Single Sheet Biodegradable Surgical Mesh for Hernia and Tissue Repair

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Background and Unmet Need

Hernia repairs are one of the most common general surgeries performed globally, with an estimated 20 million cases annually.[1] If left untreated, hernias may become obstructed and difficult to heal adequately, which potentially may be fatal to the patient. Surgical mesh is a common solution for hernia repair. Standard treatment involves synthetic surgical mesh reinforcing the compromised wall and supporting the protruding organ. Most commercially available surgical meshes are permanent, non-biodegradable synthetic polymers that stay in place for the rest of the person's life. Although non-biodegradable meshes decrease the chance of hernia recurrence, the investigators state these non-biodegradable meshes also have been known to cause major discomfort, restrict movement, and cause chronic pain for the patient.

Biological biodegradable meshes previously have been explored to address the concern of non-biodegradable meshes. As biodegradable meshes eventually disappear from the body, they do not cause long-term irritation that could lead to chronic pain and limited mobility. However, biodegradable meshes commercially available today have experienced challenges, including higher rates of hernia recurrence and mesh rejection by the body.[2] Biodegradable meshes are often made up of multiple mesh layers. As multilayered mesh is heavier than single-layer mesh, the risk of tissue irritation and mesh rejection is considerably higher.[3]

As a result, there is a distinct need for a hernia repair mesh that benefits from biodegradable aspects but also avoids the risks associated with multi-layered biodegradable mesh. Further, the investigators believe use of their mesh implant is not limited to hernia and can be employed in other procedures including wound healing, repair of injuries to the bone tissue, nerve tissue, muscle tissue or skin tissue, and the treatment of burn injuries.

Opportunity

Dr. El Sabban and his colleagues have developed a single-sheet, three-dimensional, highly porous, adhesion-resistant surgical implant that utilizes a high tensile, gradually (controlled) biodegradable polymer for tissue repair. The gradually biodegradable nature of the material that makes up the mesh guarantees that the mesh stays in place and supports the repaired site until proper scar tissue has built up, after which the mesh disappears from the body, therefore preventing persistent pain and irritability. Its single-sheet design reduces the amount of foreign material within the body and decreases the mesh rejection risk. The mesh's three-dimensional, highly porous nature supports the infiltration and proliferation of cells necessary for proper scar tissue formation, mesh integration, and wound healing.

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[1] *New Approaches, Trends Are Emerging in Hernia Repair.* American College of Surgeons, March 2023.
[2] *Mesh in Elective Hernia Repair: 10-Year Experience with over 6,000 Patients.* National Library of Medicine, July 2021.
[3] *Mesh shrinkage in hernia surgery: data from a prospective randomized double-blinded clinical study.* National Library of Medicine, August 2010.

The hernia mesh device market was valued at $4.5 Billion USD in 2021 and is expected to grow at a compound annual growth rate of 3.4% to reach $6.5 Billion USD by 2032.[4] Utilizing state-of-the-art electrospinning technology, the manufacturing of the mesh is highly scalable and economically viable to create an inexpensive yet profitable product.

The mesh can be custom designed to any desired configuration based on the application in various regions of the body. The mesh's nanofibers may also be modified to the desired size, tensile strength, and rate of resorption specification for various clinical applications. While originally designed for hernia mesh repair, this technology can be utilized for other procedures which includes but is not limited to wound healing, including bone, nerve, muscle, skin tissue repair and burn injuries.

In vivo studies conducted by the El Sabban lab confirmed adequate mesh degradability, proper incorporation into tissues, healthy wound healing, and no inflammation or necrosis was observed. Most importantly, the mesh was observed to maintain high tensile strength, and the investigators observed a complete lack of hernia recurrence in all animal studies.

Unique Attributes

- Gradually biodegradable polymer.
- Three-dimensional and highly porous architecture to better promote healthy healing.
- Customizable shapes and sizes to fit various regions of the body.
- Single-sheet design to reduce the risk of mesh rejection.
- Made from electrospinning techniques, enabling highly scalable and economical manufacturing.

Clinical Applications

A three-dimensional, porous, single-layer mesh surgical prosthesis for tissue repair, initially hernia repair. Use of the mesh implant is not limited to hernia, and can be utilized for other procedures such as, but not limited to, wound healing, repair of injuries to the bone tissue, nerve tissue, muscle tissue or skin tissue, and the treatment of burn injuries.

Stage of Development

In Vivo Studies.

Intellectual Property

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Collaboration Opportunity

Seeking licensee for commercialization or collaboration to advance preclinical development.

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[4] *Hernia Mesh Devices Market.* Future Market Insights, June 2022.