# Biomechanical and Histologic Evaluation of a Novel Absorbable Mesh in a Porcine Model of Abdominal Wall Repair

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## Background

A concerning number of patients undergoing abdominal wall repairs report postoperative chronic pain. Permanent mesh use may contribute to postoperative pain, which can lead to chronic inflammatory reaction, and mesh shrinkage[1]. These findings have led to the use of absorbable mesh, which can be biologic or synthetic. Currently-available absorbable synthetic meshes typically fall into two domains: 1) long-term meshes that remain *in situ* over the timeframe of 18 months or more carrying the same risks of late complications as permanent meshes, and 2) short-term meshes that fully absorb over less than 3 months before the remodeled tissue has reached maturation.[2]

Dioxanone-based polymers have been widely-used in surgical implant applications for over 35 years. PDO suture, for example, is often preferred for wound closure, due to its mid-range absorption profile; however, no corresponding mesh construct is available for use. This large animal study is the first investigation of a patented, FDA cleared, monofilament bioabsorbable mesh (DuraSorb®, Surgical Innovation Associates, Inc., Chicago IL), assessing its utility for soft tissue support applications.

## Research Objectives

The objective of this study was to characterize the mechanical properties, resorption profile, and histological characteristics of this mesh in a porcine model of abdominal wall repair. The test mesh was compared to a long-term, PGA-PMC-based mesh (TIGR® Matrix Surgical Mesh, Novus Scientific, Uppsala Sweden), in the reinforcement of full-thickness, excisional abdominal wall defects at 1 month, 3 months, and 1 year.

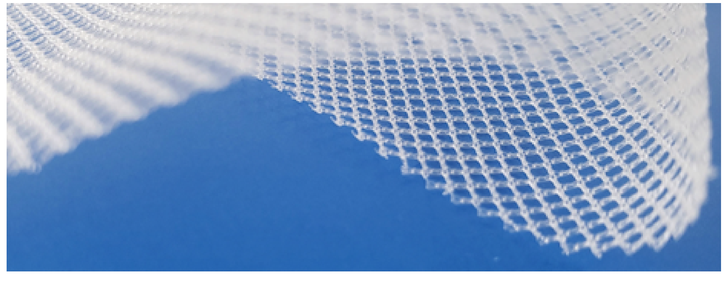


**Figure One** - Gross image of PDO mesh.

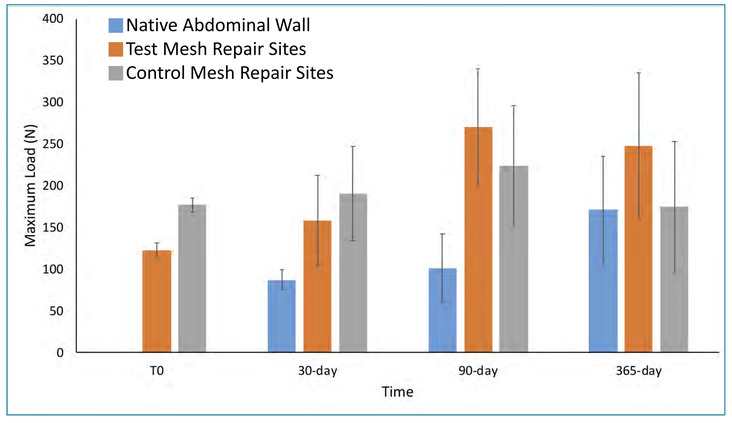
## Methods

Two full-thickness excisional defects were created in the abdominal walls of n=9 Yucatan miniature swine via midline approach. Each defect was repaired with either polydioxanone mesh or a control PGA-PMC mesh (TIGR®, Novus Scientific) in the preperitoneal plane. In-life clinical pathology, as well as and post-necropsy gross pathology (herniation, mesh migration, hematoma, seroma, necrosis), histopathology, and burst strength of the implant sites were assessed at 30 days, 3 months, and 1-year. Additionally, PDO mesh strength retention over time was analyzed *in vitro*.

**Figure Two** – Abdominal wall defects

Full thickness excisional defect taken via midline approach (left)
Repair via suture fixation in preperitoneal plane(middle)
Explanted tissue at 30-days post-op, demonstrating full tissue ingrowth (right)

**Figure Three** - Abdominal wall strength over time.




## Results

No device-associated complications were found clinically, upon gross examination, or histologically. The test mesh was well-integrated and vascularized at all time points with minimal to mild inflammation, fibroplasia, and fibrosis. The test device demonstrated lower inflammatory scores when compared to the control at all time points ($p < 0.05$ for all). Burst strength of the test repair sites was higher than that of the adjacent native abdominal wall at all time points ($p < 0.05$ for all). Further, burst strength of the test repair sites was not different from that of the control repair sites, despite full absorption of the test mesh and persistence of the control mesh.

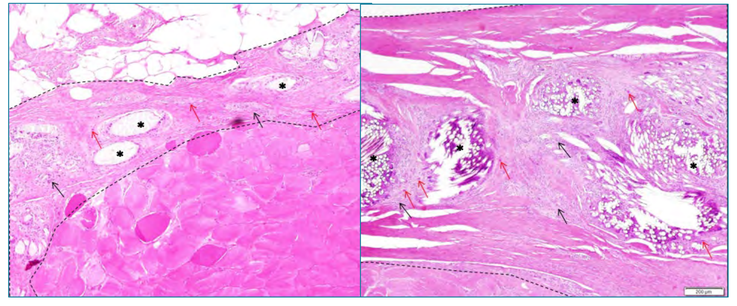
**Table One -** Inflammatory scores

| Parameters | Test Mesh | | | | | | Control Mesh | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Day 30 (n = 6) | | Day 90 (n = 6) | | Day 365 (n = 6) | | Day 30 (n = 6) | | Day 90 (n = 6) | | Day 365 (n = 6) | |
| | M ± SD | Med. | M ± SD | Med. | M ± SD | Med. | M ± SD | Med. | M ± SD | Med. | M ± SD | Med. |
| Inflammation | 2.00 ± 0.00 | 2.00 | 1.83 ± 0.41 | 2.00 | 0.17 ± 0.41 | 0.00 | 3.00 ± 0.00 | 3.00 | 2.17 ± 0.41 | 2.00 | 1.17 ± 0.41 | 1.00 |
| Neutrophils | 0.50 ± 0.55 | 0.50 | 0.00 ± 0.00 | 0.00 | 0.00 ± 0.00 | 0.00 | 0.67 ± 0.52 | 1.00 | 0.00 ± 0.00 | 0.00 | 0.00 ± 0.00 | 0.00 |
| Eosinophils | 0.33 ± 0.52 | 0.00 | 0.33 ± 0.52 | 0.00 | 0.00 ± 0.00 | 0.00 | 0.83 ± 0.41 | 1.00 | 0.50 ± 0.55 | 0.50 | 0.17 ± 0.41 | 0.00 |
| Macrophage/Histiocytes | 2.00 ± 0.00 | 2.00 | 1.83 ± 0.41 | 2.00 | 0.00 ± 0.00 | 0.00 | 3.00 ± 0.00 | 3.00 | 2.17 ± 0.41 | 2.00 | 1.00 ± 0.00 | 1.00 |
| Lymphocytes | 1.00 ± 0.00 | 1.00 | 0.17 ± 0.41 | 0.00 | 0.17 ± 0.41 | 0.00 | 1.00 ± 0.00 | 1.00 | 0.67 ± 0.52 | 1.00 | 0.67 ± 0.82 | 0.50 |
| Giant Cells | 1.00 ± 0.00 | 1.00 | 1.17 ± 0.41 | 1.00 | 0.00 ± 0.00 | 0.00 | 1.83 ± 0.41 | 2.00 | 1.50 ± 0.55 | 1.50 | 1.17 ± 0.41 | 1.00 |
| Foam Cells | 0.00 ± 0.00 | 0.00 | 0.00 ± 0.00 | 0.00 | 0.00 ± 0.00 | 0.00 | 0.00 ± 0.00 | 0.00 | 0.00 ± 0.00 | 0.00 | 0.00 ± 0.00 | 0.00 |
| Granulomas | 0.00 ± 0.00 | 0.00 | 0.00 ± 0.00 | 0.00 | 0.00 ± 0.00 | 0.00 | 0.00 ± 0.00 | 0.00 | 0.00 ± 0.00 | 0.00 | 0.00 ± 0.00 | 0.00 |

**M =** Mean; **SD** = Standard Deviation; **%** = Percent Incidence

**Inflammation/Inflammatory Cells Scoring Matrix: 0** = Absent, **1** = Rare, minimal 1-5/per high power field (hpf; 40x obj); 2 = Mild, 5-10/hpf; **3** = Heavy infiltrate, with preservation of local architecture**; 4** = Packed, with effacement of regional architecture.

**Figure Four** – Sample Micrographs (30 days)



Representative H&E-stained sections of test repair site (left) and control repair site (right).
Red arrows indicate neovascularization. Black arrows represent inflammatory infiltrate.
Dotted lines represent fibrovascular tissue. Asterisks represent monofilament test article (left) and multifilament control article (right)

## Conclusions

This study demonstrated that a novel, medium-term absorbable, monofilament mesh (DuraSorb®, Surgical Innovation Associates, Chicago, IL) provided durable, long-term support for abdominal wall repair in a porcine model, with minimal associated inflammation. Results at one year demonstrate equivalent strength and higher biocompatibility when compared to a long-term absorbable, multifilamentous control (TIGR® Matrix, Novus Scientific, Uppsala, Sweden).

(1) Oberg S, Andresen K, Rosenberg J. Absorbable Meshes in Inguinal Hernia Surgery: A Systematic Review and Meta-Analysis. Surgical innovation. 2017 Jun;24(3):289-98.

(2) Levenson SM, Geever EF, Crowley LV, Oates JF, 3rd, Berard CW, Rosen H. THE HEALING OF RAT SKIN WOUNDS. Ann Surg. 1965 Feb;161(2):293-308.