Advances in Bioabsorbable Implants for Abdominal Wall Reconstruction: Utility of GORE® ENFORM Biomaterial

Faculty

James J. Chao, MD, FACS
Director of Plastic and Hand Surgery
OasisMD Lifestyle Healthcare
San Diego, California

Matthew I. Goldblatt, MD, FACS
Professor of Surgery
Director, Condon Hernia Institute
Surgical Residency Program Director
Medical College of Wisconsin
Milwaukee, Wisconsin

Introduction

Surface texture and porosity[1] can play a crucial role in the body's reaction to surgical implants, such as those used in abdominal wall reconstruction surgery.[2] Known to be the predominant factor in the induced foreign body response,[3] implant surface topography also has been shown to be a significant factor in how tissues affected by implanted materials behave both in vitro and in vivo.[4] Certain implant materials may induce non-adherent fibrous capsules in soft tissue, which contract and stiffen over time. Initial stability and durability may be increased by selecting monofilament tissue implants that are strong, yet flexible, and offer large enough pore sizes to allow for cell infiltration into the implant as well as demonstrate the properties of the surrounding host tissue.[5,6]

In order to help meet the demands necessary for implants used in effective abdominal wall reconstruction, W. L. Gore & Associates has developed GORE® ENFORM Biomaterial, a reinforcement for soft tissue composed of synthetic bioabsorbable polyglycolic acid and trimethylene carbonate—a copolymer composition that is known to be safely, reliably, and fully absorbed into the body within 6 to 7 months.[7] This copolymer has proven to be effective for hernia repair in other products and product types including GORE® BIO-A® Tissue Reinforcement, where it has been studied extensively.

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Figure 1. GORE® ENFORM Biomaterial.

Rapid Cell Infiltration With GORE® ENFORM Biomaterial

The pore size of GORE® ENFORM Biomaterial of 10-100 µm is optimized[1] to facilitate rapid cell infiltration and vascularization. Immediately after implantation, the microstructure allows for fluids to infiltrate and pass through the device[7]; vessels begin to form as soon as 7 days post-implantation.[8] Vascularized tissue, in turn, supports the formation of healthy tissue, delivering cells and nutrients to the healing site for rapid tissue ingrowth. In 6 to 7 months after abdominal wall reconstruction surgery, GORE® ENFORM Biomaterial is completely absorbed into the body, leaving only a healthy layer of mature collagen behind.[7,9,10]

"This absorbability coupled with its pliable structure make GORE® ENFORM Biomaterial a good choice for complex cases in which there are concerns about using permanent material," said Matthew I. Goldblatt, MD, FACS, a professor of surgery and the director of the Condon Hernia Institute and surgical residency program for the Medical College of Wisconsin. "There's a number of reasons why a surgeon might be concerned about placing a permanent implant in a patient," Dr Goldblatt said. "Sometimes there's a concern for contamination or colonization by bacteria, especially in the case of patients who are at a higher risk of infection; the body cannot fight an infection on a foreign piece of plastic. If you have an implant that ultimately is absorbed into the body, that is ideal, as the body is relatively good at fighting infection in its own tissue."

James J. Chao, MD, FACS, formerly a professor of surgery in the Division of Plastic Surgery at the University of California, San Diego and now the director of plastic and hand surgery at OasisMD Lifestyle Healthcare in San Diego, California, agreed with Dr Goldblatt's assessment of GORE® ENFORM Biomaterial, adding that it provides a high degree of safety, strength, and quality for tissue repairs. "GORE® BIO-A® Tissue Reinforcement worked very well, but there were some limitations to the product. The first limitation is that it was designed to work best between 2 well-vascularized tissue planes, rather than intraabdominally or intraperitoneally, and the second was that it was stiffer than I would prefer. In thinner people, it was likely to be felt," he said. "And so the manufacturer listened to surgeon feedback and engineered a device with strength and additional flexibility.[11] In addition, GORE® ENFORM Intraperitoneal Biomaterial has been developed to be placed inside the abdomen, allowing it to safely touch sensitive areas including the bowel."

Applications and Advantages

GORE® ENFORM Biomaterial is indicated for the reinforcement of soft tissue.[12] Specific applications are in abdominal wall reconstruction, specifically those applications in hernia repair as suture line reinforcement, reinforcement in muscle flap procedures (eg, transverse rectus abdominis and deep inferior epigastric perforator surgery), and general tissue reconstructions.[12,13]

GORE® ENFORM Biomaterial is available in 2 configurations: a preperitoneal version with textured ingrowth surfaces on both sides and an intraperitoneal version that is a dual-sided device where one side is a textured ingrowth surface and the other is a smooth, shiny visceral contacting surface, which serves to minimize tissue attachment to the device (Figure 1).[14,15]

Compared with standard biologic implants, the use of GORE® ENFORM Biomaterial has been shown to result in more than 200% more vascularity, double the fibrous tissue ingrowth at 30 days from surgery, and triple the ingrowth at 90 days.[10,16] At 180 days, at which point the body responds to a biologic as it would to a foreign body with a chronic inflammatory degradation process,[10] the bioabsorbable matrix of the GORE® ENFORM Biomaterial is completely replaced by uniform, mature collagen (Figure 2).[16]

Dr Goldblatt noted that the soft structure and conformability of GORE® ENFORM Biomaterial also considerably broadens the scope of its surgical applications compared with GORE® BIO-A® Tissue Reinforcement. "GORE® BIO-A® Tissue Reinforcement has been in use for many years now, and there are good data to show that it produces successful results in hernia repair, but it remains limited in its applications because of its stiff structure," he said. "I have been using it for open hernia repairs, but the idea of using it in laparoscopic or robotic minimally invasive surgeries—in which you have to roll up the implant and place it down a trocar into the abdomen—something with a stiffer structure is not always a good solution."

However, Dr Goldblatt noted that while the material was designed for open hernia procedures, the flexibility of GORE® ENFORM Biomaterial allows for use in laparoscopic or robotic procedures, or in patient types where a lighter, softer implant is necessary. The focus on material properties and procedural conformability stemmed directly from the manufacturer's patient-focused discussions with general, plastic, and trauma surgeons.[11] "GORE® ENFORM Biomaterial is easy to sew through and conforms very well to the shape of the body, but is also surprisingly strong. I have placed a great amount of pull on it using a #1 suture, and I could not get the suture to cut through the material," Dr Goldblatt said.

Feedback on GORE® ENFORM Biomaterial

Fully Absorbable Hernia Repair—Nothing Left Behind

Both Drs Chao and Goldblatt noted that the various advances to GORE® ENFORM Biomaterial beyond other bioabsorbable implants have made it an attractive option for surgeons seeking improved outcomes and patients hoping to avoid the problems associated with earlier implant types. "Some patients are concerned that the surgeon will have to go into their abdomen more than once," Dr Goldblatt said. "As a surgeon, you're particularly concerned with patients with inflammatory bowel disease, since we have seen adverse events

like pain and infection that may be associated with permanent meshes in the past. Some patients, concerned with potential outcomes related to permanent meshes, specifically seek to learn more about alternatives, such as the copolymer-based GORE® ENFORM Biomaterial and GORE® BIO-A® Tissue Reinforcement."

"My experience with GORE® ENFORM Biomaterial is that it works very well both intra- and extraabdominally. GORE® ENFORM Biomaterial does not sacrifice any of the strength of the GORE® BIO-A® Tissue Reinforcement, but the softness and the ability for the intraperitoneal version to be placed inside the abdomen are very much appreciated," Dr Chao said. "Both the smooth, intraperitoneal version and the preperitoneal version for subcutaneous use have performed well for me. I am basically migrating my practice almost exclusively to using GORE® ENFORM Biomaterial."

The availability of GORE® ENFORM Biomaterial is another reason Dr Chao continues to select the implant for procedures he performs as well as its wide range of sizes, up to 30×40 cm. "For complex cases you need large pieces—larger than 20 by 30 cm; 30 by 40 cm would be better. There are not very many areas of the body where you can obtain that large of a piece of skin on a cadaver, and so pieces that large are available in very limited quantities," Dr Chao said. "Another factor is that biologic materials are becoming more difficult to acquire, as they are derived from a tissue donor. Biosynthetic implants, on the other hand, are manufactured making these easier to obtain, more consistent in quality, and available in large pieces, which is absolutely crucial for large complex abdominal wall reconstruction."

Safety Profile

Despite the widespread use of different types of mesh products in abdominal wall reconstruction,[17] questions regarding long-term complications or adverse events (more than 4 years postimplantation) remain related to certain mesh types, including reports of adhesion rates and other mesh-related complications, such as bleeding, bowel obstruction, and bowel perforation.[17,18]

Both Drs Chao and Goldblatt noted that the extensive and thorough methodology used by Gore in product testing and market support for GORE® ENFORM Biomaterial, and the 10 years of clinical data supporting the use of the GORE® BIO-A® Tissue Reinforcement material,[19] provide each confidence that they can better mitigate the potential adverse events that may be associated with other mesh types. "The GORE® ENFORM Biomaterial is in the same class as GORE® BIO-A® Tissue Reinforcement; however, a different manufacturing process makes it more pliable and softer," Dr. Chao said. "It is also one of the first synthetic resorbable mesh products to be released with a very good long-term safety profile." Dr. Goldblatt agreed: "GORE® ENFORM Biomaterial offers surgeons and their patients an alternative to a permanent implant. GORE® ENFORM Biomaterial takes the previously documented success of GORE® BIO-A® Tissue Reinforcement and uses patented Gore medical technologies to offer a unique and more linear strength profile, and additional flexibility.[11] As for safety, long-term results are difficult to find in the hernia literature. GORE® BIO-A® Tissue Reinforcement has been shown to be a safe alternative to permanent mesh with similar long-term results."[20,21]

Lower Cost Versus Biologics

In addition to its clinical and safety benefits, GORE® ENFORM Biomaterial offers lower cost versus biologics by completely eliminating the tissue processing costs associated with biologics in complex surgical applications. As a result, the average cost of the GORE® ENFORM Biomaterial is nearly 50% less than biologic products of an equivalent size.[16] Dr Chao noted that GORE® ENFORM Biomaterial offers clear-cut performance and financial benefits compared with biologics. "I did a case almost 2 months ago where the traditional repair method would have included use of a biologic implant. The materials alone would have cost around $20,000 to $30,000, but with GORE® ENFORM Biomaterial, the cost was easily half of that," he said.

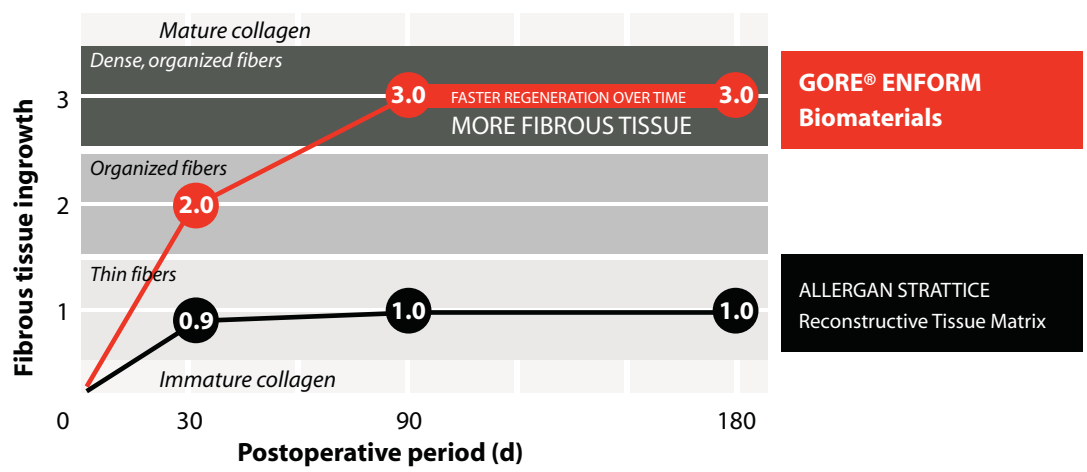

Figure 2. Postoperative fibrous tissue ingrowth for GORE® ENFORM Biomaterial compared with a leading biologic implant.

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Conclusion

GORE® ENFORM Biomaterial is a new biomaterial technology, providing a combination of product attributes not available with older bioabsorbable, biologic, and synthetic implant products for complex abdominal wall reconstruction surgery and a range of other applications.[12] Its soft, compliant structure makes it easy to handle and versatile to place, while the smooth surface on the GORE® ENFORM Intraperitoneal Biomaterial allows it to be placed directly against sensitive tissues, according to Dr Chao, providing more options for surgeons performing various procedures.

GORE® ENFORM Biomaterial represents a new category of biosynthetic mesh—one that conforms to, supports, and is ultimately absorbed by the patient.[7] "I don't expect any long-term problems with GORE® ENFORM Biomaterial," Dr Chao said. "I expect to see it adopted quickly."

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Disclosures

Dr Chao reported that he has received speaking fees from Ethicon and Gore, and owns stock in WeShareMD. Dr Goldblatt reported that he is a consultant to Allergan, Gore, and Medtronic; has received honoraria from Gore and Medtronic; and has received grant/research support from Bard and Medtronic.

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