



Clinical Trial Finds Keracis Omega3 Fish Skin Heals Wounds Significantly Faster Than EpiFix

Arlington, VA and Isafjordur, Iceland — A double-blind, prospective, randomized clinical study found that wounds treated with Keracis® Omega3 Wound healed significantly faster than wounds treated with EpiFix® from MiMedx®. The Keracis product is made from intact fish skin; EpiFix is made from human amnion membrane. Keracis 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 Landspítali – the National University Hospital of Iceland and was sponsored by a grant from the Icelandic Technology Development Fund.

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 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.

