

Histologic Analysis of GORE® BIO-A® Tissue Reinforcement 6 Months After Implantation During Laparoscopic Repair of Paraesophageal Hernia (LRPEH)

Jeffrey S. Mandel, MD, FACS, Savannah Surgical Oncology, Savannah, Georgia

Introduction

Compared with open surgery, LRPEH may offer a more rapid recovery, a shorter hospital stay, less pain, and fewer complications. Prosthetic mesh is commonly used in LRPEH with the aim of preventing hernia recurrence.

Nonabsorbable synthetic mesh, however, may erode into esophageal tissue or cause esophageal stenosis, fibrosis, dysphagia, and/or pain. “Biologic” prostheses are bioabsorbable, so their use avoids the permanent presence of a foreign body, but they may be expensive, have a limited shelf life, or require special preparation. Moreover, biologic prostheses have been associated with an increased risk of hernia recurrence.

GORE® BIO-A® Tissue Reinforcement

This synthetic bioabsorbable mesh is composed of a porous, 3-dimensional web of polymers (polyglycolic acid/trimethylene carbonate) that have long been used in the manufacture of medical products. The web is similar to the extracellular matrix in biologic materials, and it undergoes hydrolytic degradation within months, leaving behind no material that could cause late complications. The web is replaced by a collagen matrix.

Since June 2009, GORE® BIO-A® Tissue Reinforcement has been used in 15 LRPEH procedures with Nissen fundoplication in our center. There have been no known complications or hernia recurrences.

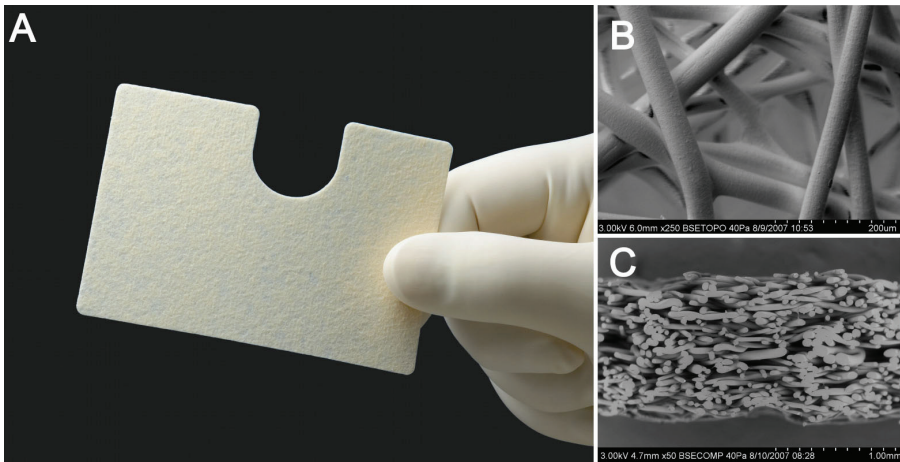


FIGURE 1. GORE® BIO-A® Tissue Reinforcement. **(A)** Configuration for LRPEH, a 7 cm x 10 cm device with “U” cut-out. **(B)** Scanning electron microscopy (SEM) image shows the web of polymers constituting the material, showing the highly porous structure (magnification x250). **(C)** SEM image shows cross-sectional view of the material (magnification x50).

Case Report

A 71-year-old woman underwent LRPEH with Nissen fundoplication and implantation of GORE® BIO-A® Tissue Reinforcement. There were no perioperative or postoperative complications. The patient had complete resolution of reflux symptoms and an increased ability to exercise. However, six months later the patient, who had known gallstones, began experiencing biliary colic and required cholecystectomy. The patient consented to a biopsy of the LRPEH repair site during laparoscopic cholecystectomy.

Histologic Findings

The repair-site specimen showed dense fibrocollagenous tissue with scattered clusters of lymphocytes and rare foreign-body giant cells. The middle region of the tissue was extensively vascular, with the vascularity bordered by fatty tissue. A few remnants of the prosthesis were present, surrounded or covered by fibrovascular tissue containing fibroblasts. Foreign-body giant cells and histiocytes were adjacent to the remnants. There was no evidence of bacteria or mineralization.

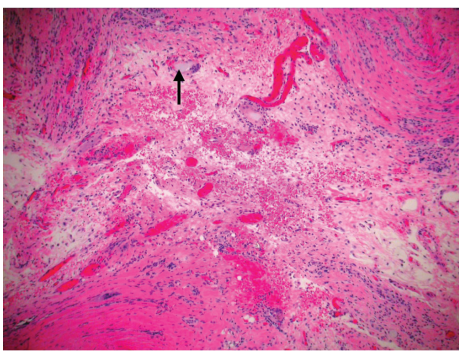


FIGURE 2. Specimen of site of LRPEH obtained 6 months after surgery shows that fibrovascular tissue has almost completely replaced the GORE® BIO-A® Tissue Reinforcement, a small remnant of which is indicated by the arrow (H&E stain, magnification x10).

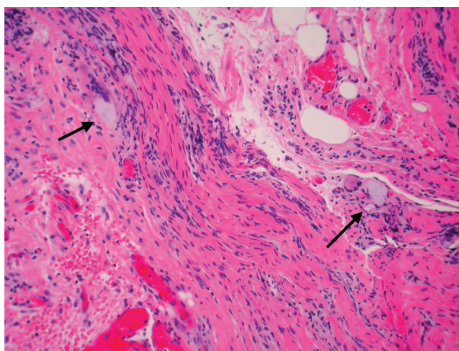


FIGURE 3. Higher magnification of repair-site specimen shows a few fragments of GORE® BIO-A® Tissue Reinforcement (arrows), scattered lymphocyte clusters, and small and large blood vessels (H&E stain, magnification x20).

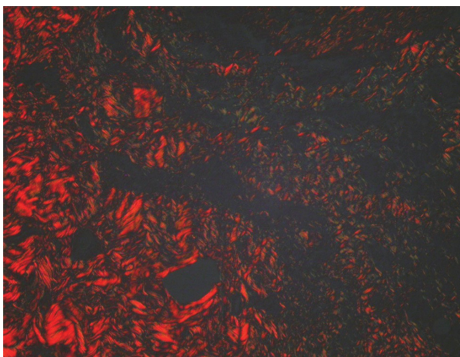


FIGURE 4. Polarized light microscopy image of repair-site specimen shows predominantly mature type I collagen (bright orange). A few type III collagen fibers (green) appear at the outer margins (Picrosirius Red stain, magnification x40).

Conclusions

This rare “second look” at a clinical site of implantation of GORE® BIO-A® Tissue Reinforcement showed that the material was almost entirely absorbed within 6 months and replaced by fibrovascular tissue. These findings suggest that the prosthesis had encouraged ingrowth of new tissue and that a foreign body was no longer present.

Use of bioabsorbable synthetic mesh in LRPEH has the potential to avoid long-term complications associated with nonabsorbable mesh. GORE® BIO-A® Tissue Reinforcement has the advantages of a biologic mesh without the disadvantages of limited shelf life, high cost, or need for preparation. Studies of the possible role of this prosthesis in reducing hernia recurrences after LRPEH are warranted.