

LIMB SALVAGE OF DFUs USING ON101 TOPICAL CREAM: REAL-WORLD EVIDENCE

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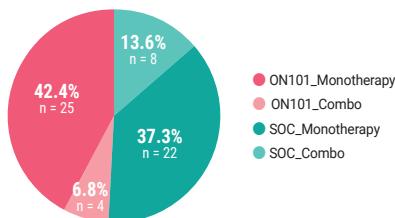
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INTRODUCTION

Diabetic foot ulcers (DFUs) are a serious and frequent complication of diabetes, particularly in patients with poor glycemic control, foot deformities, and infection. Infected DFUs (Wagner Grade 1–3) are notoriously difficult to manage and carry a high risk of amputation. ON101 is a topical medical device developed to support the wound healing process in clinical settings. This prospective real-world study evaluated ON101's effectiveness in limb salvage and wound healing among high-risk patients with infected diabetic foot ulcers (iDFUs).

METHODS

- Study Type: Prospective observational study
- Population: 59 patients with IDSA Grade 2 infected DFUs
- Treatment Groups:



Baseline Conditions	ON101	SOC
Mean HbA _{1c}	9.8%	11%
Mean ulcer size	30 cm ²	23 cm ²
Wagner grade 1; 2; 3	2; 13; 14	1; 28; 1
Ulcers located on plantar surface	18	23

Treatment Duration: Up to 16 weeks

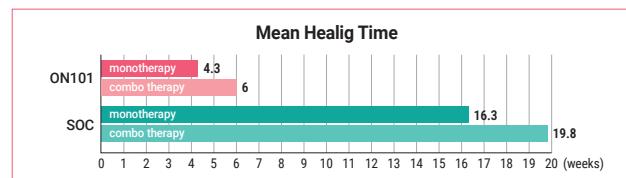
Concomitant Management: Etiology-specific interventions (e.g., vascular support, offloading)

EXECUTIVE SUMMARY

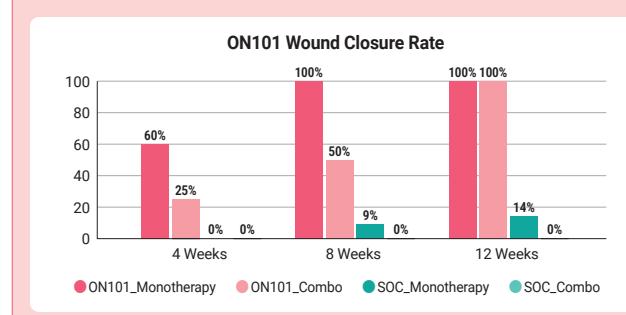
This RWE study confirms that ON101 topical cream is an effective treatment option for high-risk iDFUs, both alone and as part of a combined advanced wound care strategy, as it:

- Enhances granulation and epithelialization
- Reduces amputation risk
- Lowers overall clinical burden and treatment time

These real-world results reinforce ON101's value as a critical addition to the DFU treatment algorithm.



RESULT



Case Example (ON101_Monotherapy)



- Age: 39, Male
- Diabetes Duration: 3 months
- Ulcer Size: 24 cm²
- HbA_{1c}: 10.4 → 7.1
- Wagner (Prior ON101): 3
- IDSA (Upon ON101): 2
- Tube Consumption: 2 tubes

Healed in 7 Weeks

- Product Usage: <2 tubes per patient (avg.)
- Combo Group: In complex cases (e.g., tendon/bone exposure), ON101 + NPWT optimized the wound bed for grafting or closure within 2–3 weeks, reducing hospitalization needs
- Safety: No AE reported

ON101 reduced
amputation rate by
36.7%

Reduced
re-admission rate by
86.7%