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Clinical Discussion of Advances In Tissue Reinforcement for Abdominal Wall Reconstruction

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The Current Landscape of Tissue Reinforcement

Tissue reinforcement has become a standard of care for preventing recurrent hernias or other abdominal wall reconstruction (AWR) repair failures, and currently a variety of synthetic, absorbable synthetic, and biologic devices are available to meet these needs.[1-3] The expansion of options supporting these repairs allows surgeons more ability to customize their approach to durable AWR and potentially lowers the risk for complications.[2] When absorbable mesh is the surgeon's choice in the repair, utilizing a fully absorbable, synthetic material can help avoid the limitations of biologic meshes, including the high acquisition cost and variability in strength.[4]

The COVID-19 pandemic has raised the prospect that a perceived risk for contracting the virus may lead to a delay in patients scheduling their surgeries and thus result in greater complexities (eg, infection, pain). In fact, investigators in a multicenter retrospective cohort study in Spain found a 26.4-hour mean delay in presentation to the emergency room for acute care surgery during the pandemic compared with a pre-pandemic control period.[5] Patient morbidities were increased in the pandemic period.[5] Cheguevara Afaneh, MD, an assistant professor of surgery at NewYork-Presbyterian Hospital in New York, New York, reported that many patients with asymptomatic inguinal or ventral hernias at his institution delayed surgery altogether. With patients potentially becoming more complex, the choice of biomaterial is critically important to support quality outcomes.[2]

In early 2021, as part of the Gore Medical Mastery Series, a faculty of surgeons convened in a virtual hybrid symposium in the midst of the COVID-19 pandemic to discuss their approaches to AWR, hernia repair, and tissue reinforcement. Three of the faculty later agreed to be interviewed to expand on their conference remarks. Although emphasizing that selection of tissue reinforcement must be individualized to achieve

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the highest-quality outcomes for patients,[2] each surgeon discussed the role of GORE® ENFORM Biomaterial (Figure 1), a fully synthetic absorbable tissue reinforcement composed of poly(glycolide:trimethylene carbonate) copolymer (PGA:TMC), a synthetic bioabsorbable material also utilized in GORE® BIO-A® Tissue Reinforcement.[6,7] Unlike other mesh materials, not a single complete mesh removal due to infection following a complex ventral hernia repair has been reported with GORE® BIO-A® Tissue Reinforcement.[8] Combined, these surgeons have performed hundreds of cases with GORE® ENFORM Biomaterial since its introduction in 2018,[9] and when absorbable tissue reinforcement is their choice for a repair, they believe it represents an important advance over alternatives.

Switching From Biologics

Before switching to GORE® ENFORM Biomaterial, Dr Afaneh considered alternative solutions instead of biologics for cases in which permanent mesh was not appropriate or was declined by the patient. Specifically, he was not convinced biologics offered a lower risk for complications and he was seeking consistent performance. "I have not used biologic mesh for abdominal wall reconstructions in several years. It's very expensive without added value to the patient," he said. However, if possible, he was interested in a device that was easier to manipulate while providing high-quality benefits.

Omar E. Bellorin-Marin, MD, FACS, an assistant professor of surgery at NewYork-Presbyterian Hospital in New York, New York, acknowledged that GORE® ENFORM Biomaterial provides a supple alternative and represents an advance over the biologic or permanent synthetic alternatives. Similar to Dr Afaneh, he preferred biosynthetic absorbable mesh to biologics.

Matthew I. Goldblatt, MD, a professor of surgery and the director of the Condon Hernia Institute at the Medical College of Wisconsin, in Milwaukee, Wisconsin, uses a biologic only a few times a year for specific circumstances. "I consider a biologic when bridging a large defect and I'm not ready to perform a full repair in the retrorectus plane. Placement of a biologic mesh was my bailout that allows me to come back another day," he said. Overall, Dr Goldblatt was unhappy with his outcomes using biologics, including the formation of seromas, so he switched to GORE® BIO-A® Tissue Reinforcement when it became available. "[BIO-A® Tissue Reinforcement] was a game changer for me and I see [ENFORM Biomaterial] brings more. It uses the same bioabsorbable polymer, and it is softer with strong repair, in my experience," he said.

Figure 1. GORE® ENFORM Biomaterial.

Dr Goldblatt continues to use BIO-A® Tissue Reinforcement for hiatal hernia repair for which he feels the greater material shape memory is an advantage. Like the other surgeons he asserts that the more supple ENFORM Biomaterial conforms more easily to the contours of the anatomy, potentially providing improved tissue apposition in more complex cases.

Advantages of GORE® ENFORM Biomaterial

Rapid Tissue Ingrowth

The new technology borrows on the established Gore targeted mid-term absorption characteristics of PGA:TMC, and research shows that the scaffolding and optimized pore size of ENFORM Biomaterial (10-100 mcm) facilitates tissue ingrowth in an animal model.[10-12] In fact, vascularization is detected within 7 days.[13] By 30 days, the 3D matrix of the ENFORM Biomaterial is completely infiltrated with vascularized collagenous tissue (Figure 2) and is completely resorbed in 6 to 7 months.[10,14-16] PGA:TMC has over 300 clinical papers demonstrating quality outcomes, in contrast to other mesh on the market.[8]

"I have had the opportunity to look at repairs several months after the procedure when I had to go back in for another reason," said Dr Afaneh. "If the relook is more than 6 months after the repair, the device is gone, but there is new collagen formation and regrowth." Dr Bellorin-Marin also is convinced by his visual inspections that ENFORM Biomaterial performs consistently with the animal models. "When there was a reason to go back in, I have clearly seen newly vascularized tissue where [ENFORM Biomaterial] was placed," he said (Figure 3). Dr Goldblatt, who has had the opportunity with some patients to follow up with imaging to verify the integrity of repairs with tissue reinforcement, agrees: "The bottom line is that the fascia looks normal after healing," he said.

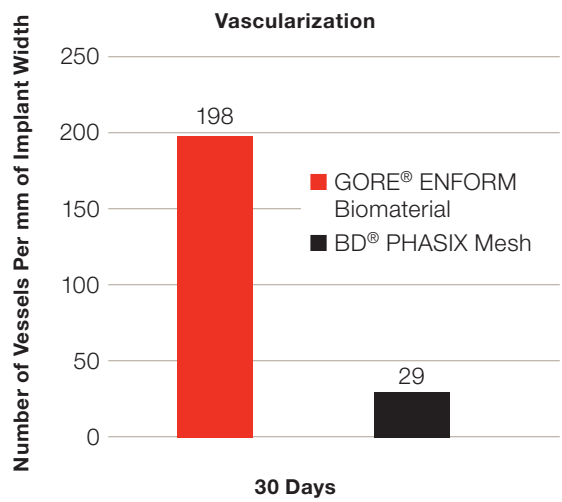

Figure 2. GORE® ENFORM Biomaterial has more than 6 times the vascularity as BD® PHASIX Mesh at 30 days after implantation in animal studies.

Based on reference 15.

Strength and Handling

According to Dr Afaneh, the strength of GORE® ENFORM Biomaterial is comparable, if not superior, to other options, and when he wants to avoid permanent mesh, it is his mainstay in hiatal or paraesophageal hernias of 5 cm or larger. In addition, he finds the soft and pliable composition more adaptable and easier to position and fix. Dr Goldblatt appreciates its versatility, noting how the material retains its integrity when the device is cut or trimmed. He added that with its conformation to the anatomy and strength, GORE® ENFORM Biomaterial anecdotally seems more likely to hold sutures than his previously used meshes even when there is substantial tension at the suture.

In Dr Bellorin-Marin's experience, GORE® ENFORM Biomaterial feels strong, and he derives "peace of mind" at the end of procedures because of its supple handling and greater ability to conform to the space where it is applied. He added that it is simple to trim the device intraoperatively for better placement. "The flexibility of [ENFORM Biomaterial] is advantageous in almost all cases. When the tissue replacement is robust, it conforms less well to the curve of the anatomy. I use more of the intraperitoneal than the preperitoneal [ENFORM Biomaterial], but the advantage for both is the soft and flexible handling," he said. "When an absorbable mesh is indicated, I have not used anything but [ENFORM Biomaterial] in some time."

Configurations Supporting Placement

GORE® ENFORM Preperitoneal Biomaterial and GORE® ENFORM Intraperitoneal Biomaterial both share the same favorable flexibility and handling characteristics. The preperitoneal device has porous textured surfaces on both sides to encourage tissue ingrowth.[6,11,12] The intraperitoneal device has a durable [bioabsorbable] film on one side to minimize the risk for adhesions when in contact with visceral organs. The film is perforated to allow fluids to pass through and to minimize seroma formation.[10,17]

Dr Afaneh uses the ENFORM Preperitoneal Biomaterial for filling soft-tissue deficits and repairing muscle flaps, and ENFORM Intraperitoneal Biomaterial for AWR. "I use tissue reinforcement to reinforce AWR, which means that I work with [ENFORM Intraperitoneal Biomaterial] more commonly," he said. Dr Bellorin-Marin also uses the intraperitoneal version more frequently and reiterated that the preperitoneal version is useful for addressing soft-tissue deficits with a material that supports rapid tissue ingrowth and incorporation. His primary application, however, is the reinforcement of abdominal wall closures. "For tissue reinforcement that comes in contact with viscera, microporous film is essential to minimize adhesions, which is a common adverse event," he said. Dr Goldblatt, on the other hand, occasionally uses the intraperitoneal version for open AWRs but more commonly uses the preperitoneal configuration. "I believe that the ideal place for [ENFORM Biomaterial] is the retrorectus position, which does not require the nonporous coating," he said.

Patient Factors and Outcomes

Dr Goldblatt considers GORE® ENFORM Biomaterial for patients with clean surgical fields but with factors that put them at high risk for infection (eg, diabetes mellitus, smoking, obesity).[18] "I also consider [ENFORM Biomaterial] for patients who have had prior complications with AWR as well as for those who specifically object to having a permanent foreign material," he

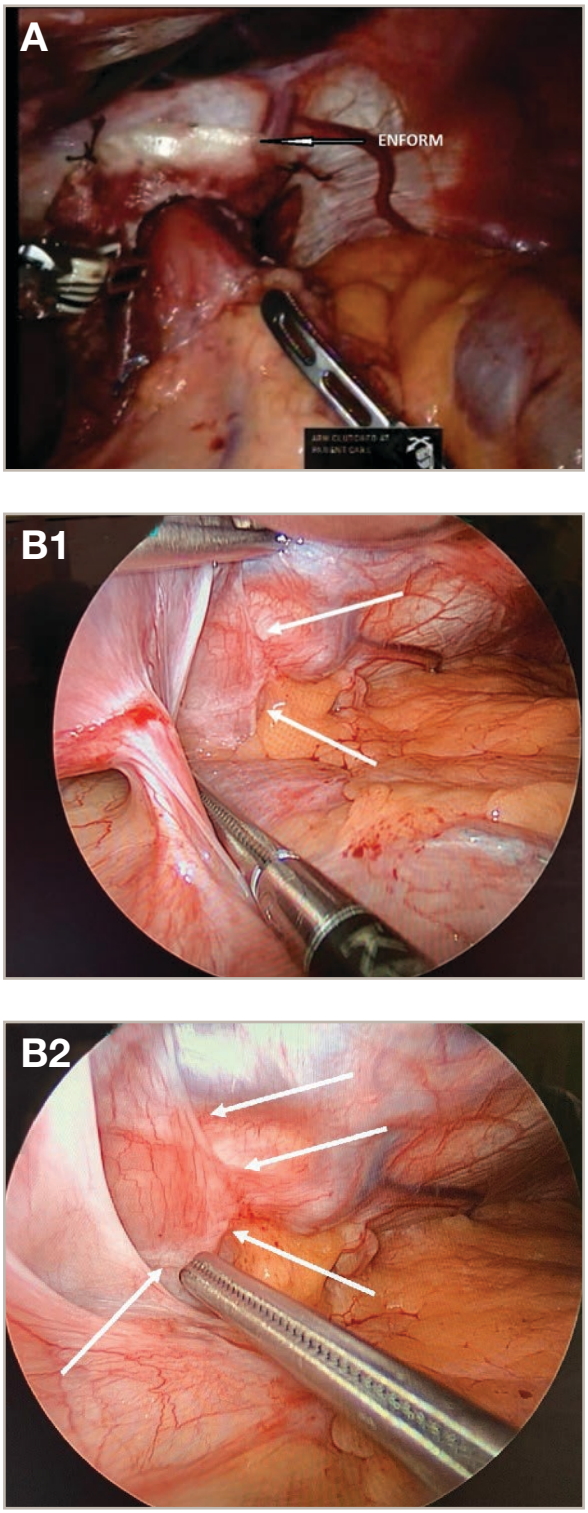

Figure 3. Dr Bellorin-Marin performed a hiatal hernia repair on his patient with GORE® ENFORM Biomaterial (A). Unrelated to the repair, the patient underwent diagnostic laparoscopy 7 months later (B1 and B2). White arrows point to new vascularized tissue.

Photos courtesy of Omar E. Bellorin-Marin, MD, FACS

said. “Many patients have significant reservations about permanent mesh.” Although he attempts to inform patients about the risks of permanent mesh relative to the risks for recurrences if he believes it is the best option, he says “[ENFORM Biomaterial] can be a nice alternative” for those in whom an absorbable mesh is a reasonable option and who have been appropriately educated about the relative risks of each approach. The surgeons agree that GORE® ENFORM Biomaterial may not be a substitute for permanent mesh when there is a high risk for failure, such as in patients with large defects or where permanent support from a device is needed; they will, however, consider it for some individuals who may be better suited to a permanent device but fear complications and have strong objections. Dr Afaneh’s own review of 48 hiatal hernia repair cases with GORE® ENFORM Biomaterial revealed 0% intraoperative morbidity and 4% postoperative morbidity. With a mean follow-up of 12 months, he has had no radiographic or endoscopic recurrences.

Conclusion

Tissue reinforcement technology has continually evolved to achieve durable surgical repairs while minimizing complications.[2] GORE® ENFORM Biomaterial builds on the technology that made GORE® BIO-A® Tissue Reinforcement a leading product among absorbable meshes and with a softer, more supple construction. “There are several gains with [ENFORM Biomaterial] relative to the absorbable mesh I used previously, but little, if anything, is lost,” Dr Afaneh said.

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