

A Prospective, Postmarket, Compassionate Clinical Evaluation of a Novel Fish-skin Graft Which contains Omega-3 Fatty Acids for the Closure of Hard-to-heal Lower Extremity Chronic Ulcers

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Study: The primary objective was to assess the percentage of wound closure area from baseline after 5 weekly fish-skin graft applications in 18 patients with at least 1 “hard-to-heal” criteria.

KEY POINTS:

- The 20 subjects in this study had full-thickness ulcers that were either $> 20 \text{ cm}^2$ or had been present for at least 52 weeks, both factors defined as markers of hard-to-heal wounds.
- Exclusion criteria consisted of patients undergoing chemotherapy, being treated with immunosuppressive drugs or corticosteroids, or were previously evaluated for treatment.
- Over a 5-week period, 5 weekly applications of the product and secondary dressings resulted in a 40% decrease in wound surface area.

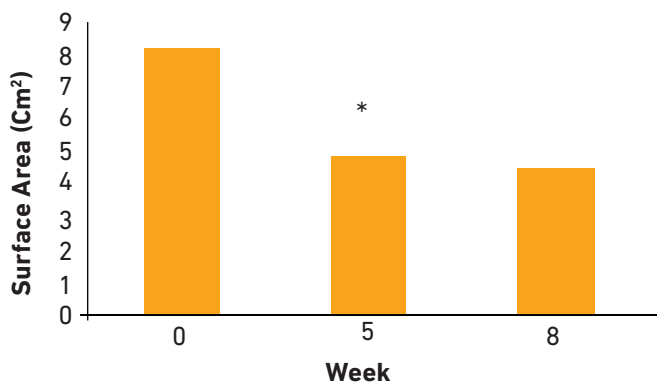


Figure 1: Wound surface area. A 40% decrease in wound surface area was seen in week 5; * $P < 0.05$.

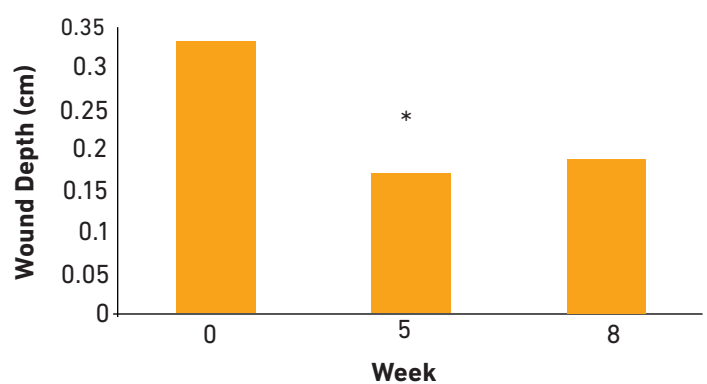


Figure 2: Wound depth. A 48% decrease in wound depth was seen in week 5; * $P < 0.05$.

Representative wounds from study

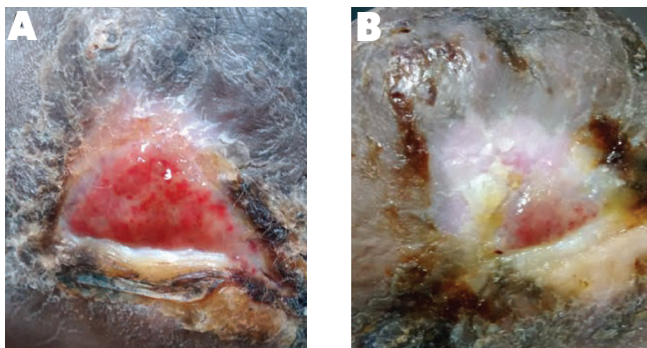


Figure 3.

Ulcer at (A) week 0 and (B) week 5 following weekly application and secondary wound dressing.

Method: The primary objective was to assess the percentage of wound closure area from baseline after 5 weekly fish-skin graft applications in 18 patients with at least 1 “hard-to-heal” criteria. Patients underwent application of the fish skin for 5 sequential weeks, followed by 3 weeks of standard of care. Wound area, skin assessments, and pain were assessed weekly. Wound demographics are shown in the table.

Table 1. Demographics and etiology of study participants.

Patient ID	Gender	Age (years)	Wound Age (months)	Initial Wound Size (cm ²)	Etiology	Comorbidities
1	Male	63	126	13.0	V	Tobacco
2	Male	59	34	4.2	V, DM	HTN, tobacco
3	Male	31	8	1.5	DM	Tobacco
4	Male	49	5	14.7	DM	HIV, CKD, HTN
5	Male	59	6	1.8	DM	HTN
6	Male	65	102	25.5	V	CKD, HCV
7	Female	84	54	20.4	V	HTN
8	Male	53	23	2.6	DM	Tobacco
9	Male	70	42	2.2	V, DM, PAD	HTN, tobacco
10	Male	38	38	11.4	DM	CKD, DM
11	Male	49	7	6.7	DM, PAD	CKD, HTN
12	Female	67	40	4.2	V, DM	
13	Female	35	46	8.9	DM	CKD, HTN
14	Female	64	13	7.8	DM	CKD, HTN
15	Male	63	34	7.0	V	HTN, HCV, tobacco
16	Male	62	43	7.8	V	HTN, tobacco
17	Male	39	10	1.8	DM	CKD, HTN
18	Male	47	3	6.0	DM	CKD, HTN, tobacco

V: venous; PAD: peripheral artery disease; HTN: hypertension; DM: diabetes mellitus; HCV: hepatitis C virus; HIV: human immunodeficiency virus; CKD: chronic kidney disease

Results: A 40% decrease in wound surface area ($P < 0.05$) and a 48% decrease in wound depth was seen with 5 weekly applications of the fish-skin graft and secondary dressing ($P < 0.05$).

Conclusion. This fish-skin product appears to provide promise as an effective wound closing adjunctive. This is true when used in this compassionate setting, where many other products fail.



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