Intact Fish Skin Compared to Human Amnion/Chorion Membrane Allograft: A Double-Blind, Prospective, Randomized, Clinical Trial of Acute Wound Healing

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Introduction
Chronic non-healing wounds are a major public health problem associated with high morbidity and major economic costs. Grafting is commonly used in these wounds to speed up the healing process.

Kerecis Omega3 Wound is Icelandic fish skin that is a natural microbial barrier homologous to human skin and used for tissue regeneration. Because there is no viral or prion transfer risk from Atlantic cod, the source material, we can process it gently for medical use and maintain the natural structure and indigenous elements of the skin. When grafted onto damaged human tissue such as a burn or a diabetic wound, it recruits the body’s own cells ultimately regenerating the tissue.

Aim
Our aim was to compare the time to healing of full thickness wounds on human volunteers, using a 4mm punch biopsy model to create standardized wounds. The wounds were treated with either Kerecis® Omega3 Wound: intact fish skin or Epifix®: dehydrated amnion/chorion membrane allograft (dHACM).

Methods
In this prospective, double-blind, randomized, comparative, clinical trial, participants acted as their own control with one forearm wound randomized received fish skin and a second wound on the same forearm received dHACM. The wounds were full thickness 4-mm standard punch biopsy wounds. Two physicians conducted the study; The trial physician that applied the products and the evaluating physician that assessed the wounds and was blinded to the treatment. Wounds were followed on day 7, 14, 18, 21, 25 and 28 and evaluated for wound closure and adverse events. A mixed-effects Cox-Proportional Hazard model was used to assess the primary endpoint.

Results
The study found that the fish-skin cohort both promoted faster wound healing and had more wounds brought to full closure in 28 days. Fish skin cohort healed significantly faster healing with a significant hazard ratio of 2.34 and a p-value of 0.0014. DHACM treated wounds were 76% more expensive compared to fish skin treated wounds on average in this study.

Conclusions
In this double blinded, healthy, cohort study, more wounds treated with fish skin grafts healed in 28 days and the wounds healed significantly faster than wounds treated with amnion membrane. Amnion-membrane products have enjoyed increased clinical adoption in recent years although comparative evidence for their efficacy has been scarce. Double-blind comparative studies such as these can help health care practitioners better select the most efficacious treatment for their patients.

This study was funded by the Icelandic Technical Development Fund.