Clinical Trial Finds Kerecis Omega3 Fish Skin Heals Wounds Significantly Faster Than Epifix

A double-blind, prospective, randomized clinical study found that wounds treated with Kerecis® Omega3 Wound healed significantly faster than wounds treated with EpiFix® from MiMedx®. The Kerecis product is made from intact fish skin; EpiFix is made from human amnion membrane. Kerecis will unveil detailed results of the study at the annual scientific meeting of the American Podiatric Medical Association (APMA) July 12-15 in Washington, D.C. (booth 741).

Dermal regeneration usually fails in full-thickness wounds, resulting in scar formation. The study design is established and validated for comparative dermal regeneration in full thickness tissue injury. Specifically, the study compared the length of time needed for 170 full-thickness wounds to heal, which was defined as "full epithelialization." Each of the 85 participants had two 4mm wounds where one wound was treated with the fish-skin product and the other with the human amnion membrane. The full-thickness wounds were evaluated at days 7, 14, 18, 21, 25 and 28.

Study Results

The study found that the fish-skin cohort both promoted faster wound healing and had more wounds brought to full healing in 28 days. The fish-skin cohort healed significantly faster with a significant hazard ratio of 2.34 and a p-value of 0.0014. By the end of the study, 10 percent more fish-skin-treated wounds had healed than amnion-membrane-treated wounds.

Specifically:

- Day 7: No wounds had closed.
- Day 14: 68 percent more fish-skin-treated wounds had closed than amnion-membrane-treated wounds.
- Day 18: 83 percent more fish-skin-treated wounds had closed than amnion-membrane-treated wounds.
- Day 21: 50 percent more fish-skin-treated wounds had closed than amnion-membrane-treated wounds.

- Day 25: 26 percent more fish-skin-treated wounds had closed than amnion-membrane-treated wounds.
- Day 28 (the final day of the trial): 10 percent more fish-skin-treated wounds had closed than amnion-membrane-treated wounds. At the end of the trial, 11 percent of wounds treated with the fish skin and 20 percent of wounds treated with amnion-membrane remained open.

"Amnion-membrane products have enjoyed increased clinical adoption in recent years," said Dr. John C. Lantis II (MD, FACS), Director of Clinical Research at Mt. Sinai St. Luke's and West Hospitals, one of the study investigators. "In this blinded, healthy, cohort study the acute wounds treated with fish-skin grafts healed faster than wounds treated with amnion membrane. We believe comparative studies such as these can help health care practitioners better select the most efficacious treatment for their patients."

The study was approved by the Icelandic Medicines Agency and the Icelandic National Bioethics Committee. The study was performed at Landspitali – the National University Hospital of Iceland and was sponsored by a grant from the Icelandic Technology Development Fund.

About the Kerecis Fish-skin-based Products

Kerecis Omega3 is intact fish skin that, when grafted onto damaged human tissue (such as a wound), recruits the body's own cells and ultimately is converted into living tissue.

The Kerecis fish-skin-based product helps wounds heal because of the structure of the fish skin and the presence of Omega3 polyunsaturated fatty acids. Because there is no risk of disease transmission, the fish skin needs only minimal processing. The result is that the fish skin is much more similar in structure to human skin than other skin substitutes are. Also, fish skin is rich in Omega3, which possesses multiple health benefits.

More than 50 studies have been performed to gauge the effectiveness of the Kerecis product. In an earlier in vitro study, 150 percent more cells migrated into the acellular fish skin than into the amnion membrane, suggesting a mechanism of action explaining the faster healing rates.

In another randomized, controlled human study on 162 wounds, those treated with Kerecis Omega3 acellular fish skin closed significantly faster than wounds treated with a porcine-tissue-based product. Up to twice as many wounds closed at the study time points.

The Kerecis Omega3 fish-skin product has been approved by the FDA and European regulatory authorities. The product is covered by Medicare in all 50 states and is widely covered through private insurers.

About Kerecis

Kerecis is the creator, manufacturer and patent holder of fish-skin-based therapeutic products that speed up the healing of human wounds and repair tissue damage.

The Kerecis wound-healing product is patented in the United States and multiple other countries. The products are available in the United States, Iceland, Germany, and several other European and Asian countries. In collaboration with the U.S. Department of Defense, Kerecis is adapting the product for use in battlefield conditions, where skin substitutes have traditionally not been used.

The Kerecis technology was invented by the company's founder and CEO, Fertram Sigurjonsson. The fish skin comes from wild cod, sustainably caught in pristine Icelandic waters. Production takes place in the Kerecis manufacturing facility in Iceland, which uses electric power generated from geothermal and hydroelectric energy. For more information, visit www.kerecis.com. Distributor inquiries are welcome.

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