EscharEx® for DFU

Post-hoc analyses from phase 2 (MW2013) and planned clinical study

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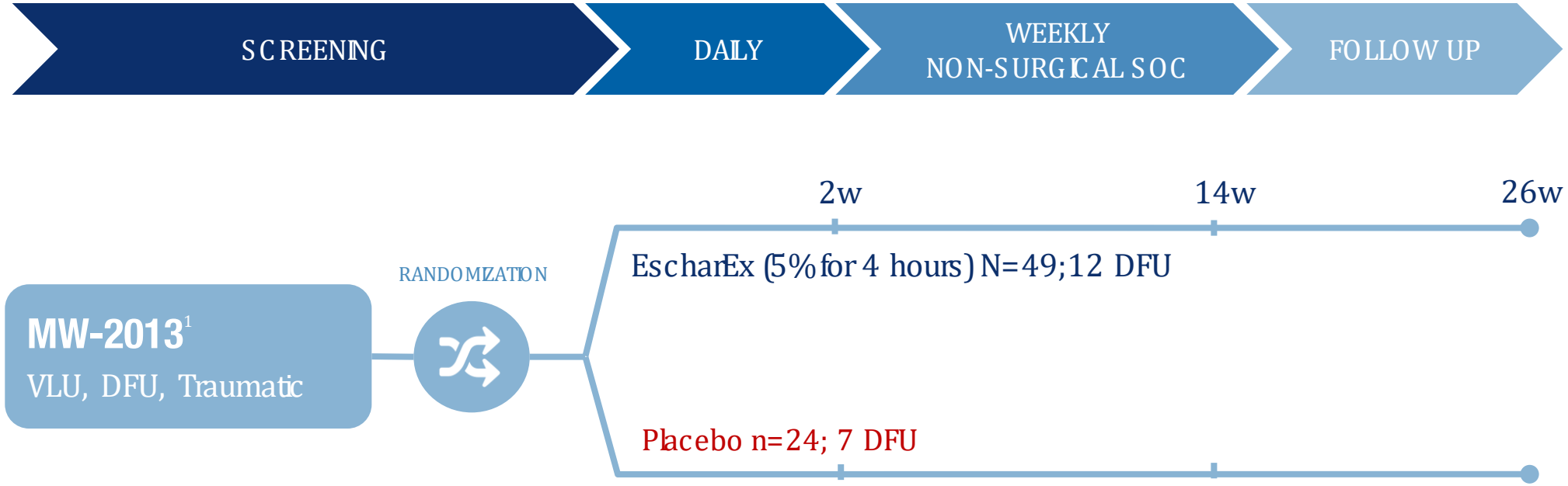
MW2013 Study Design



1.Shoham et al. 2021; Wound Rep Reg

Key Eligibility Criteria

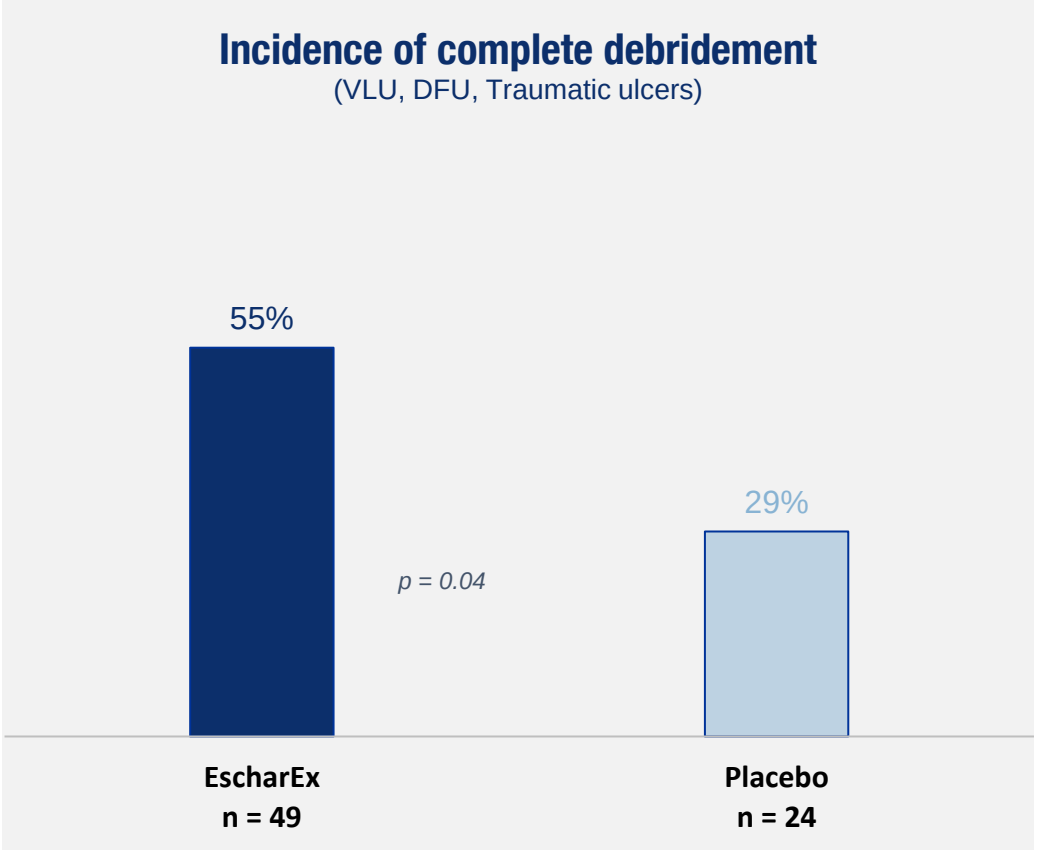
Key inclusion criteria

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]: EscharEx® Effective in Both VLU and DFU



Results

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

1. Shoham et al. 2021; Wound Rep Reg

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

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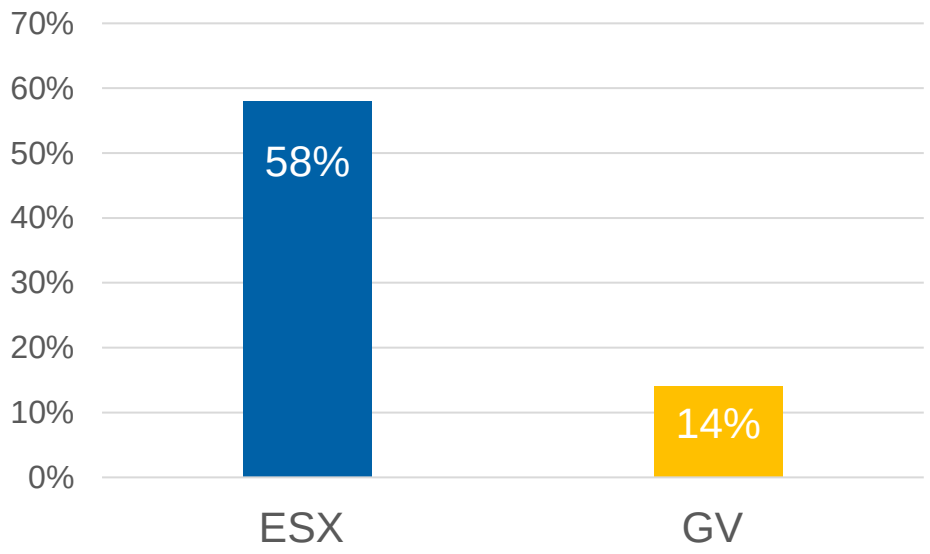
Demographics and Baseline Wound Characteristics

	EscharEx (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)

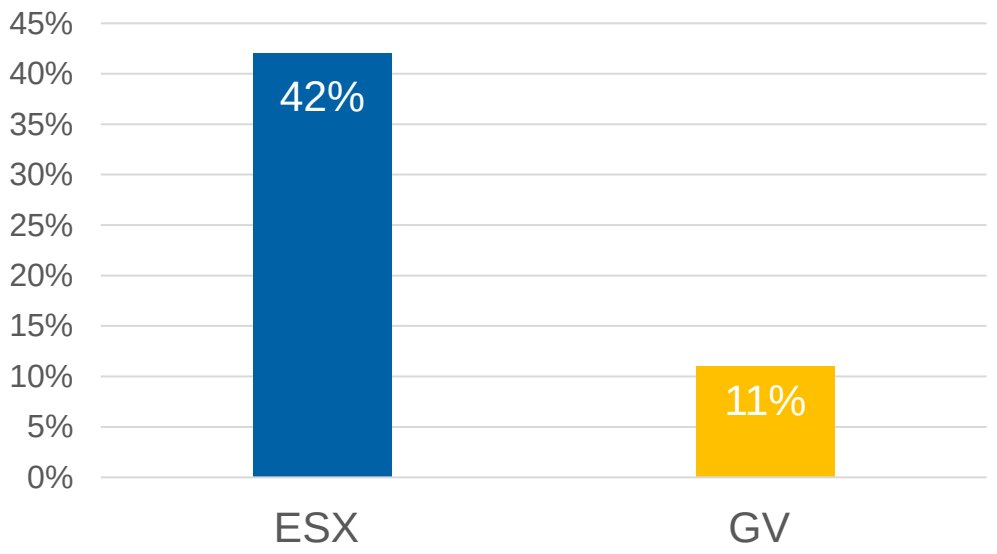
DFU wounds treated with GV had comparable size to those treated with EscharEx, but longer duration, and higher percentage of Wagner grade ≥2 and ischemic wounds

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

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

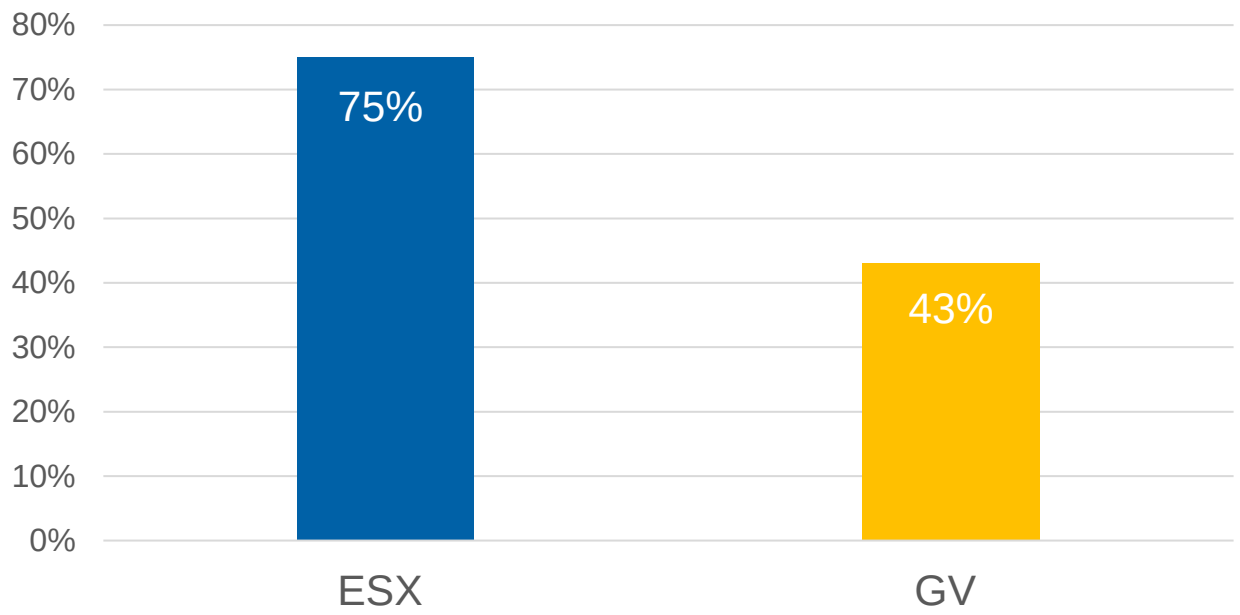


75%-100% Granulation in up to 2 weeks



This subgroup analysis was not powered to detect statistically significant differences

Wound Bed Prepared Achieved During Study

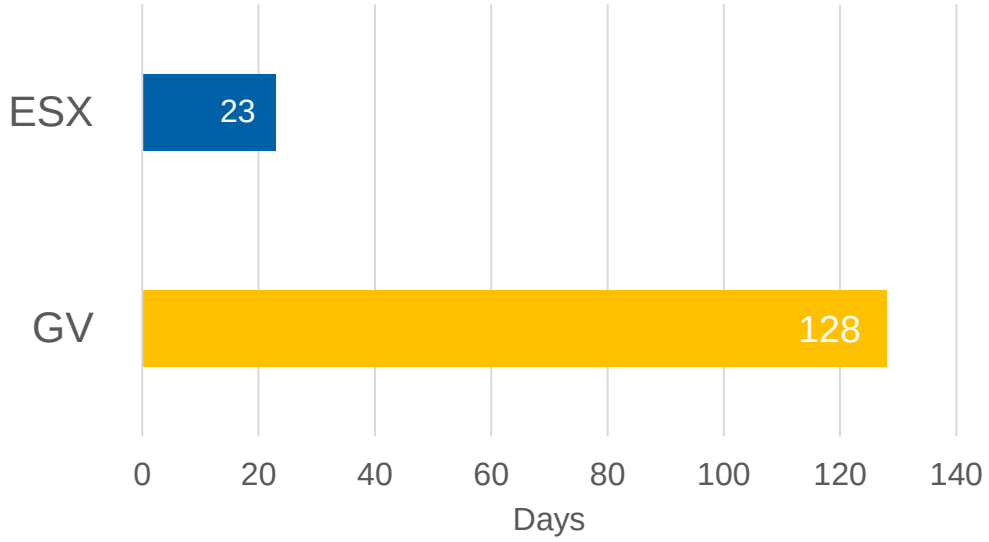


Wound bed preparation (WBP) - defined as 100% removal of non-viable tissue with 75% - 100% granulation

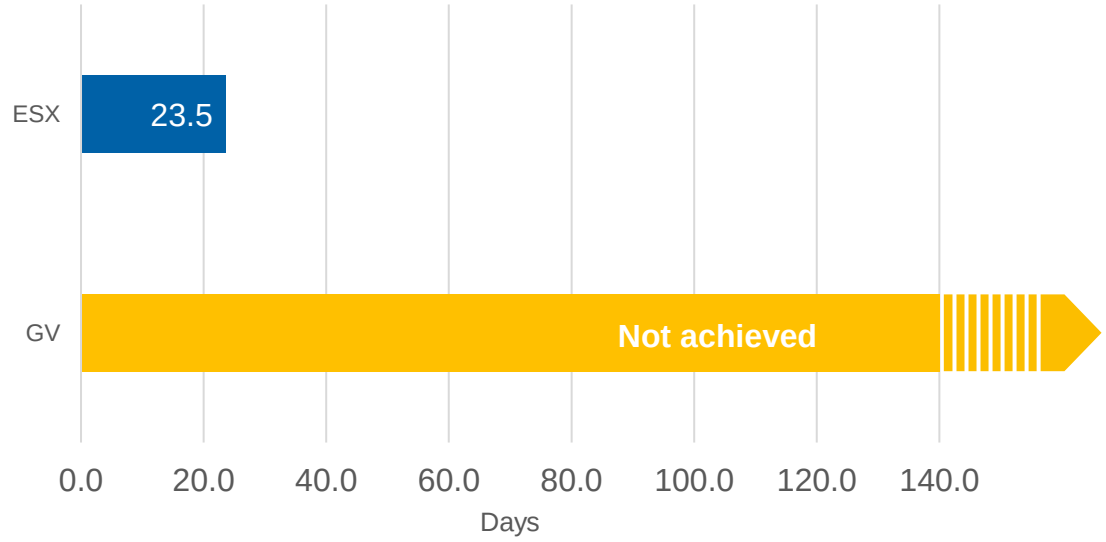
This subgroup analysis was not powered to detect statistically significant differences

Time to Complete Debridement and Time to WBP

Median Time to Complete Debridement



Median Time to WBP



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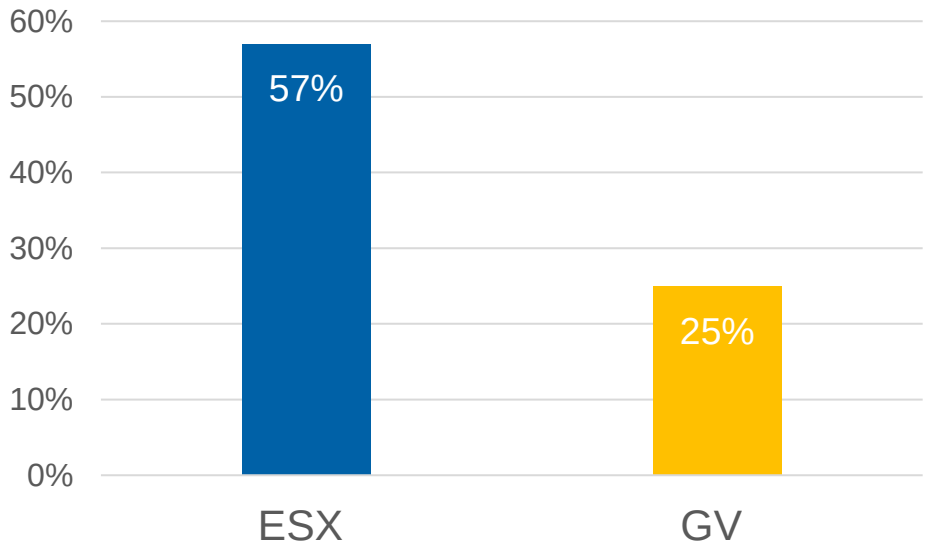
Wound Closure



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

EscharEx for DFU

Clinical Study Design

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Adaptive Clinical Study Design

Study Objectives:

Assess the safety and efficacy of EscharEx compared to Gel Vehicle (placebo control) in DFU patients

Study Design

- A multicenter, prospective, randomized, double blind**,** adaptive designed study for treatment of DFUs
- Study arms: ESX vs. Gel Vehicle vs. SOC
- Pre-defined interim assessment for sample size reassessment
- Screening: period: 2 weeks (30% reduction in wound size excluded)
- Treatment period: up to 8 daily applications within 2 weeks
- Follow up: 14 weeks
- Design: Mandatory cover with CTP if WBP (complete debridement + complete granulation)
- Mandatory off-loading

Endpoints

Primary endpoint

Incidence of complete debridement within 2 weeks

Secondary efficacy and safety endpoints

- Complete granulation, wound bed prepared, wound closure
- Safety and tolerability

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Thank you!

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