Techniques for Using Biologics in Ventral Hernia Repair

Introduction

Although more than 100,000 incisional ventral hernia repairs are performed in the United States each year,1 short-term morbidity (eg, seroma, diastasis, infections) continues to be a major problem and recurrence rates remain high (ranging from 32% to 63% for direct suture repairs).2,3 The use of prosthetic mesh materials has significantly reduced recurrence rates; however, the use of synthetic mesh has led to complications, particularly in complex repairs.1

Biologic grafts of various types (human, bovine, and porcine) have been developed to offer improved biocompatibility and to minimize complications associated with high-risk wounds.4 These grafts are designed to serve as an extracellular matrix (ECM) scaffold for neovascularization and eventual remodeling of tissue to resemble the native type.5 In fact, the use of biologic mesh is increasing and is particularly useful as an adjunct to surgical procedures such as abdominal wall repair, where high tensile strength is important for the promotion of durable repairs.4 However, the characteristics of mesh considerably differ—even within the same class—partly as a result of tissue-specific manufacturing processes.4
**Patient and Mesh Selection**

There are a variety of surgical approaches available for ventral hernia repair in the setting of stable soft tissue. Determinants of the approach include wound characteristics, past medical history and number of prior surgeries, anatomy, vascularity, blood supply, and the presence of a malignancy.\(^3\)

Synthetic mesh-related infections are a major problem with open repairs of incisional hernias, and strategies to minimize the risk for infection are important when formulating an operative approach.\(^5\) Mesh-related infection rates were as high as 25% in some series and, importantly, mesh-related infection is a risk factor for hernia recurrence.\(^3,6\)

Mesh-related infection also can cause substantial short-term morbidity associated with complications, including enterocutaneous fistulae and reoperation to remove an infected mesh.\(^7\) Infections may be associated with preexisting infection, skin ulceration, obesity, bowel obstruction, and perforation of the bowel during hernia repair—\(^3\)—a constellation of problems that underscore the importance of risk assessment when selecting a mesh material. The clinical and economic costs of treating wound infections in a high-risk patient population are important considerations in matching patients to the most appropriate hernia repair strategies.

Assessing a patient’s risk for wound infection may influence the approach to surgery and mesh placement, as well as the choice of an appropriate prosthetic repair material. No material is a substitute for meticulous surgical technique.\(^4\) Wound-healing problems, however, must be anticipated in this population and risks must be communicated clearly to patients during preoperative planning.

The problem with using less expensive synthetic meshes is that if the patient develops a wound infection or a wound dehiscence and the mesh becomes exposed, you now have to reopen them and excise the mesh,” said Kurtis Moyer, MD, FACS, assistant professor of surgery, Division of Plastic Surgery, Penn State Milton S. Hershey Medical Center, Hershey, Pennsylvania.

Biologic meshes can be used in an open wound, even when you cannot get the skin closed. “You can put dressings directly on top of these dermal meshes—something you can’t do with the majority of synthetic meshes—and just allow them to heal, while retaining the benefit of the hernia repair,” said Dr. Moyer. He prefers biologic meshes due to the high-risk patient population he treats, but he emphasized the importance of matching the right patient with the right repair material, noting that patients who require a routine hernia repair are not candidates for a biologic mesh. “These [biologics] are for complex abdominal wall reconstruction in patients who have had multiple failures and recurrences and are at high risk for wound infection and wound dehiscence,” he said. Additionally, standard mesh prosthetics generally are not recommended when contact between the material and the intraabdominal viscera is inevitable.\(^3\)

Robert Southard, MD, assistant professor of surgery, Washington University School of Medicine, St. Louis, Missouri, also is mindful of the risks for complications in patients with complex problems, as well as the need for a strong repair material that will promote a durable repair. “In the very early time point, I feel that many of my patients need a very strong mesh,” he said, noting that his biologic mesh of choice is a porcine acellular dermis and that he has used XCM with positive results (Figure 1). In addition to strength, Dr. Southard considers elasticity in his clinical decision making around mesh materials. “The human products have a higher concentration of elastin in them than the porcine products do, and therefore will slowly bulge and stretch over time,” he said.

**Hernia Repair Techniques**

No algorithm has been developed to suggest best practices for surgical approach or mesh positioning. “There’s not one good technique or agreement on a technique for a particular scenario. And therefore we’re still kind of struggling to come together with an agreed-upon algorithm. And we’ll get there. It’s just going to take time and data,” said Dr. Moyer. However, there is substantial experiential data to aid surgeons in optimizing hernia repair with mesh prosthetics. Although surgeon experience has been identified as the most important prognostic factor for ventral hernia repair,\(^7\) clinical outcomes may be influenced by surgeons’ understanding of the indications for current mesh placement techniques and factors influencing the selection of a repair material.\(^8\)

The 4 main techniques that are used for mesh placement in abdominal wall reconstruction are as an onlay (overlay); as a bridge secured to the fascial edges (interpositional); as an underlay (sublay) in either a retrorectus, preperitoneal, or intraperitoneal position (Figure 2); or as a sandwich, which generally is characterized by a mesh inlay (or underlay), a primary repair with or without components separation (CS), and finally, an onlay mesh placement.\(^3,9\)

Each technique has benefits and limitations. For example, Dr. Moyer suggested that onlay should be reserved for scenarios in which complete fascia-to-fascia repair has been achieved; the interpositional (bridging) technique is performed when edges of the abdominal fascia—the composite layers of which are the abdomen’s source of structural integrity\(^9\)—cannot be reapproximated. Ultimately, the goal of hernia repair is to return uniformity of abdominal wall counter-pressure against the viscera, to improve the counter-pressure where it is weak, and sometimes, to weaken the abdominal wall where it is strong.\(^10\)

Current mesh placement techniques are underrepresented in the literature.\(^3\) “It’s very important, then, for surgeons to understand what is going on, how this is evolving, and the techniques and terms,” said Dr. Moyer. Knowledge of the anatomy of the abdominal wall and the forces acting on it are critical when selecting an approach and technique.
**Onlay (Overlay)**

Eduardo Rodriguez, MD, DDS, associate professor and chief of plastic surgery, R Adams Cowley Shock Trauma Center, Baltimore, Maryland, has transitioned from using human acellular dermal matrix to porcine biologic mesh for abdominal wall surgery, and he places mesh primarily in the onlay position as a means of buttressing the abdominal wall or fascia. “The percentage of patients who will develop recurrent hernia is pretty high,” he explained in describing his approach. “Even though I am able to approximate fascia primarily, I prefer to buttress the abdominal wall to eliminate the recurrence. I don’t want even a small potential of hernia or even a bulge,” he said of his approach, which he modifies depending on the available amount of native abdominal wall musculature or fascia, the complexity of the operation, and the patient’s health during the operation (eg, obesity, pulmonary dysfunction). For patients in whom it is not possible for Dr. Rodriguez to primarily repair the fascial defect, he performs a CS (external oblique and fascial release). “If I am able to approximate fascial release, afterward I will buttress the midline repair as well as the fascial release with the biologic material to avoid further lateralization of the external oblique fascial release,” he said.

He sometimes uses the interpositional mesh placement technique. “Perhaps patients are morbidly obese, or they had a significant amount of intraabdominal surgery, or maybe they lack fascia,” Dr. Rodriguez said in delineating his decision-making process. “In these cases, I will use the material for interpositional application.”

In the past, he used human biologics but found them to have an unpredictable amount of elasticity. “In my hands, when used as an interpositional material, we always had recurrences with human biologics,” said Dr. Rodriguez. He has now entirely transitioned to porcine products for abdominal wall surgery. “They are durable and much stronger. This is especially true for XCM; I have not had any problems with it,” he said. Because all biologic meshes have the potential—histologically as well as clinically—for some stretching, Dr. Rodriguez places mesh under “a modest amount of tension,” thoroughly securing it to abdominal fascia with nonresorbable sutures.

Compared with an underlay placement, onlay mesh positioning is easier to perform and the technique does not mandate the devascularization of the rectus. Limitations of the onlay technique include its fairly high potential for wound breakdown, risk for mesh exposure, and the development of seroma.

Among his recent experiences with XCM, Dr. Rodriguez recounted a case where, despite the patient experiencing wound dehiscence, the abdominal wall had healed well. “I ended up treating the wound conservatively, brought the patient back to the OR [operating room] once the wound had healed, excised the hypertrophic scar, and closed the subcutaneous tissue without any additional fascial reconstruction,” he said. The patient’s progress currently is being evaluated on a monthly basis.

XCM has been evaluated for its biomechanical properties (tensile, suture pullout strength) and measures of host response. XCM offers the greatest tensile strength compared with the other mesh products that were tested, including...
those made from polytetrafluoroethylene (PTFE), heavy-weight macroporous polypropylene, midweight macroporous prolene/cellulose/polydioxanone (PDS), and normal human fascia (Figure 3). XCM also has the greatest suture pullout strength compared with PTFE and midweight macroporous prolene/cellulose/PDS mesh materials (Figure 4).

Another important consideration for ventral hernia repair with mesh is the availability of different sizes. “When you get a sheet that is large enough to reconstruct the fascial defect or buttress the fascial repair, I think the results are more favorable,” Dr. Rodriguez said. To accommodate the needs of surgeons who perform ventral hernia repair, XCM is available in 18 different sizes, ranging from 2 cm × 4 cm to 20 cm × 30 cm.

**Interpositional and Inlay**

Dr. Moyer’s preferred approach, when feasible, is to place mesh as an inlay between the layers of the anterior and posterior sheaths as part of a primary fascial closure. Depending on the specifics of a hernia repair, he may use an onlay or interpositional technique. “For anyone doing hernia repair, the gold standard is to get it closed primarily,” he said.

Dr. Moyer’s hernia repairs usually involve CS with mesh placed as an inlay, due to the nature of his cases. “If I don’t perform a separation of components, it usually indicates that the hernia cannot be primarily repaired. In those cases—more than 90% of the time—it necessitates the interpositional or ‘spanning’ mesh placement (ie, ‘bridging’).”

CS generally provides surgeons with up to 5 cm of additional length on either side, for a theoretical total gain of 10 cm (a variation known as the Memphis modification may add an additional 20 cm overall). The additional length aids in primary repair of the fascia. “If you can get it closed primarily without a lot of tension and it heals, that’s the strongest repair with the greatest likelihood of no recurrence,” Dr. Moyer said.

He sees a complex patient population for whom primary hernia repair often is not possible. In this setting, interpositional mesh placement may represent the best approach. He characterizes mesh placement techniques as “evolving” and has modified his approach, guided by improved clinical outcomes and reduced recurrence rates. Dr. Moyer reported that he has gathered data at Penn State for a retrospective study of hernia repair cases in which several techniques and prosthetic materials were used. He has used several types of porcine dermal meshes, but most of his experience is with XCM, a product he finds notable for its ease of use as well as its good clinical results.

Dr. Moyer reserves the interpositional mesh placement for patients in whom primary hernia repair cannot be obtained, perhaps as a consequence of scarring or chronicity that has resulted in a loss of abdominal domain. Surgeons who perform abdominal wall reconstruction see patients with numerous problems that increase the risk for developing complications. “These aren’t routine hernias,” he said of the cases referred to him. “These are morbidly obese patients, or patients with large, chronic hernias that have been repaired multiple times, people with a BMI [body mass index] above 30 [kg/m²], aged 50 years or older. Some have a past history of tobacco use, or have diabetes.”

**Underlay**

Dr. Southard’s preferred technique, in general, is ventral hernia repair with an underlay mesh placement, ideally with primary closure of the native fascia. “I think the data, though not necessarily robust, suggest that underlay meshes give a longer-term repair,” he said. Dr. Southard sees the majority of his patients in the emergent-care setting (eg, bowel
obstructions and other intraabdominal pathologies). “If the patient is unstable, or you’re just trying to get the abdomen closed and get out as quickly as possible, then the other options are reasonable,” he said. He occasionally buttresses the fascial closure with an onlay mesh in a sandwich-style technique, using the additional buttress to help keep the rectus muscles in the midline. Dr. Southard said he thinks this might turn out to be a better approach. Because durable repairs may partly hinge on being able to close native fascia, Dr. Southard considers CS to be a useful adjunct in some cases. “Sometimes you can get the native fascia closed just with the use of the buttress,” he noted.

At Barnes-Jewish Hospital, surgeons can decide which mesh materials they use; Dr. Southard generally prefers a non-crosslinked, porcine acellular dermis, such as XCM Biologic. Dermis-based meshes are useful because resorbable mesh materials may not require removal if they become infected. Infected synthetics, on the other hand, often require removal, which usually results in a difficult and expensive hernia repair. Gaertner and colleagues described some potential advantages of biologic materials, such as better host tissue infiltration and improved vascularization and tolerance against infections when compared with synthetic-based materials. Although there are no meshes currently approved for use in an infected field, Dr. Southard is hesitant to place synthetic meshes in the types of patients he sees in the emergent setting who are at increased risk for infection.

He recounted a recent case that involved a 136-kg woman with a bowel obstruction. Once in the OR, it quickly became apparent that a portion of her transverse colon was truly incarcerated. “She was at very high risk for an infection if a synthetic mesh was placed, and we elected to place a biologic mesh,” said Dr. Southard. “We chose XCM [Biologic] in this case because the size available matched up well with what the patient needed. We did an underlay in the retrorectus position and were able to close the posterior fascia as well as the anterior fascia over the top of the underlay, and then buttress that with a piece of the mesh that we had trimmed off.” Primary fascial closure was obtained without a CS and the onlay was placed to reinforce the repaired hernia. “By definition, most of these patients with ventral hernias have suspect fascia, at best.”

Dr. Southard tends to choose dermal biologics for higher-risk patients because of their relative strength. “The dermal products seem to be strong and for many of our patients, the strength of the mesh itself is extremely important—especially when we’re unable to buttress the repair and we’re using the material as a bridge,” said Dr. Southard. That strength is very important during the initial repair. Over time, the ultimate strength of a repair depends on how well the tissue is incorporated—but early on, “my patients need a very strong mesh and the dermal products are preferred,” he said.

Figure 5. Primary repair of the abdominal wall using the components separation technique. Image courtesy of Anthony Dardano, DO.

**Sandwich Technique**

Anthony Dardano, DO, FACS, assistant professor of biomedical sciences and surgery, Charles E. Schmidt School of Medicine, Florida Atlantic University, Boca Raton, Florida, performs the sandwich technique, which involves an intraperitoneal underlay of biologic mesh, primary closure of the abdominal wall using a CS technique (Figure 5) or primary repair of the midline, and a biologic mesh onlay to reinforce the midline repair. The onlay is used not only to reinforce the suture line, but also to reconstruct the external oblique fascia (Figure 6). He finds this approach works well for durable repairs of large ventral hernias and failed primary repairs. Early data are favorable and support the technique. In 53 patients who underwent hernia repairs with the sandwich technique at his institution, there has been a 3.7% recurrence rate, 21% infection rate, and 7.5% wound dehiscence rate at 2-year follow-up.

The sandwich technique is not yet in every surgeon’s toolkit, and Dr. Dardano noted that it has its detractors. “Some people feel that this may be overkill and don’t understand why this technique was developed,” he said. “I explain my answer to them by comparing the abdominal wall to a barrel in which the abdominal pressure is exerted outward equally in
all directions. When there is a hernia present, or a weakness in the abdominal wall, the contents of the abdomen find their way through this area where the pressure is unequally distributed. Eventually, pressure will develop in that area, such that almost the entire abdominal contents could end up passing through this weak area with no resistance. So, just placing a patch over the defect doesn’t work … if just tissue is primarily brought together with suture, then it could break open and recur.” The underlay uses this physiologic principle as an advantage by patching the defect from the inside and allowing the pressure to distribute itself against the abdominal wall equally and outwardly, he added.

The sandwich technique is not for use in patients with large soft tissue losses of the abdominal wall or for large lateral or posterolateral defects, and it is not appropriate for routine hernia repairs.9 “It’s not for your everyday, run-of-the-mill primary hernia that’s 5-, 6-, or 7-cm in size,” said Dr. Dardano. “This technique is specific to the recurrent ventral, the incisional, and the giant hernia that has failed before—or that has just become so large that there’s loss of abdominal domain and something needs to be done to correct it.” Although the sandwich technique is technically challenging, those interested in mastering the technique should foster a collaborative approach. “When you get a good general surgeon and a good plastic surgeon working together, I think the outcome is the best,” he said.

One of Dr. Dardano’s goals in abdominal wall reconstruction is to reinforce suture-line repairs in a way that is conducive to ingrowth and revascularization and incorporation of the mesh (Figure 7). “The difference between biologic and synthetic mesh is that with biologic, you have the body accepting, incorporating, and revascularizing the tissue as opposed to the body rejecting it [treating it as a foreign body] and developing a scar or an inflammatory response,” he said. “I have had patients who developed complications and fared well with a biologic mesh who would not have done so well had they had synthetic mesh placed,” he said. “Once the wound becomes colonized with bacteria and the underlying mesh is exposed, you’re in a failure situation. With biologic mesh, we don’t have to worry about that.”

In fact, animal data have shown that the XCM maintains strengths greater than native tissue throughout the healing process (Figure 8).11,12 This was shown in a study conducted by Hackett and colleagues, which reported that porcine-hydrated dermis ECM mesh performed favorably when compared with native fascia.15

A one-time proponent of using synthetic mesh in combination with biologic mesh, Dr. Dardano now uses only porcine biologic mesh and has been impressed by the availability of large sizes and by the body’s incorporation of these grafts. Even in patients who experience wound-healing issues, Dr. Dardano can manage the infection successfully without compromising the hernia repair because the biologic tissue does not have to be removed, “which is its greatest advantage.”
One challenging case helped Dr. Dardano decide to “go completely biologic.” The repair was performed with a biologic underlay and a synthetic onlay. The patient developed a postoperative seroma and subsequent colonizing wound infection; the synthetic mesh scarred to the abdominal wall. “The infection was so difficult to eradicate that we had to surgically remove the mesh and in doing so, removed most of his abdominal wall fascia with it. So, despite a successful hernia repair, we had to remove most of his abdominal wall tissue and reconstructed him with onlay biologic material,” Dr. Dardano explained. “It made me stop and think as to why I would not be using biologic material throughout from the beginning.”

Differential Characteristics of Biologic Meshes

Among the many biologic products commercially available for use in abdominal wall reconstruction are products derived from ethylene oxide–treated porcine submucosa matrix\textsuperscript{16}; $\gamma$-irradiated chemically crosslinked acellular porcine dermal matrix\textsuperscript{17}; and ethylene oxide–treated, chemically crosslinked acellular porcine dermal matrix.\textsuperscript{18} More recently, ECM-derived biomaterials have been developed for surgical applications in which it is advantageous to have a more natural material; among them is XCM Biologic tissue matrix,\textsuperscript{19} a sterile, non-crosslinked, 3-dimensional matrix derived from porcine dermis.

An important aspect of decellularized ECM materials as nonpermanent foreign bodies is the balancing of strength and resorption.\textsuperscript{14} For example, postoperative infection of the adjacent soft tissue does not require the removal of a resorbable mesh material.\textsuperscript{14} The microstructure, composition, mechanical properties, and processing methods vary among biologic mesh materials.\textsuperscript{15}

Decellularization methods of biological matrices may affect the extracellular components\textsuperscript{19} and specific tissue-processing techniques; rather than biologic source of origin, appear to be the more important determinants of product function as a consequence of yielding modified collagen matrices.\textsuperscript{20} Clinically, this may be associated with scar tissue formation, inflammatory responses, graft pleating, minimal integration, and absence of vascularization.\textsuperscript{20}

In a preclinical study, XCM was demonstrated to exhibit minimal inflammatory response, low surgical site morbidity, and appropriate tissue regeneration in conjunction with a high tensile strength—an important attribute in clinical applications such as abdominal wall repair, for which it is indicated along with other types of soft tissue repairs.\textsuperscript{11,12} A study by Hackett and colleagues investigated the tensile strength of a porcine dermis ECM mesh and compared it with both native and defective fascia.\textsuperscript{15} The authors then compared these findings with those from their previous study, which tested 2 commercially available biologic meshes versus native and defective fascia.\textsuperscript{15,21} The preimplantation strength of the porcine dermis ECM mesh was more than 5 times greater than that of meshes made from porcine small intestinal submucosa and bovine crosslinked collagen; additionally, it was more than 8 times stronger than native fascia.\textsuperscript{15,21} Immunohistochemical evaluation has shown that after processing, XCM retains a complex array of ECM proteins and cytokines present in native tissue, including collagen III, IV, and VII; laminin and fibronectin; vascular endothelial growth factor; and transforming growth-factor $\beta$.\textsuperscript{14} Further study will help to define the most beneficial soft tissue applications of this mesh, which has demonstrated good utility in abdominal wall reconstruction.\textsuperscript{14}

Conclusion

Surgeons can choose mesh materials of various biologic origins and manufacturers for ventral hernia repair. XCM Biologic offers several potential advantages for patients, including good tensile strength and suture pullout strength. XCM Biologic is manufactured to remove cells and DNA for improved host acceptance. Its biologic integrity is conducive to cellular infiltration, offering surgical site healing that is stronger than native fascia.

Having an appropriately sized mesh that requires minimal preparation time is another important consideration for ventral hernia repair. XCM Biologic comes in a wide variety of sizes and immediately is ready for use—a practical benefit offered by prehydration. “Very easy to use; it’s ready out of the package,” said Dr. Moyer. XCM Biologic requires no irrigation prior to being placed in the patient. Dr. Moyer believes that this characteristic compares favorably with meshes that are supplied in a form which requires soaking or rehydration.

\begin{figure}[h]
\centering
\includegraphics[width=\textwidth]{figure8.png}
\caption{Postoperative tensile strength of XCM Biologic versus native fascia (sheep study).}
\end{figure}

From references 11 and 12.
References


Financial Disclosures:
Dr. Dardano reported that he is a consultant of and serves on the speakers’ bureau for Cook Medical, Inc. He also serves on the speakers’ bureau for Kinetic Concepts, Inc., and Synthes. Dr. Moyer reported no relevant financial conflicts of interest. Dr. Rodriguez reported receiving honorarium and research funding from Synthes CMF. Dr. Southard reported that he serves on the speakers’ bureau for Synthes.

Disclaimer: This monograph is designed to be a summary of information. While it is detailed, it is not an exhaustive clinical review. McMahon Publishing, Synthes, and the authors neither affirm nor deny the accuracy of the information contained herein. No liability will be assumed for the use of this monograph, and the absence of typographical errors is not guaranteed. Readers are strongly urged to consult any relevant primary literature.

Copyright © 2012, McMahon Publishing, 545 West 45th Street, New York, NY 10036. Printed in the USA. All rights reserved, including the right of reproduction, in whole or in part, in any form.