ARTICLE SUMMARY

Intact Fish Skin Graft to Treat Deep Diabetic Foot Ulcers: The Odinn Trial

Dardari D, Piaggesi A, Potier L, Sultan A, Diener H, Francois M, Dorweiler B, Bouillet B, M'Bemba J, Chaillous L, Clerici G, Kessler L, Wetzel-Roth W, Storck M, Davidsson OB, Baldursson B, Kjartansson H, Lantis JC, Charpentier G. Intact Fish Skin Graft to Treat Deep Diabetic Foot Ulcers. NEJM Evid. 2024 Oct 4:EVIDoa2400171. doi: 10.1056/EVIDoa2400171. Epub ahead of print. PMID: 39365895.

Largest RCT on DFUs with Exposed Bone or Tendon

The Odinn Trial is a landmark randomized controlled trial (RCT) focused exclusively on UT grade 2 and 3 DFUs -- wounds with exposed bone or tendon. It compared standard of care (SOC) to intact fish skin graft (IFSG), and involved 255 patients across 15 centers and 4 countries. The scale and focus of this trial provides unprecedented insights into the management of these complex wounds, offering clinicians and patients a new level of evidence in an area where it had been lacking. By specifically targeting these severe ulcers, the study addresses a critical unmet need in diabetic foot care.

Primary Endpoint

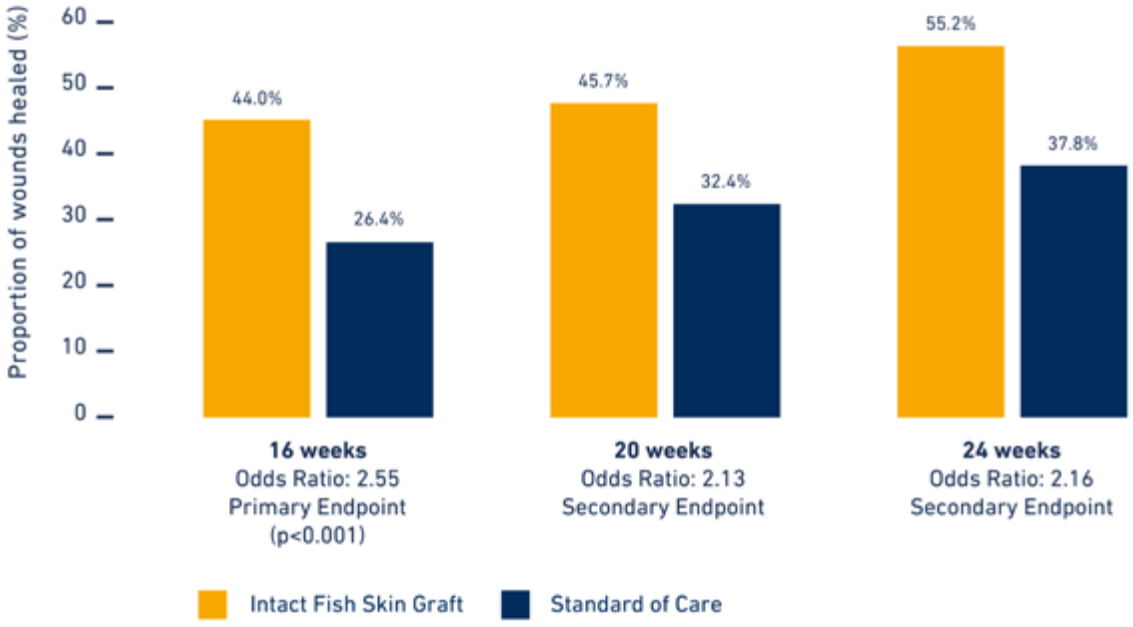
Patients treated with fish skin grafts demonstrated a **1.6 times greater** chance of healing at any given timepoint and healed close to two weeks earlier. These results represent a marked improvement over current standard of care, offering new hope for patients with these difficult to treat ulcers, and potentially reduce the risk of severe complications associated with prolonged ulceration.

The clinical improvements shown in the Odinn Trial are significant. At 16 weeks, **44.0%** of wounds treated with fish skin grafts had healed, compared to only 26.4% with standard of care ($p<0.001$).

66%

more relative wounds healed at week 16

Proportion of Wound Closure: IFSG vs. SOC



Learn More

Wounds in this study

UT Grade 2

UT Grade3

DFUs classified as University of Texas (UT) grades 2 and 3 are some of the most challenging wounds to treat, and are associated with higher rates of infection, delayed healing, and increased risk of amputation. The increased risk associated with grade 2 and 3 diabetic foot ulcers stems from their depth and complexity.[1]

The stakes are high for patients with UT grade 2 and 3 ulcers

- Up to 80% increased risk of amputation.[3]
- 5-year mortality rates of up to 45%.[5]
- Higher risk of infection.[2]
- Increased healthcare costs per patient.[4]

Increased Depth and Complexity creates

- Penetration down through the dermis and subcutaneous tissue.
- Depth creates an environment ripe for bacterial growth.
- Exposed structures with low blood flow have a limited capability for fighting infection.
- Granulation tissue needs to migrate over exposed structures.

> **"The Odinn Trial represents true level 1 evidence that advanced therapeutics such as intact fish skin grafts make a difference in the real world of deep and complex diabetic foot wounds**
>
> Dr. John Lantis, MD, Site Chief of Surgery at the Mount Sinai West Hospital, and study co-author

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