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

2 TREATMENT ARMS

ActiGraft[PRO] + Standard of Care (SoC) (Debridement, Alginate or Hydrogel & offloading)

Standard of Care (SoC) (Debridement, Alginate or Hydrogel & offloading)

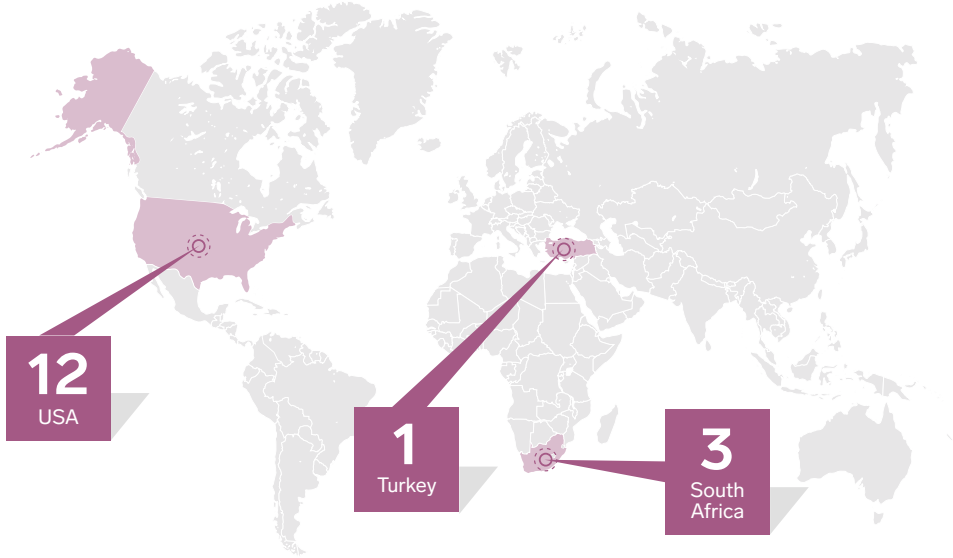
119 PATIENTS ENROLLED

59 ActiGraft

60 Standard of Care

16 SITES

USA - **12**
South Africa - **3**
Turkey - **1**



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 cm^2 (post debridement)
3. **Ulcer free** of infection.
4. **HbA1c ≤ 12.0%**

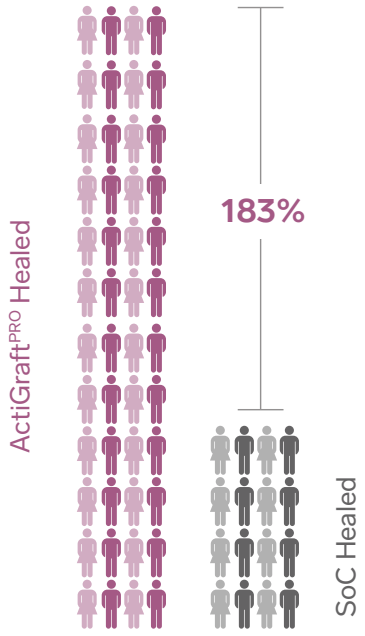
Major exclusion criteria:

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

-14 Days
14 days (+2) run-in period

Day 0
Randomization

12 Week
Treatment phase

Run-in Phase

Treatment Phase

- 2 week run-in phase of the best SoC treatment.
- Only wounds which did not decrease by **greater than 30%** were randomized and entered into the study.

Randomization and enrollment using RedCap.® *(Electronic data capture, EDC system).*

The subject is treated once a week, by ActiGraft[PRO] or Standard of Care (SoC) **up to 12 weeks** or until the study ulcer has completely healed.

For healed wounds

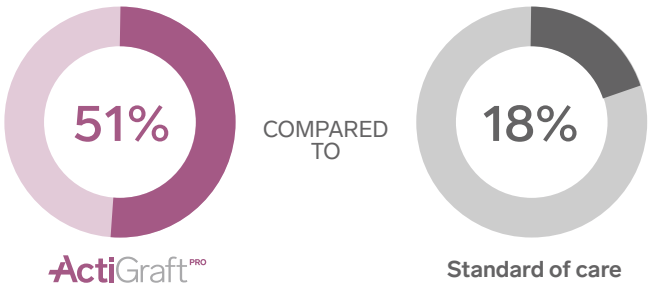
Confirmation of healing:
- 100% re-epithelization
- No drainage
- No need for more dressings

2 Weeks
Post initial healing confirmatory visit

Confirmed healed

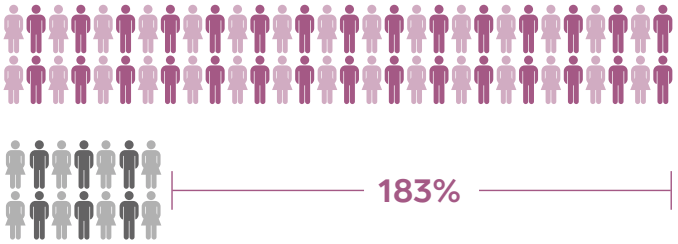
Follow Up
Up to 12 additional weeks

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



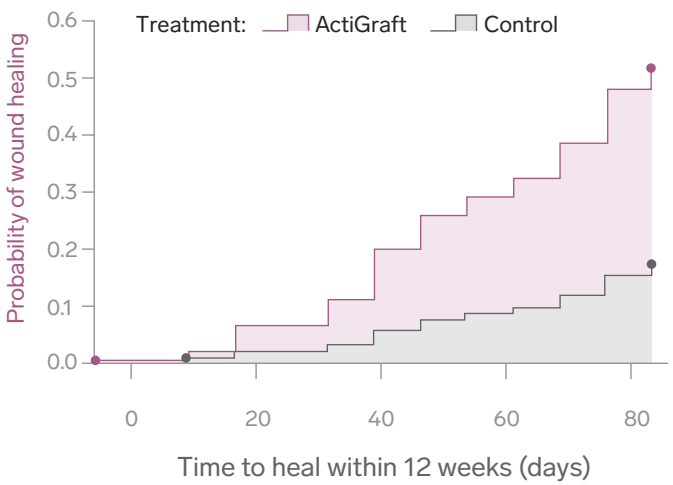
Complete Wound Closure (PP)

ActiGraft[PRO] Healed

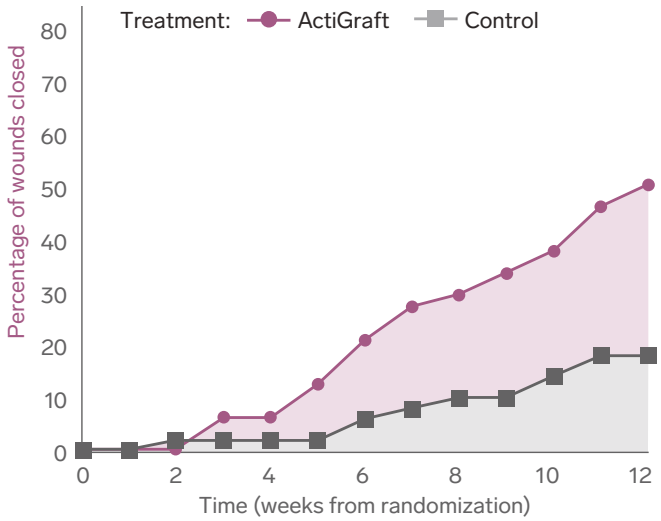


SoC Healed

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.

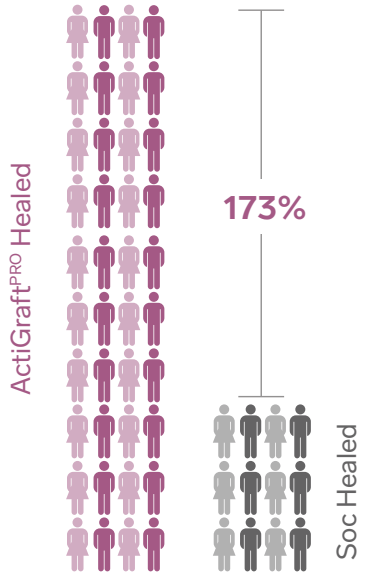
Outcomes	ActiGraft^{PRO} (N=59)	Control (N=60)
ActiGraft^{PRO} demonstrated better healing durability, with wounds remaining healed for additional 3 months after the initial healing	71%	55%
ActiGraft^{PRO} had a better outcome in patients with history of minor amputation at the wound site	60%	25%
Debridements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

Results (ITT)

173% more patients healed in the intervention arm compared to standard of care using Intent to treat (ITT) population, **giving ratio of 2.73**.

Complete Wound Closure (ITT)



ActiGraft PRO

Arm Healed

2.73x

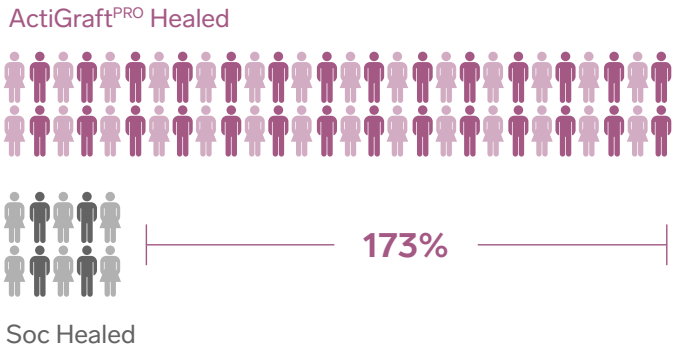
More wounds than standard of care, with **faster and more durable** healing outcomes

Intent to treat (ITT)

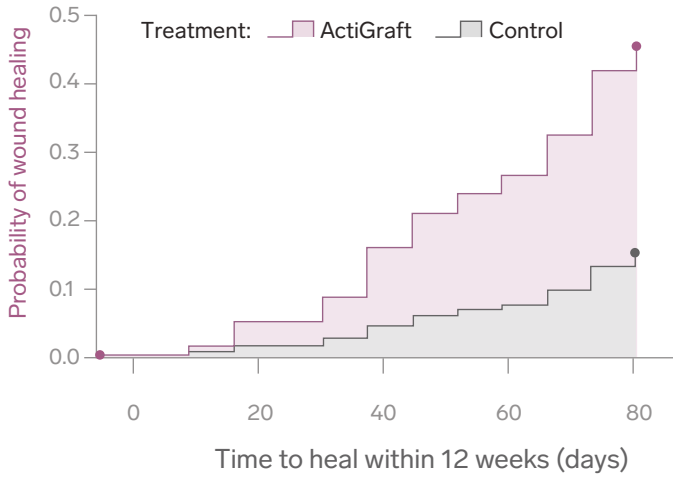
Complete healing rate by 12 weeks

Intent to treat (ITT) Population P=0.002

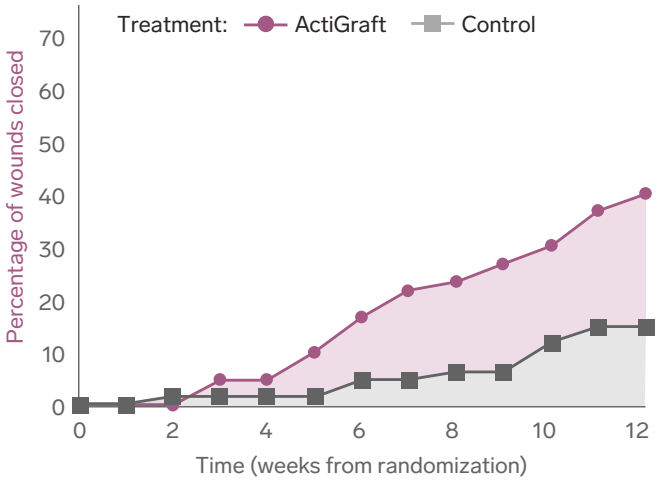
Complete Wound Closure (ITT)



Complete Healing Rates - Kaplan Meier Plot (ITT)



Weekly Percentage of Wounds Closed (ITT)



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

LEGACY MEDICAL CONSULTANTS

Order and Customer Support

Phone: (817) 961-1288 | Fax: (866) 300-0431
www.legacymedicalconsultants.com
customerservice@legacymedicalconsultants.com

25-ACT-0019-rev1 12/25