

Non-Woven Matrix Surgical Mesh (SURGIMESH®) Demonstrates Key Fibrous Connective Tissue Healing Advantage Over Knitted, Woven and Expanded Surgical Mesh Technologies Based Upon Advanced Digital Histopathologic Analysis Techniques

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Currently available knitted and expanded Surgical Meshes used in hernia repair represent extremes in terms of mesh pore size and resulting healing properties. Knitted configurations have pores in the material that have been described as millimeter in size. This large size allows tissue to fall into the pores when the surgical site is closed at the end of a hernia repair. At the other end of the spectrum are expanded material configurations which possess pores sizes of less than 75 microns, a pore size that has been considered the lower limit for adequate tissue incorporation¹⁾. This situation can be described as one extreme which is “non-selective” in terms of tissue incorporation (knitted) and the other extreme which is “exclusionary” in terms of full tissue incorporation (expanded).

A tissue incorporation study using an established experimental hernia model²⁾ was performed to compare the morphology, quality and quantity of healed tissue within the plane of a Surgical Mesh. Square sections of a variety of current clinically used Surgical Meshes were implanted on the anterior surface of the rabbit abdominal wall and retrieved after 180 days. Standard histological thin section processing techniques were used and the thin sections stained with H&E. The histological thin sections were analyzed for morphology of tissue incorporation, quality of tissue formed and quantity of tissue formed within the plane of the mesh. The quality of tissue formed was assessed using a scale of none (0) to severe (5). The relative linear quantity of fibrous connective tissue and fat present between the fibers of a Surgical Mesh implant were measured digitally using an Aperio ScanScope CS System with a resolution of 0.5 microns/pixel and 100% reproducibility.

All Surgical Meshes yielded a minimal level of inflammatory response as expected for clinically used biocompatible synthetic meshes. The knitted meshes demonstrated a concentric mesh fiber inflammation and fibrosis with fat infiltrates between fibers presenting a discontinuity of fibrous response across the breadth of the mesh. In the case of non-woven and expanded configurations, a planar zone of inflammation and fibrosis either to the surface of the mesh in the case of the expanded configuration or throughout the plane of the mesh in the case of the non-woven was found. The expanded configuration lacked any cellular infiltration through the inner bulk of the mesh. The non-woven mesh demonstrated a continuous, laminar inflammation and fibrous connective tissue response throughout the bulk of the mesh and was highly exclusionary to fat penetration or formation.

Using the method outlined above, the relative amounts of fat to fibrous connective tissue was quantified and found to vary significantly by type of Surgical Mesh configuration. All knitted configurations were found to have fatty tissue levels that were 4.6 to 93.5 times greater than either non-woven or expanded configurations. The expanded configuration was found to have no fibrous connective tissue response within the thickness of the plane of the mesh. Only the non-woven configuration had complete fibrous connective tissue formation throughout the plane of the mesh with no to very minimal (< 0.2% on average) amounts of fat infiltration.

As knitted Surgical Mesh designs have become lighter weight with less synthetic material to address such P.O.

complications as discomfort, chronic pain, scarring reactions³⁾; their lighter weight has led to knitted central mesh mechanical failures and increased hernia recurrence³⁻⁵⁾. The discovery that knitted configurations allow significant portions of the interfiber spaces of a piece of mesh to be populated by non-reinforcing fat versus strong fibrous connective tissue longer term, has significant implications for the long term repair strength of a knitted mesh abdominal hernia repair. Expanded configurations of Surgical Mesh being devoid of fibrous connective tissue throughout the bulk of the plane of the mesh rely primarily on the strength of the implanted synthetic for any reinforcing strength across a hernia defect.

Non-woven designs, such as SURGIMESH, by excluding fat infiltration during/after surgery and becoming fully integrated with a laminar layer of fibrous connective tissue longer term, provide an ideal tissue integration response for the reinforcement of hernia defects long term. The SURGIMESH non-woven mesh configuration, in use since 2007 in the US, has never been reported to have a central mesh mechanical failure following the postoperative period in over 180,000 shipments for clinical implant. Hernia surgeon response to this discovery has been very positive with many appreciating the comprehensive scientific approach and subsequently deciding to trial SURGIMESH WN and XB hernia meshes in clinical hernia repair. For additional information on SURGIMESH hernia repair configurations visit the www.surgimesh.com web site.

References:

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