

Proof, Not Promises

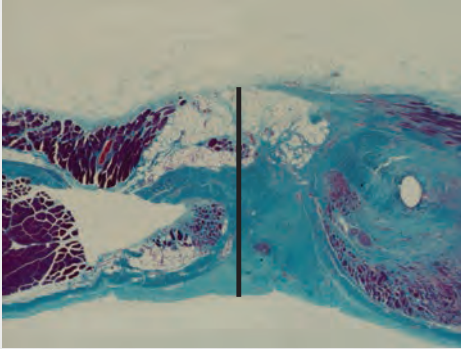
Why all bioabsorbable meshes are not the same.

PERFORMANCE by design



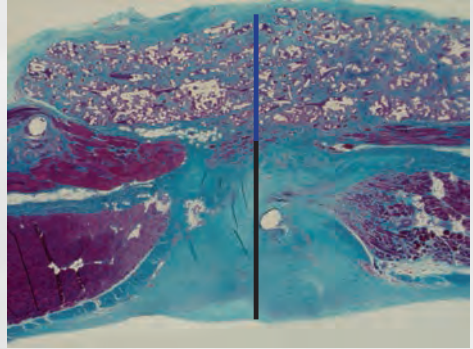
Generates Quality Tissue Fast

Mag 16x



Unreinforced Suture Line (black line)

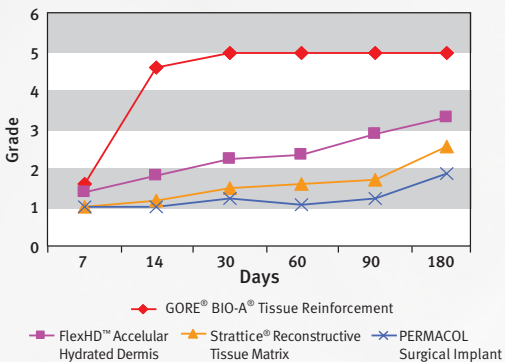
Mag 16x



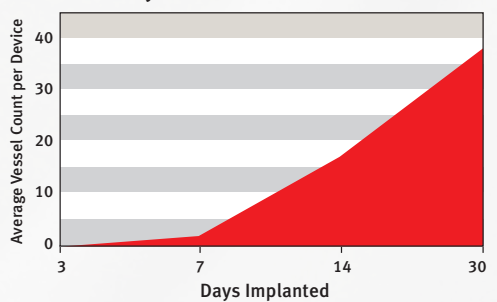
Suture Line (black line) Reinforced with GORE® BIO-A® Tissue Reinforcement (blue line)

Single animal comparison 30 days after suture closure.*

Total Cellular In-Growth¹



Vascularity Within Device Increases Over Time[†]



[†] GORE® BIO-A® Tissue Reinforcement; Rabbit abdominal wall implant. Data on file.

* Data on File

1. Zemlyak AY, Colavita PD, Tsirlin VB, *et al.* Absorbable glycolic acid/trimethylene carbonate synthetic mesh demonstrates superior in-growth and collagen deposition. Abdominal Wall Reconstruction (AWR) Meeting; June 14-16, 2012; Washington, DC. Abstract 35. <http://www.awrconference.com/abstracts2012/35rev.pdf>. Updated July 09, 2012. Accessed July 31, 2012.

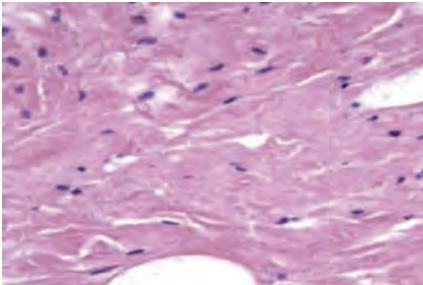
Histology

Review of Mesh at 1 Year³

3-D Bioabsorbable Scaffold



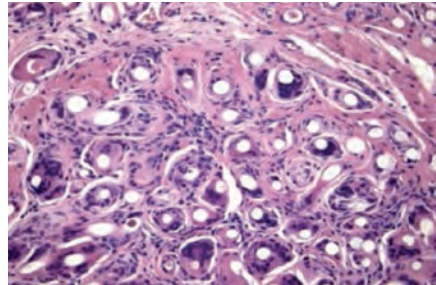
GORE® BIO-A® Tissue Reinforcement



2-D Bioabsorbable Knitted Mesh



TIGR® Mesh

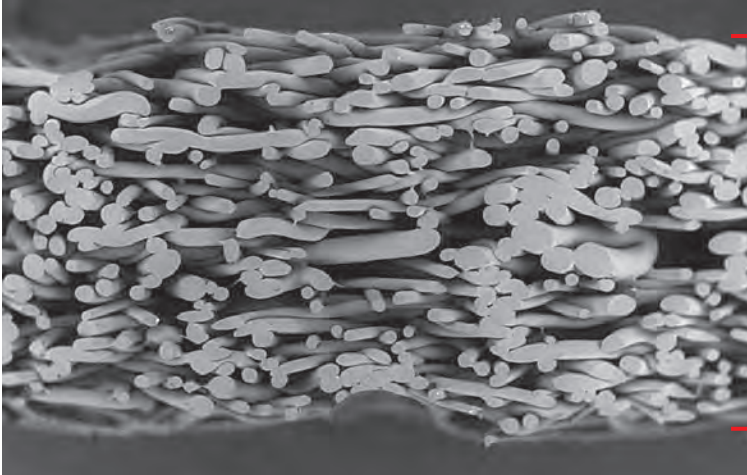


- GORE® BIO-A® Tissue Reinforcement mesh group: all meshes were completely absorbed, and dense; well organized connective tissue was present, with no signs of inflammation.
- 2-D Meshes: were only partially integrated in the host tissue and as in the polypropylene mesh group, intact mesh filaments were surrounded by variable organized host tissue and a pronounced foreign body reaction, which was also found 2 y after bridging of small defects in a sheep model.

3. Peeters E, van Barneveld K, Schreinemacher M, *et al.* One-year outcome of biological and synthetic bioabsorbable meshes for augmentation of large abdominal wall defects in a rabbit model. *Journal of Surgical Research*. In press.

Unique 3-D Structure

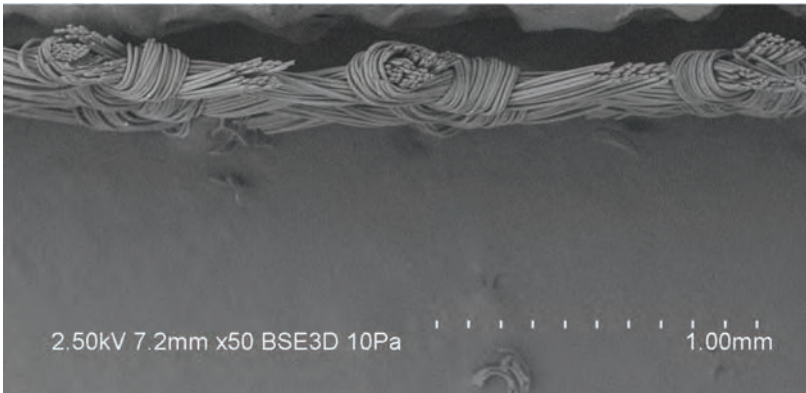
Mag 50x



Thickness of
new tissue
generated

GORE® BIO-A® Tissue Reinforcement

Mag 50x



2-D Bioabsorbable Knitted Mesh

► Demonstrated Use in Contaminated Fields

The only bioabsorbable mesh with favorable early outcomes in complex ventral hernia repair as evidenced by the COBRA Study – a prospective multicenter study – with a hernia recurrence of 4% and a wound infection of 19% after a mean follow-up of 210 days.²

Purpose

Study to assess outcomes after use of a bioabsorbable material to reinforce the midline fascial closure in single-stage, open, clean-contaminated or contaminated ventral hernia repairs. At the time data was available for 42 men and 62 women with a mean age of 58 years and a mean body mass index of 27 kg/m².

Results

Results of the 104 patients enrolled, 80 patients had a contaminated field and 24 a clean-contaminated field. The mean defect width and area were 9 cm (range 3-25 cm) and 138 cm² (range 10-540 cm²), respectively. Of the 18 patients with postoperative infections, 19 infections were noted: 2 suture abscesses, 8 superficial, and 9 deep, where 3 deep infections began as seromas. No removals of an infected bioabsorbable material were required. Mean follow-up was 210 days (range 8-464), with 37 patients receiving long term follow up assessment at 12 months.

2. Rosen M, Bauer J, Carbonell A, *et al.* Quality of Life Improves After Complex Ventral Hernia Repair Using a Bioabsorbable Material: Preliminary Results of a Prospective, Multicenter Study. Poster presented at the 15th Annual American Hernia Society Congress; March 13 - 16, 2013; Orlando, FL.



T I S S U E
R E I N F O R C E M E N T



W. L. GORE & ASSOCIATES, INC.

Flagstaff, AZ 86004

+65.67332882 (Asia Pacific)

00800.6334.4673 (Europe)

800.437.8181 (United States)

928.779.2771 (United States)

goremedical.com

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