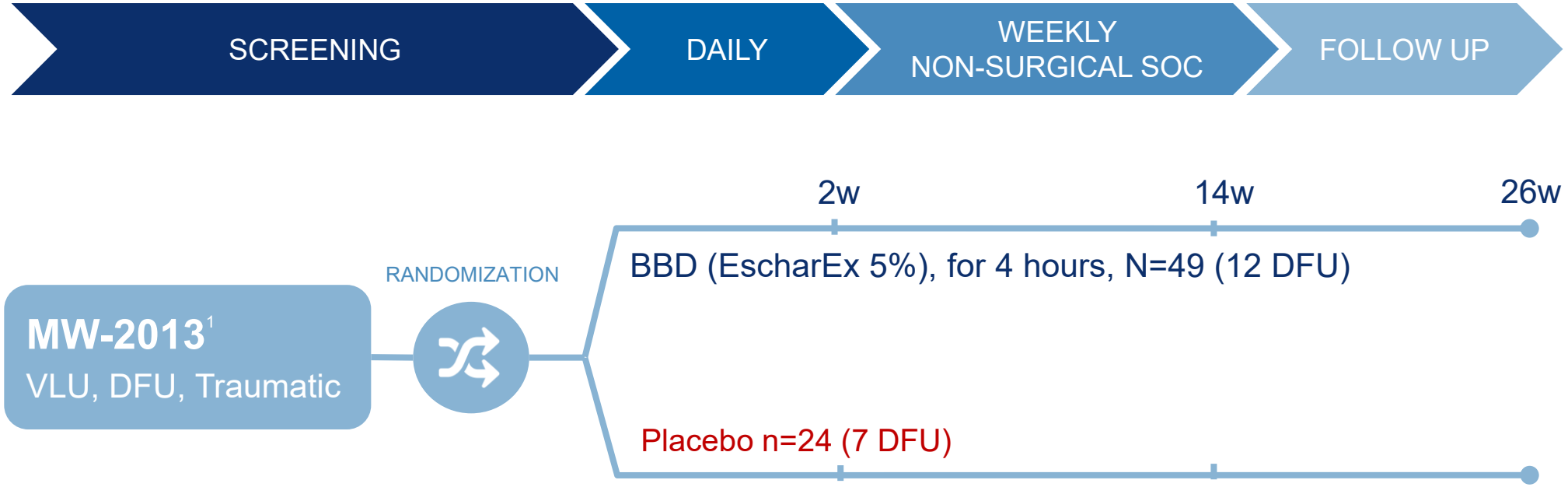
Conflict of Interest Disclosure

Dr. Snyder is Senior Vice President, Global Medical Affairs at MediWound Ltd.

He reports no other relevant conflicts of interest.

MW2013 Study Design



1.Shoham et al. 2021; Wound Rep Reg

Key Eligibility Criteria

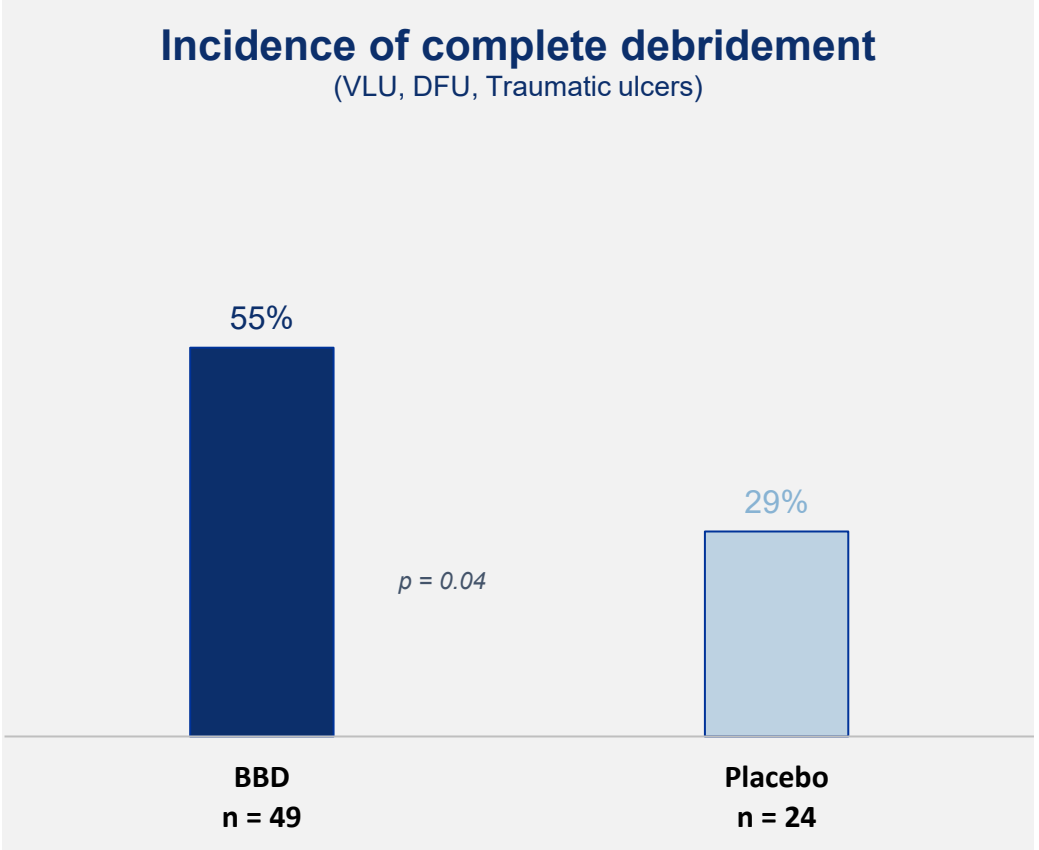
Key inclusion criteria

1. Venous leg ulcer or diabetic (lower extremity) ulcer or traumatic/post operative wound (determined by medical history and physical examination)
2. Wound age ≥ 4 weeks
3. Non-viable tissue area ≥ 50% (assessed clinically)
4. Wound area of 5- 200 cm^2

Key exclusion criteria

1. Active osteomyelitis
2. Presence of purulent discharge, deep-tissue abscess, cellulitis, gangrene or signs of systemic infection
3. Wound size decreased by > 20% during screening period, on SOC
4. Ankle-Brachial Index (ABI) ≤ 0.7 or a significant decrease in the blood flow by US doppler
5. Sinus tracts or tunnels

Phase 2 MW-EX01 Trial[1]: BBD Effective in Both VLU and DFU



Results

93% of the patients who completed debridement with BBD, achieved full debridement within 7 days

1. Shoham et al. 2021; Wound Rep Reg

Post-hoc analyses assessed safety and efficacy of BBD in the DFU sub-cohort

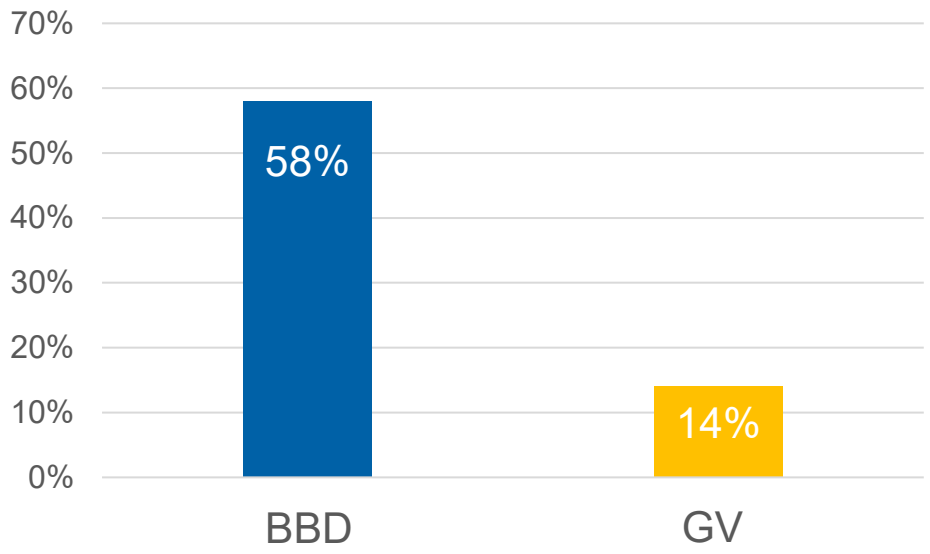
Demographics and Baseline Wound Characteristics

	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 grade (n, (%))		
Grade 1	4 (33.3)	--
≥ Grade 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)

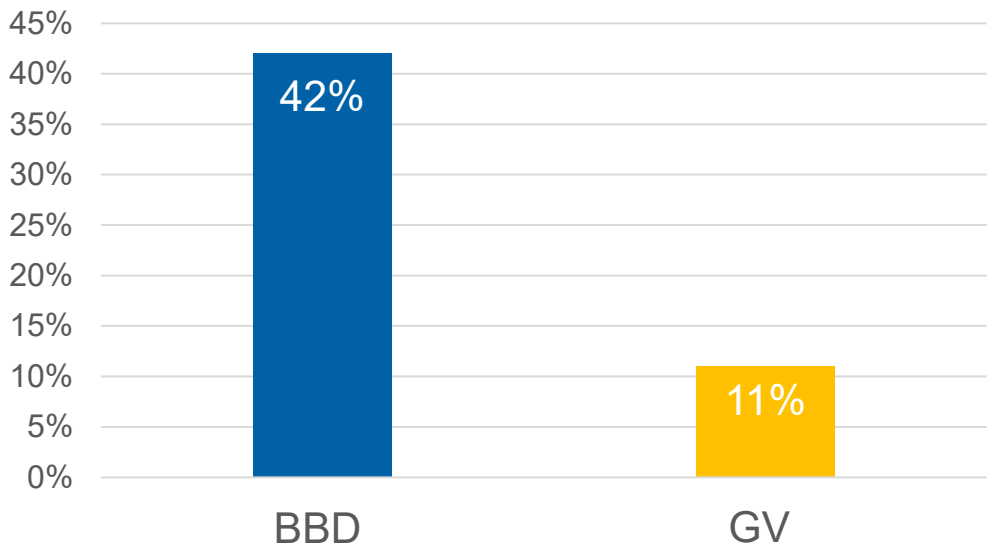
DFU wounds treated with GV had comparable size to those treated with BBD,
but longer duration, and higher percentage of Wagner grade ≥2 and ischemic wounds

Complete Debridement and ≥75% Granulation in up to 2 Weeks

Complete Debridement (≥ 90%) in up to 2 weeks

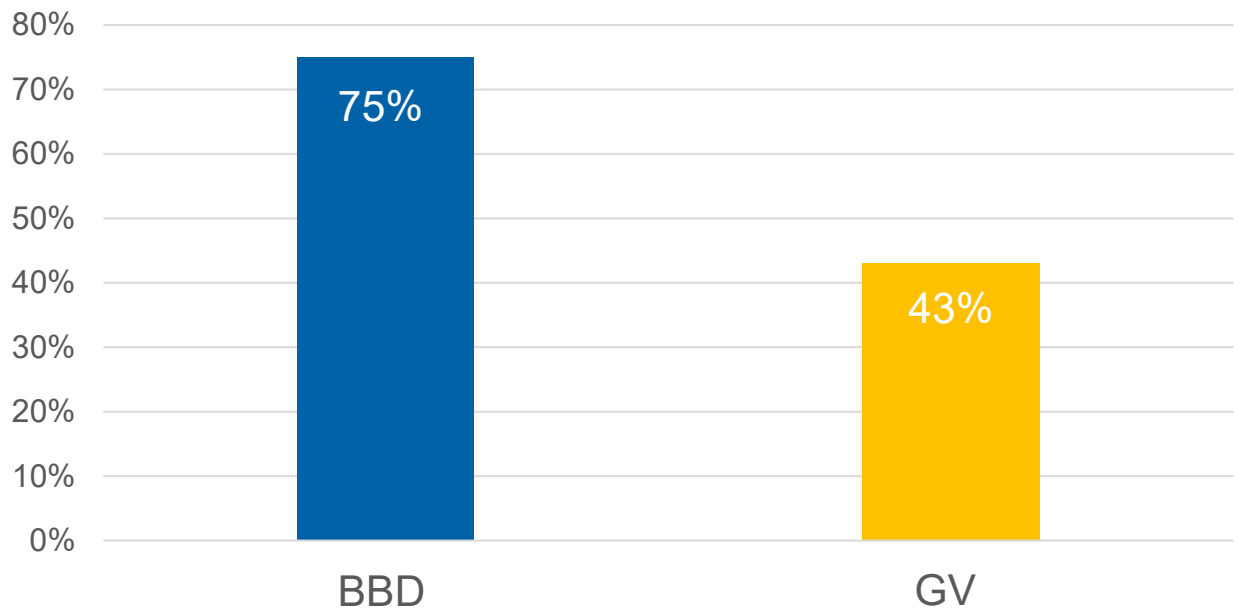


75%-100% Granulation in up to 2 weeks



This subgroup analysis was not powered to detect statistically significant differences

Wound Bed Prepared Achieved During Study

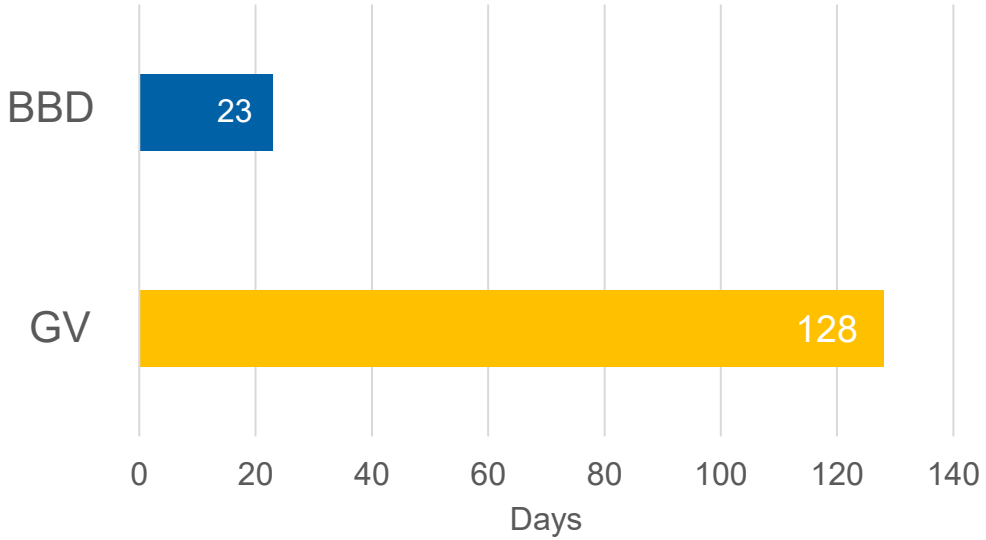


Wound bed preparation (WBP) - defined as 100% removal of non-viable tissue with 75% - 100% granulation

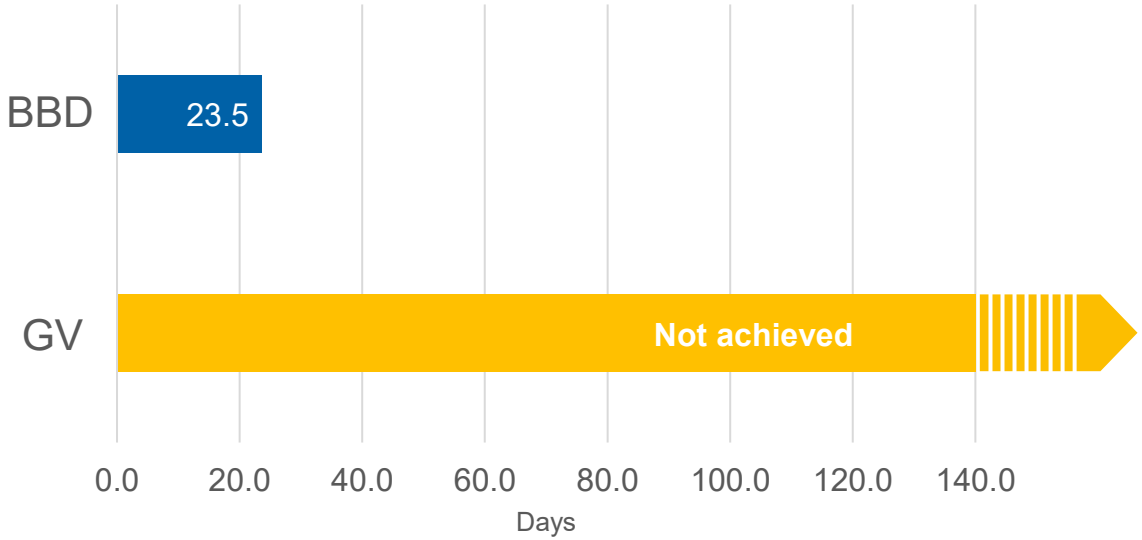
This subgroup analysis was not powered to detect statistically significant differences

Time to Complete Debridement and Time to WBP

Median Time to Complete Debridement



Median Time to WBP



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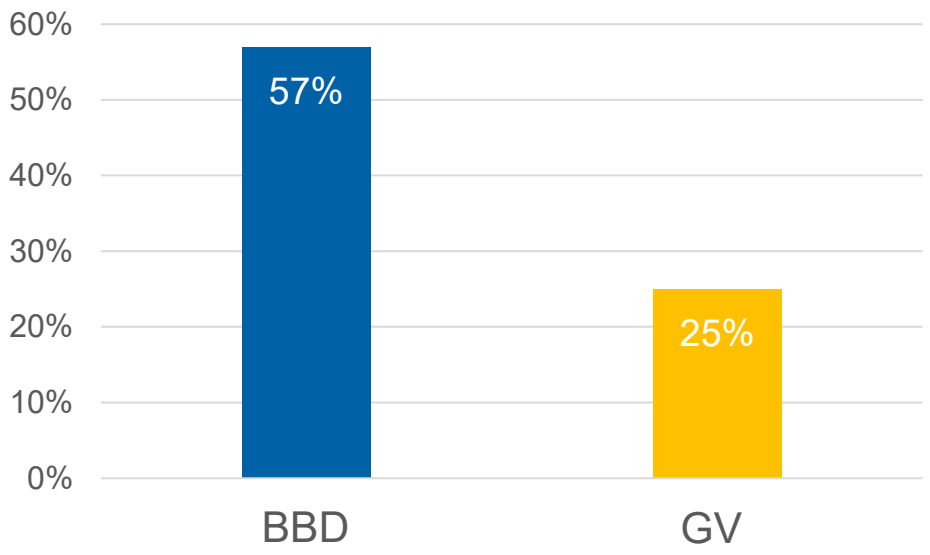
Wound Closure



Wound closure: Complete epithelialization without drainage or dressing use for two weeks

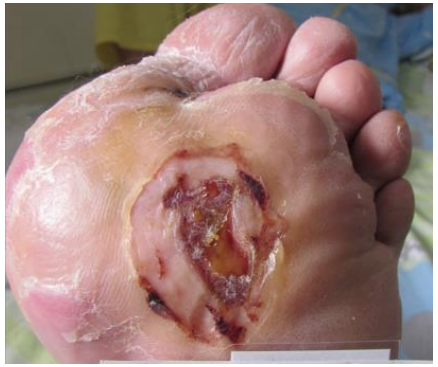
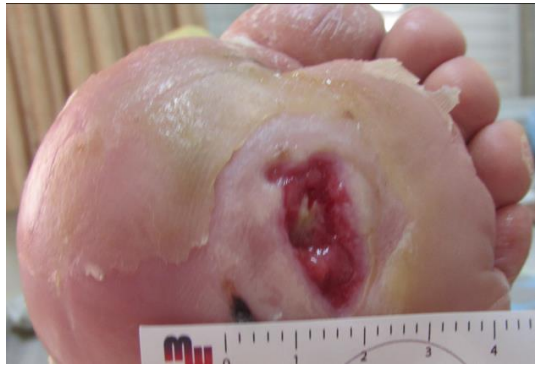
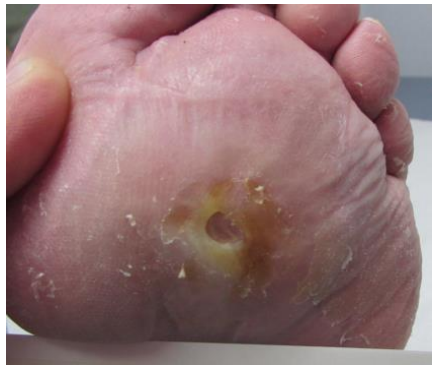
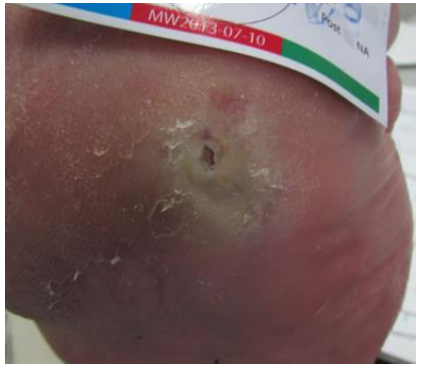
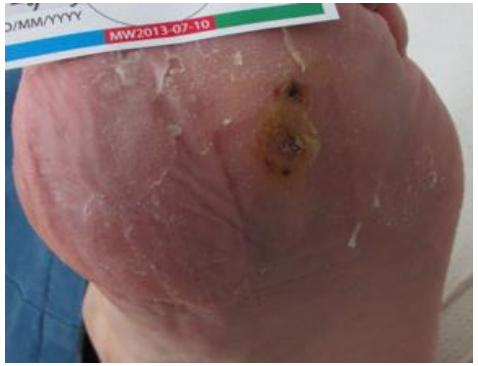
This subgroup analysis was not powered to detect statistically significant differences

Safety

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

Case Study 1

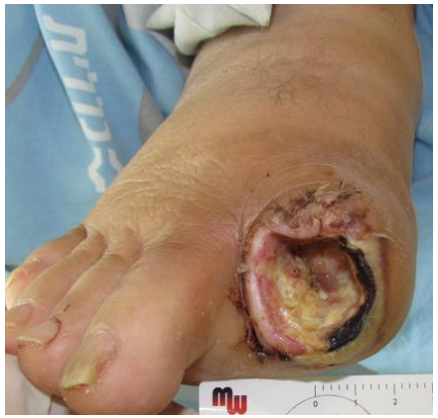
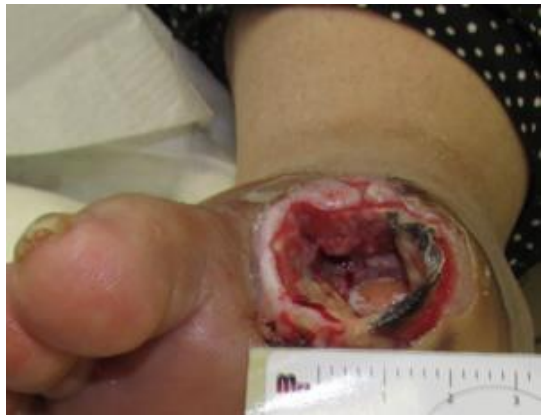
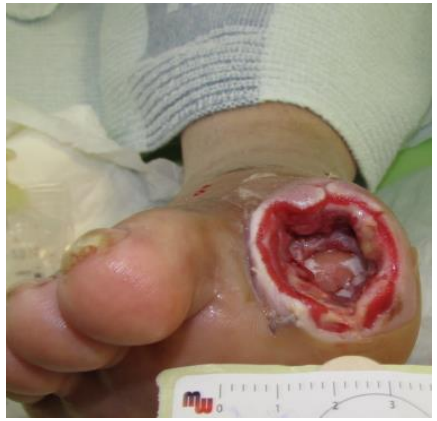
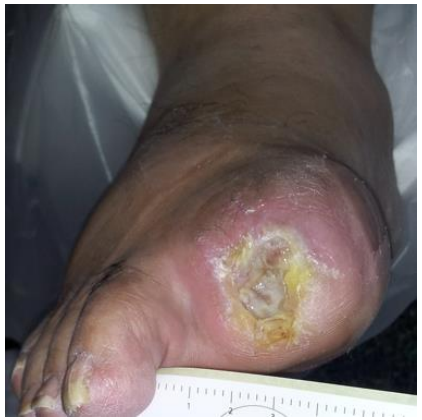
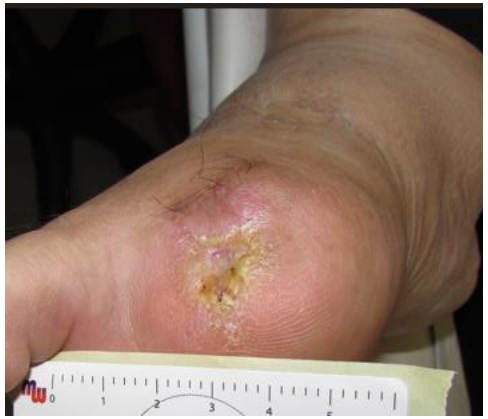
Patient: 70-year-old male
Clinical presentation: 9.0cm² metatarsal DFU(Wagner Grade 1)
Treatment: Debridement with BBD; spontaneous wound closure

Baseline	Post 3rd Tx	Week 3	Week 6	2M follow up
				

Treatment timeline

Case Study 2

Patient: 49-year-old female
Clinical presentation: 6.0cm² DFU(Wagner Grade 2)on the large toe, following amputation
Treatment: Debridement with BBD; spontaneous wound closure

Baseline	Post 1st Tx	Post 4th Tx	Week 8	3M follow up
				

Treatment timeline

Phase 2 Trial

STUDY OBJECTIVES

Assess safety and efficacy of BBD compared to placebo in DFU patients

STUDY DESIGN

A multicenter, prospective, randomized, double blind, adaptive design study in DFU patients

Two arms: BBD vs. placebo, 1:1 ratio

Sample size: 50 DFU patients

Study design:

- Up to 8 applications over 2 weeks, followed by 12 weeks of standardized wound management
- Advanced wound closure (CTP/ Autograft) for patients reaching WBP
- 3-month patient follow-up

Collaborations:
Convatec, Coloplast, B Braun, Medline

ENDPOINTS

Primary:

Time to complete debridement

Secondary:

Incidence of complete debridement

Incidence of complete healthy granulation tissue

Time to wound bed prepared

Exploratory:

Incidence of complete wound closure

Time to complete wound closure

Safety:

Safety & tolerability

Wound infection rates

Thank you!