

# EFFICACY AND SAFETY OF ON101 TOPICAL CREAM FOR DIABETIC FOOT ULCERS: A MULTINATIONAL CENTERS REAL-WORLD STUDY ON LIMB SALVAGE & FAST HEALING

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## + INTRODUCTION

Diabetic foot ulcers (DFUs) are among the most serious complications of diabetes, often associated with delayed healing, infection, high rate of limb loss, and frequent hospital re-admissions. ON101 is a topical medical device formulated to support wound healing by promoting fast painless tissue healing process in a adequate wound environment. This multinational, real-world study assessed ON101's clinical effectiveness, safety and lower morbidity and frequency of hospital re-admissions across diverse healthcare settings in the United States, India, and Egypt.

## + METHODS

- ▶ **Design:** Retrospective single-arm observational study
- ▶ **Population:** 42 patients with chronic DFUs
- ▶ **Sites:** 6 clinics across USA, India, and Egypt
- ▶ **Treatment:**
  - ON101 applied twice daily for up to 16 weeks
  - Etiological factors managed concomitantly (e.g., offloading, debridement, glycemic control)
- ▶ **Outcome Metrics:**
  - Pain level
  - Erythema
  - Wound morphology and exudate changes
  - Patient-reported quality of life

## + EXECUTIVE SUMMARY

This multinational real-world study confirms that ON101 has broad effectiveness even in difficult to manage subgroups (e.g., patients with high HbA<sub>1c</sub>, large ulcers or plantar ulcers, etc.), with the following positive results:

- **Reduced healing time up to 62%**
- **Reduced more than 50% of clinic visits per week**
- **Home care and easy to use**
- **Robust clinical outcome in various clinical setting**

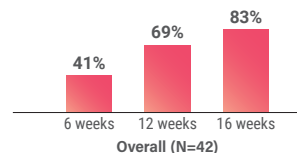


- Age & Sex: 43, Male
- Ulcer Duration: 5 years
- Ulcer Size: 20 cm<sup>2</sup>
- Wagner (Upon Starting ON101): 2
- IDSA (Upon Starting ON101): 2
- Tube Consumption: 1 Tubes

**Healed in 5 Weeks**

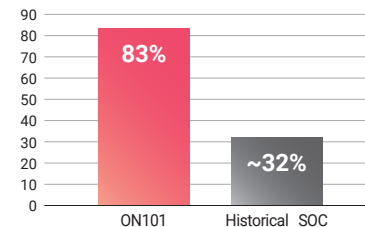
## Multinational Clinical Outcomes (Us, Egypt And India)

42 DFU subjects - completed and data verified demonstrating consistent clinical efficacy in 6 to 16 weeks regardless of the ulcer locations.



Country	Healing Time	Clinic Visits	Visit Frequency
USA	2~16 weeks	2~16 visits	1/wk
India	2~13 weeks	1~4 visits	1/2-3 wks
Egypt	2~14 weeks	1~7 visits	1/2 wks

### Complete Healing at 16 Weeks



	ON101	Historical SOC	P-Value
Complete Healing at 16 Weeks	83% (35/42)	~32%	p < 0.0001
Median Healing Time	48 days	~78 days	-
Safety	0 AE / 0 re-admissions	-	-

## + CONCLUSION

ON101 demonstrated high healing rates, faster wound resolution, and excellent safety in the treatment of DFUs across varied healthcare settings. The reduced number of clinic visits highlight ON101's clinical and economic value. These findings support ON101 as a promising global option for DFU management and re-admission prevention.