Clinical Use of GORE® BIO-A® Tissue Reinforcement in Ventral Hernia Repair Using the Components Separation Technique

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Approximately 4 to 5 million laparotomies are performed in the United States each year.[1] The prevalence of incisional hernia after laparotomy varies according to patient characteristics such as obesity, but rates of 2% to more than 20% have been reported.[2,3] Some incisional hernias are asymptomatic and remained untreated, but more than 200,000 are repaired in this country annually.[1] The goals of repair include the alleviation of pain, discomfort, and functional limitations, as well as the prevention or treatment of incarceration and strangulation.[4] Unfortunately, many repaired incisional or ventral hernias recur; thus, the primary objective of research and technological developments pertaining to these hernias has long been to minimize recurrences without increasing treatment-related complications.

Suture-Only and Nonabsorbable Synthetic Mesh Repairs

Ventral hernia repair is especially challenging if the defect is large, recurrent, or "complex" (that is, associated with a higher potential for infection, contamination, or recurrence). Many different repair procedures have been used over the years. The oldest, the suture-only method, involves simple approximation of the edges of the fascia. Because this technique creates tension in the tissue and is associated with high recurrence rates,[5] it has generally been abandoned as an option for treating large or complex abdominal wall hernias. Today, tension-free repairs that include implantation of nonabsorbable synthetic mesh are commonly employed. Billroth once commented that "if we could artificially produce tissues of the density and toughness of fascia and tendon, the secret of the radical cure of hernias would be discovered."[6] Indeed, most of the mesh materials designed for use in ventral hernia repair do have considerable density and toughness. In fact, most have been engineered to withstand supraphysiologic forces.[7] The permanent presence of these "heavy" foreign bodies increases the risk of postoperative infection, bowel adhesion, mesh extrusion, mesh erosion, fistula formation, seroma development, and pain, especially in patients with large or complex defects.[7,8] Moreover, the mesh may eventually shrink or bulge, causing the patient discomfort or pain,[7,9] or the abdominal wall may become noncompliant, causing a feeling of stiffness.[7,10]

Components Separation

In dedicated hernia centers today, the use of autologous tissue repair, which involves fascial grafts, musculocutaneous and musculofascial flaps, or both, continues to increase. Along with strength, repairs using native muscular tissue offer vascularity at the repair site. Vascularity provides resistance to infection by delivering inflammatory cells, nutrients, and oxygen.[11]

The most commonly used autologous tissue technique for repairing incisional hernias is creation of a bilateral sliding rectus abdominis myofascial flap, that is, the components separation (CS) method. This repair, which was first described by Ramirez et al[12] in 1990, includes the following steps: the skin and subcutaneous tissue are mobilized from both sides of the abdominal wall; incisions are made in the aponeurosis lateral to the rectus sheath bilaterally; the external and internal oblique muscles are separated by blunt dissection laterally to allow the myofascial unit to slide medially (with additional mobilization obtained, if necessary, by incising the posterior rectus sheath and dissecting it off the rectus muscle); and the flaps are brought to the midline for suture closure (Figure 1).[12,13] Reported hernia recurrence rates after CS repair have varied widely—from 4% to 53%[14]—but the rate in the only prospective, randomized study of the CS method was 53% (with a 3-year follow-up period).[13] Because of the risks assumed to be associated with placement of nonabsorbable synthetic mesh in patients with large or complex ventral hernias, many surgeons have begun to use "biologic" prostheses in CS repairs.

Biologic Prostheses

Biologic prostheses are composed of human (cadaver) or nonhuman tissue that is processed to achieve sterility, viral deactivation, and in some instances, chemical cross-linking. Implantation of a biologic prosthesis provides a surgical site with an extracellular matrix (ECM), which is a scaffold of structural and functional proteins. Cells that populate the ECM following implantation orchestrate inflammation, healing, and tissue remodeling that results in tissue restoration.[15] Ideally, the prosthesis is completely absorbed and replaced by new native tissue.[16] During the remodeling process, the device must maintain mechanical strength similar to that of native tissue to avoid early graft failure and graft weakness, stretching, and bulging.[8,11] The completely remodeled area must have sufficient collagen deposition and neovascularization to provide a durable repair.[16]

Several types of biologic prostheses are available, but only three have been the subject of multiple clinical studies: decellularized human cadaver dermis, decellularized porcine small intestinal submucosa, and decellularized cross-linked porcine dermis. So far, no investigation of a biologic prosthesis has been a randomized controlled trial that enrolled patients with a ventral or incisional hernia. Data on long-term outcomes with biologic prostheses are also lacking.[16] As Hiles et al[17] noted in a 2009 review, experience with these materials is still miniscule in comparison to that with nonabsorbable synthetic grafts, and level 1 evidence of the safety and efficacy of biologic prostheses is almost nonexistent.

Incision of external oblique muscle

Release of posterior rectus sheath

Midline closure of linea alba

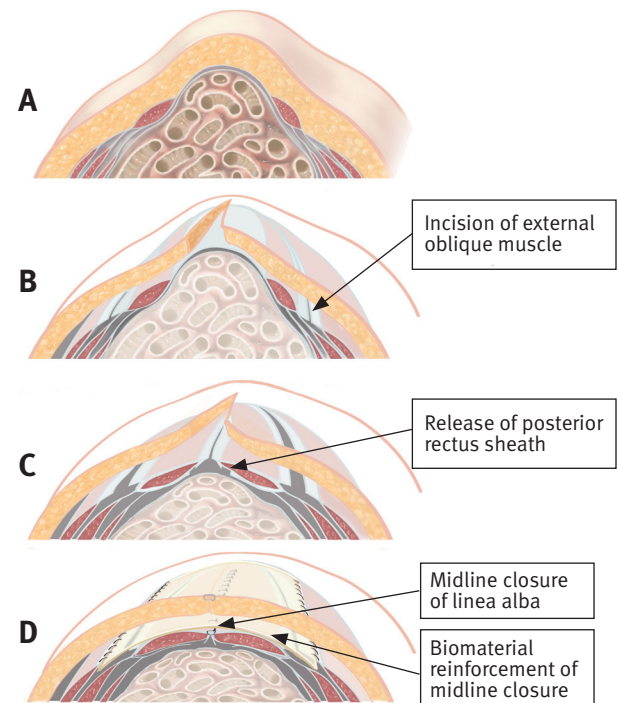Biomaterial reinforcement of midline closure

Figure 1. Components separation method for repairing a ventral hernia. A) Ventral hernia. B) Release of the external oblique muscle allows a gain of approximately 2 cm in both the upper and lower third and about 4 cm in the middle. C) Release of the posterior rectus sheath allows gains of approximately 3 cm, 5 cm, and 3 cm, respectively, in the upper, middle, and lower third. Thus, the total gain includes 5 cm in the upper third, 9 cm in the middle, and 5 cm in the lower. D) Ventral hernia repair with onlay biomaterial reinforcement.

Although some of the clinical results achieved with biologic prostheses in ventral or incisional hernia repair have been promising,[18,19] overall, the reported rates of postoperative wound complications and hernia recurrence do not appear to be substantially lower than those associated with other devices or methods. It might be assumed that this is because biologic prostheses have been used primarily for repairs in contaminated or potentially contaminated fields. However, as both Harth and Rosen[16] and Hiles et al[17] have noted, little of the reported experience with biologic mesh has actually been in such fields.

The high cost of biologic prostheses is often mentioned as one of their primary disadvantages. Costs vary widely among institutions, making comparisons difficult, but Rosen[20] estimated that the purchase price of a biologic prosthesis may be 10 to 20 times that of a similarly sized nonabsorbable synthetic graft.

Certain biologic prostheses have specific drawbacks. Some must be soaked for several minutes to achieve rehydration before implantation. Xenografts that have undergone cross-linking during processing have been shown to be susceptible to mechanical failure, disintegration, and poor tissue incorporation in the setting of infection.[16] Particular disadvantages of human tissue grafts include their relatively small sheet size, possible limitations in supply related to their cadaveric origin, and the tendency of the material to stretch, which may result in a clinically evident abdominal bulge that requires additional reconstruction.[21,22]

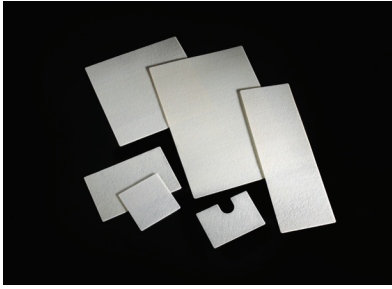## GORE® BIO-A® Tissue Reinforcement

Figure 2. GORE® BIO-A® Tissue Reinforcement is available in sizes up to 20 cm x 30-cm.
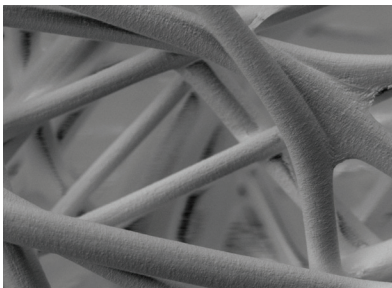

Figure 3. GORE® BIO-A® Tissue Reinforcement consists of an open, highly porous 3D matrix (SEM 250x).

GORE® BIO-A® Tissue Reinforcement, (W. L. Gore & Associates, Flagstaff, AZ; Figure 2), may represent an improvement over a biologic prosthesis in CS repairs that require mesh for reinforcement of a midline fascial closure. This synthetic product is composed to a [co]polymer (polyglycolic acid:trimethylene carbonate [PGA:TMC]) that is gradually absorbed by the body. The device has a three-dimensional matrix consisting of open, interconnected pores (Figure 3). Like ECM, the matrix serves as a scaffold for tissue regeneration, but consists of polymer fibers instead of decellularized tissue. After implantation, the bioabsorbable material undergoes hydrolytic degradation over a period of about 6 months, leaving behind no synthetic material that could cause late complications. The PGA:TMC also encourages the development of vascularized tissue, a well-known effect of implanted porous materials.[23,24] As a result, the polymer scaffold is replaced by a layer of new tissue that reinforces the suture closure.

PGA:TMC has a long history of use in the manufacture of absorbable sutures. Since the mid-2000s, stapler sleeves or covers made of PGA:TMC (GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement; W. L. Gore & Associates) have been used successfully to reinforce or buttress staple lines and thereby reduce leakage and/or bleeding in patients undergoing weight-loss surgery,[25] colorectal surgery,[26] pancreatectomy,[27] or appendectomy.[28]

The development of GORE® BIO-A® Tissue Reinforcement has made PGA:TMC available in a sheet form (of up to 20 x 30-cm in size) that allows substantial flexibility of use in soft-tissue reinforcement. The prosthesis is easier to handle than most biologic meshes and has a longer shelf life and a lower cost. Its use requires neither tissue tracking, preoperative soaking, nor operative stretching of the prosthesis.

Clinical Experience with GORE® BIO-A® Tissue Reinforcement

Two previous clinical investigations of the tissue scaffold have been reported. Mussack et al[29] used it to reinforce the pelvic floor in patients who underwent laparoscopically assisted abdominoperineal resection for anorectal carcinoma. Two wound infections occurred postoperatively, but both were treated successfully without removing the material. Cine magnetic resonance imaging performed 3 months postoperatively showed complete integration of the prosthesis into the pelvic floor, without evidence of seroma, infection, or perineal hernia.

Massullo et al[30] employed the scaffold to repair hiatal hernias larger than 5 cm in 17 patients, 14 of whom had gastroesophageal reflux disease. During the mean follow-up period of 13 months in the 16 patients evaluated, there were no mesh infections, mesh erosions, or cases of fistula formation. One patient (6%) had a hernia recurrence.

In our hernia center, the device was used to reinforce the fascial closure during abdominal wall reconstruction with primary fascial reapproximation in 33 patients (mean age, 55 years [range, 26-78]; 19 women [55%]) between October 2008 and September 2010 (Figure 4). The patients' mean preoperative body-mass index (BMI) was 28.5 kg/m^2 (range, 19-42). Twenty percent of the patients had diabetes mellitus, 15% were current smokers, and 11% were undergoing long-term management of metastatic cancer after hyperthermic intraperitoneal chemotherapy. Sixteen patients had a recurrent hernia that had been repaired a mean of 2.4 times previously (range, 1-6).

In most patients (59%), abdominal wall access was obtained through a low-lying transverse incision, with elevation of the skin on the anterior wall (Figure 4A). In 50% of cases, panniculectomy was performed concomitantly with hernia repair. If possible, the CS procedure consisted of a simple external oblique release to allow mobilization of the rectus muscles to the midline. If necessary to obtain reapproximation, a posterior rectus sheath release was also done. Initially in our experience, the device was simply positioned in the midline as an onlay reinforcement and held in place with absorbable tacking sutures placed circumferentially in the fascia of the anterior rectus sheath (Figure 4B). Subsequently, we switched to an onlay with a wider coverage, and in 17 (50%) of our patients, the edges of the device were sutured to the released fascia of the external oblique muscle by using absorbable sutures. In eight patients, we placed the prosthesis in a retrorectus position (Stoppa technique) after evaluating the quality of the abdominal fascia and musculature. A combined anterior onlay and retrorectus placement was performed in another patient. Because we observed that the device was useful in supporting tissue transfers in large flank hernias, we employed it as either an underlay (one patient) or an onlay (one patient) in repairs of lateral flank defects after fascial reapproximation.
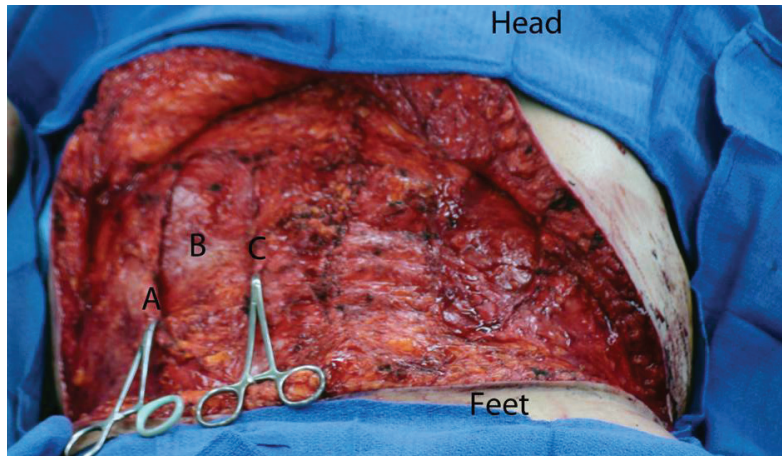

Figure 4A. Transverse incision. A) Released external oblique fascia. B) The internal oblique transversus complex. C) The lateral edge of the anterior rectus fascia.
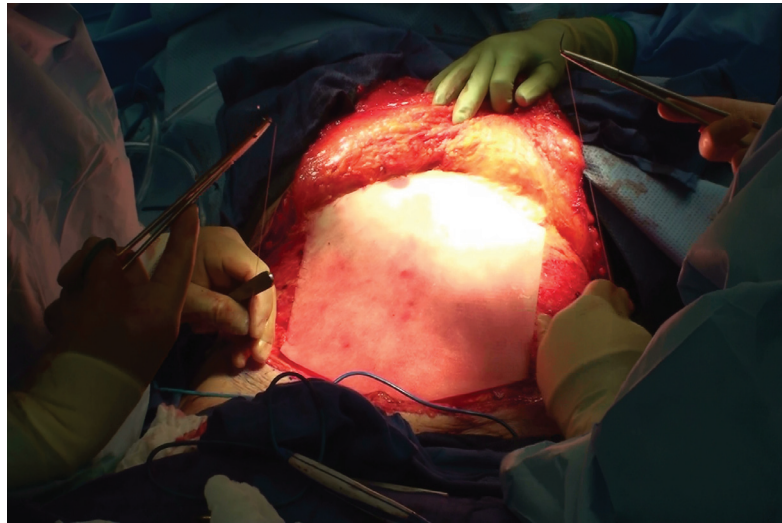

Figure 4B. Intraoperative photograph of onlay placement of the GORE® BIO-A® Tissue Reinforcement.

The operative field was clean in 26 cases in our series, clean-contaminated in 4, and contaminated in 3. The clean-contaminated cases involved either a bowel resection or stomal relocation. In two of the contaminated cases, removal of large sheets of infected prosthetic material was necessary; in the other, the patient had a perforated ischemic parastomal hernia. In patients who underwent either anterior CS or retrorectus placement, drains were placed between the skin flap and anterior rectus sheath.

The mean ± SD hernia defect length was 11.8 ± 6.5 cm, the width was 10.7 ± 6.0 cm, and the surface area was 145 ± 164 cm^2. In the first half of the series, two 9 x 15-cm sheets of the device were required to reinforce the midline fascial closure and site of external oblique release; subsequently, the 20 x 30-cm size was used routinely. The mean operating time was 2.5 hours (range, 45 minutes to 6 hours). The average hospital stay was 5.4 ± 5.4 days. Drains were left in for a mean of 16 ± 8 days and were usually removed at the first clinic visit 2 weeks postoperatively.

No patient died during the observation period. The most serious adverse event in the series was necrosis of the skin flap, which developed within a week of surgery in two patients with recurrent hernias who had panniculectomy concomitantly with hernia repair. One of the patients was a 73-year-old woman with a BMI of 30 and a 180-cm^2

defect who had undergone a sixth hernia repair (an anterior release and onlay placement of the device). The other was a 66-year-old woman with a BMI of 26 and a 6-cm^2 defect who had a third repair (a primary reapproximation and onlay placement of the device). Neither patient was a smoker, and their hernia repair in our unit had been performed in a clean field; however, their histories of multiple repairs through various abdominal wall incisions put them at a higher risk of complications. Both patients required operative skin debridement and vacuum-assisted closure, but neither explantation nor debridement of the device was necessary. For the first patient, it has now been more than a year since her repair. A clinic visit on postoperative day 331 showed that she was fully recovered, without any clinical evidence of recurrence. For the second patient, more than 2 months have passed since her surgery and she is scheduled to undergo an abdominal scar revision.

Another patient in our series, a 60-year-old woman, required prolonged ventilatory support after her hernia repair. She had previously undergone six repairs at various institutions and presented to us with an infected biologic mesh (crosslinked acellular porcine dermis) that had been used to bridge a large defect (900 cm^2). Her most recent repair, at another institution, had required tracheostomy, which had been removed by the time we first saw her. In our unit, the patient underwent staged therapy that included excision of the infected prosthesis and placement of multiple skin grafts over a 1-year period. The skin grafts eventually ulcerated, however, resulting in chronic bleeding requiring intermittent transfusion. Finally, the patient underwent excision of the ulcerated grafts, anterior and posterior fascial release, reapproximation of the midline fascia, and onlay buttressing with a 20 x 30-cm sheet of the device anchored to the released external obliques. At closing, her peak expiratory pressure was high (33 cm H$_2$0), mandating admission to the intensive care unit for ventilatory support. A percutaneous tracheostomy was performed preemptively on postoperative day 8, and the patient was subsequently weaned to a tracheostomy collar. Decannulation was performed on postoperative day 15, and the tracheostomy and drains were removed on postoperative day 18. More than 2 months after her CS hernia repair, the patient is doing well.

Three patients had postoperative development of a seroma, with all of the fluid collections located between the skin and anterior abdominal wall. Two of the patients had undergone external fascial release and onlay implantation of either two 9 x 15-cm pieces of the device (one patient) or one 20 x 30-cm piece (one patient). In the third patient, a 9 x 15-cm device had been placed in an onlay position to buttress a flank reconstruction. The drains were removed 20, 24, and 17 days after surgery, respectively, and all three patients observed a subcutaneous collection approximately a week later. Two of the seromas were drained percutaneously at a single office visit; the third required placement of an indwelling catheter for a week. Culture of one of the seromas yielded methicillin-resistant *Staphylococcus aureus* (MRSA), and the patient underwent antibiotic therapy. This patient had undergone removal of a MRSA-contaminated mesh at the time of abdominal wall reconstruction. The three patients with seroma formation were last seen on postoperative day 213, 101, and 56, respectively, and were doing well. Our seroma rate of 9% compares favorably with the 25% rate we had observed when using traditional biologic materials in procedures similar to those performed in this series.

Case Series Summary	
Number of patients	33
Hernia defect size	Mean, 145 cm^2
Age	Mean, 55 years (range, 26-78)
BMI	Mean, 28.5
Patient factors	48% had recurrent hernia (mean, 2.4 previous repairs) 20% diabetic 15% smokers 11% undergoing chemotherapy
Placement	55% onlay 34% rectorectus 11% other
Operative field	79% clean 21% clean-contaminated or contaminated
Results	
Follow-up	Range, 6-687 days Mean, 120 days
Complications	3 seromas
Recurrences	0

The mean follow-up time in our series is currently 120 days (range, 6 to 687). Two patients have been followed for at least 1.5 years, 9 for more than a year, and 18 for at least 6 months. None have shown evidence of recurrence on physical examination. The second patient to be enrolled in our series underwent computerized tomographic (CT) scanning on post-operative day 647 for reasons unrelated to the hernia repair; images obtained then and before surgery are shown in Figure 5. Figure 6 is a positron emission tomographic (PET) scan showing a 20 x 30-cm sheet of the Gore device implanted 3 months earlier in a patient undergoing cancer surveillance. The shield-shaped area where the product was placed (center of image) is visible due to cellular metabolic activity.

The performance of GORE® BIO-A® Tissue Reinforcement in this small series of patients undergoing abdominal wall reconstruction of ventral hernias was good. Although seven cases were performed in either a clean-contaminated or contaminated field, only one infection, of a seroma, occurred postoperatively. In no patient did the device become in-fected or require removal. The other major adverse events in the series were not related to the prosthesis. No ventral or incisional hernia recurrence has developed in a patient in whom a device was implanted, although the follow-up time is still relatively short. The handling properties of the mate-rial are excellent. It is very easy to tailor, allowing precise tissue approximation and the potential for reduced seroma formation. The device is also easy to manipulate and sew, and it is ready to use on removal from its packaging. If more pliability of the material is desired to enhance conformability to the body, it can be soaked in sterile saline for a few minutes before use. Finally, the cost of the device at our institution is approximately one third to one sixth that of biologic scaffolds, which represents a considerable advantage in this era of great concern about the cost of health care. We are very impressed by the short-term to medium outcomes with GORE® BIO-A® Tissue Reinforcement, although large, multicenter, long-term studies of its use in CS repairs are needed.
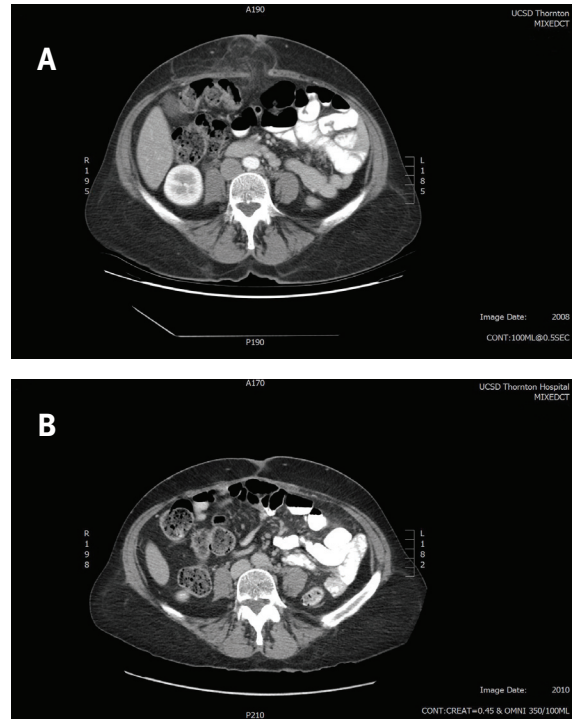

Figure 5. CT scans obtained before (A) and 1.8 years after (B) anterior components separation repair with onlay placement of GORE® BIO-A® Tissue Reinforcement.

Figure 6. PET scan showing a 20 x 30-cm sheet of the Gore device implanted 3 months prior. The shield-shaped area where the product was placed (center of image) is visible due to cellular metabolic activity.

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