

Results from the International Multicenter Randomized Controlled Trial on 119 Hard-to-Heal Diabetic Foot Ulcer Patients Comparing ActiGraft^{PRO} to Standard of Care

Study Objectives

Primary Objective

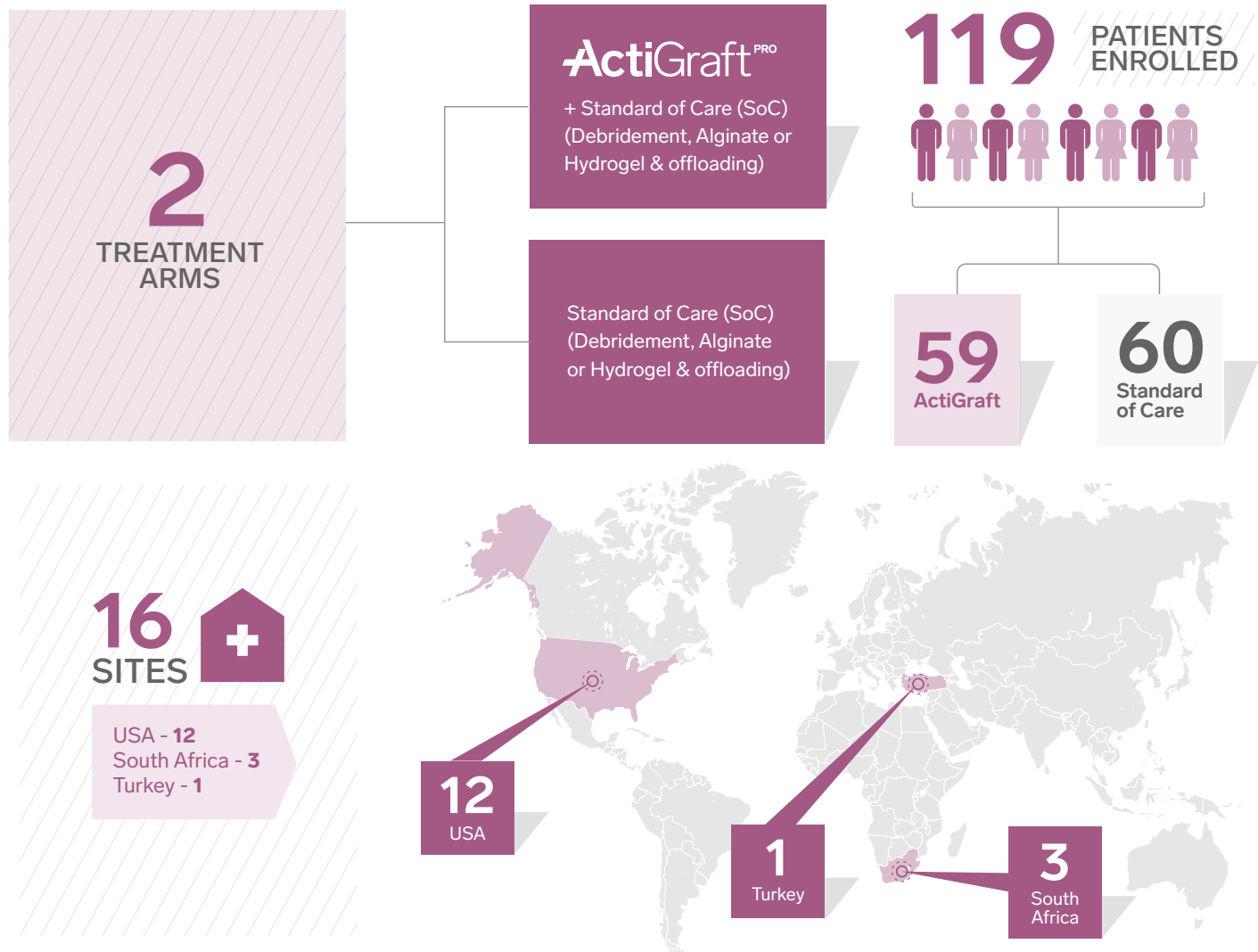
1 Complete Wound Closure by 12 weeks

Secondary Objective

2

- Time to complete wound closure
- Percent area reduction at 4 and 8 weeks
- ActiGraft^{PRO} safety analysis
- Durability assessment of healed wounds up to 12 weeks

Study Design



Study Design

2 week run-in period



Only hard-to-heal wounds, with less than **30%** reduction in wound size, were randomized into the study.

Blinded assessment of healing

- Blinded assessment.
- eKare® device used to automatically measure the wound size.

Major inclusion criteria:

- 1 Chronic DFUs in adults, duration **>30 days**
- 2 Wound size 1-28 cm² (post debridement)
- 3 **Ulcer free** of infection.
- 4 **HbA1c ≤ 12.0%**

Major exclusion criteria:

- 1 Presence of underlying Osteomyelitis.
- 2 Active Charcoat.
- 3 Known coagulation problems. Patients taking anticoagulants, weren't excluded.

Results (PP)

183% more patients healed in the intervention arm compared to standard of care using Per Protocol (PP) population, **giving odds ratio of 2.83.**

Complete Wound Closure (PP)



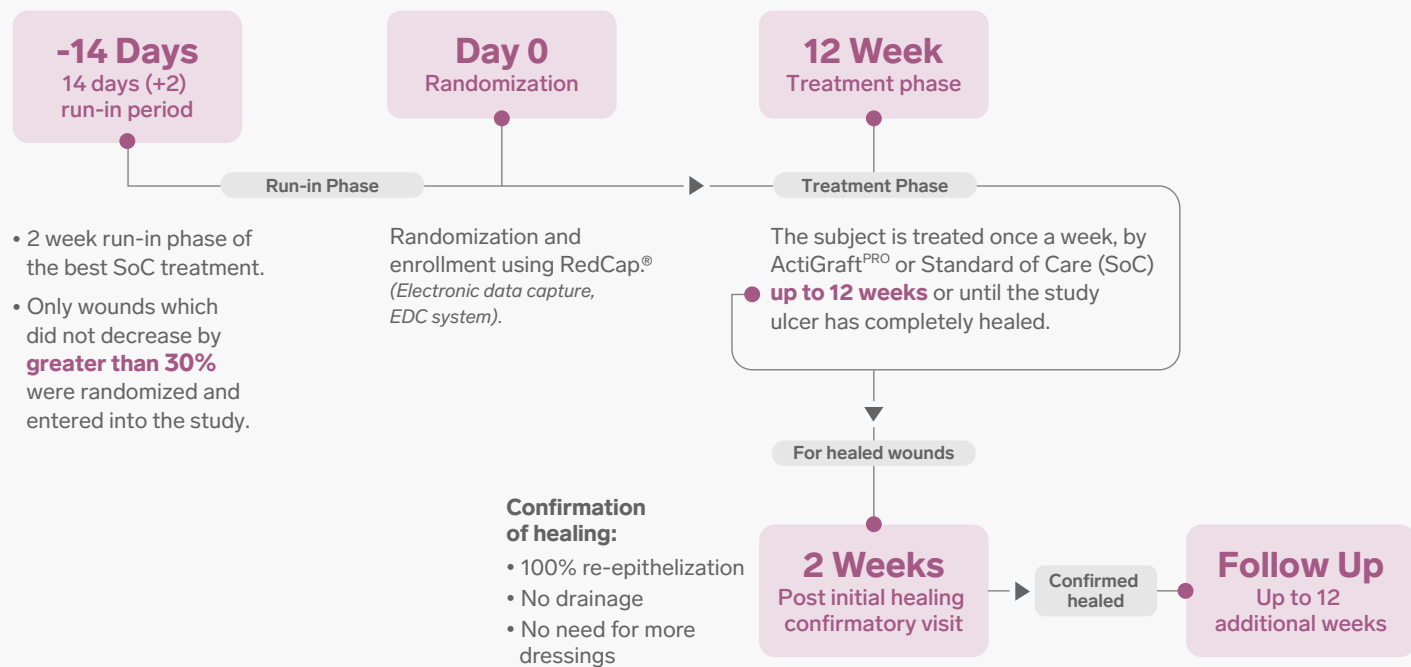
ActiGraft^{PRO}
Arm Healed

2.83x

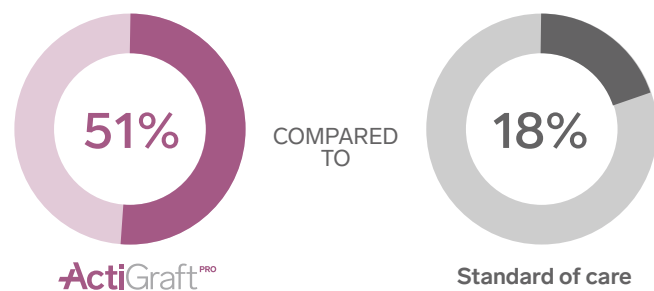
More wounds than standard of care,
with **faster and more**
durable healing outcomes

Per Protocol (PP)

Enrollment Timeline

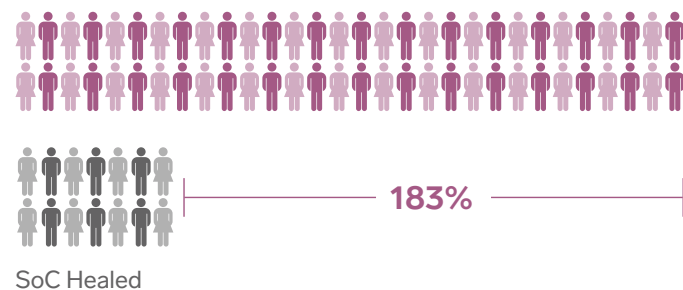


Complete healing rate by 12 weeks
Per Protocol (PP) Population P=0.0075

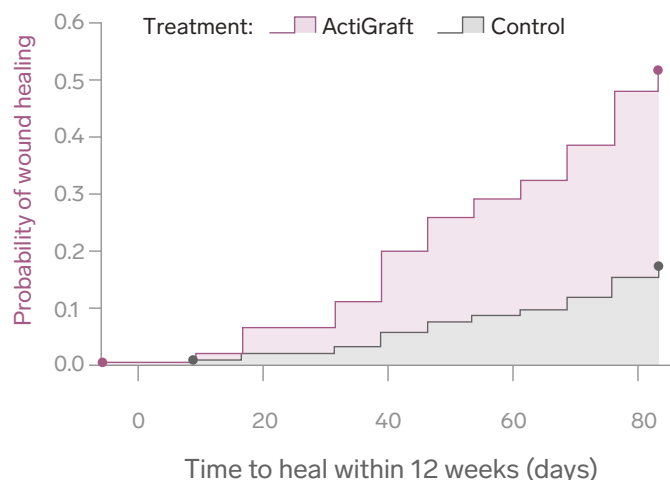


Complete Wound Closure (PP)

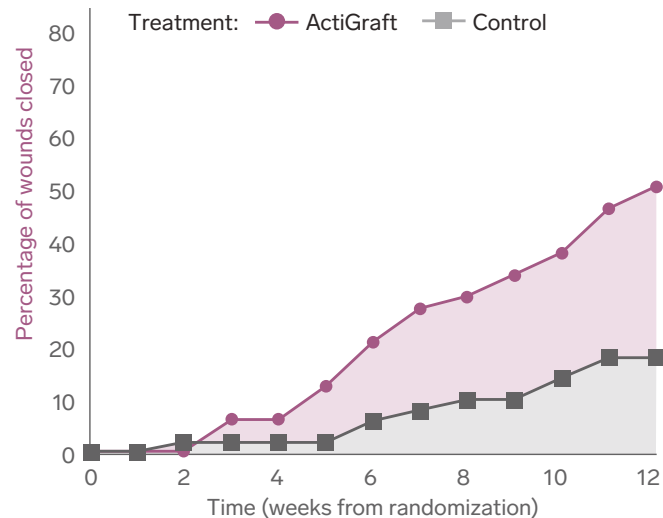
ActiGraft^{PRO} Healed



Complete Healing Rates - Kaplan Meier Plot (PP)



Weekly Percentage of Wounds Closed (PP)



Notable Results



Greater healing durability in the ActiGraft^{PRO} arm

71% of ActiGraft^{PRO} healed wounds remained closed **vs. 55%** with standard care, demonstrating better long-term healing durability.



No wound age limit - older wounds included

27% of treated wounds were over a year old, showing ActiGraft^{PRO}'s effectiveness on chronic wounds.



Potential greater healing rate with additional ActiGraft^{PRO} applications

An additional **12%** of wounds might heal with extended ActiGraft^{PRO} treatment beyond the standard 12 weeks.



Large wounds treated, with bigger ones in the ActiGraft^{PRO} arm

ActiGraft^{PRO} arm included larger wounds, **5.3 cm² vs. 4.6 cm²** in standard care arm.



Positive Safety Outcomes

No differences in wound related or serious adverse events between arms; no device-related adverse events.



Shorter healing time with ActiGraft^{PRO}

Chronic wounds of an average of 78.8 weeks, healed in an average of **10 weeks** post ActiGraft^{PRO} application.

Outcomes	ActiGraft ^{PRO} (N=59)	Control (N=60)
ActiGraft ^{PRO} demonstrated better healing durability, with wounds remaining healed for additional 3 months after the initial healing	71%	55%
ActiGraft ^{PRO} had a better outcome in patients with history of minor amputation at the wound site	60%	25%
Debridements needed	7	9

Reference: Snyder R, Nouvong A, Ulloa J, et al. Efficacy and safety of autologous whole blood clot in diabetic foot ulcers: a randomized controlled trial. Journal of Wound Care. 2024; Published Online: 30 Aug 2024. <https://doi.org/10.12968/jowc.2024.0195>



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