Updates in Mesh and Biomaterials

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KEYWORDS

• Hernia • Abdominal wall • Biological mesh • Synthetic mesh • Biosynthetic mesh

KEY POINTS

- Additional evidence highlighting the low morbidity associated with synthetic mesh and biosynthetic mesh in clean-contaminated and contaminated fields is provided.
- Additional evidence discussing the limitations of using biologic mesh is provided.
- The future of mesh research may involve trialing novel polymers, alternative ways to deliver antibiotics to surgical sites, and involve data registries including patient-centered outcomes and direct surgeon feedback.

INTRODUCTION

Prior publications of the *Surgical Clinics of North America* have highlighted the technical challenges of abdominal wall reconstruction. In 2008, the issue dedicated to abdominal wall reconstruction discussed the biology of hernia formation, the history of hernia repair, open and laparoscopic ventral hernia repair, and the benefits of the use of prosthetic mesh on patient outcomes. Despite the vast selection of mesh brands available, nearly all mesh continues to use 1 of 3 basic materials—polypropylene, polyester, or polytetrafluoroethylene in various combinations with or without barrier coating. The mesh types differ in many characteristics, including their tensile strength, elasticity, and weight, which depends on pore size and the weight of the polymer. Heavy weight mesh uses thick polymers, small pore size, and high tensile strength, whereas light weight mesh uses thinner polymers and larger pores.

In the 2008 *Surgical Clinics of North America* publication, Bachman and Ramshaw[1] discussed the wide variety of mesh products available for abdominal wall reconstruction and the challenge facing surgeons to choose the most appropriate mesh for ventral hernia repair. Interestingly, they concluded that there was no "best" mesh. Still

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a decade later, the decision of which mesh to use is based on several factors: the type of procedure being performed, the clinical situation (elective vs emergent, Centers for Diseased Control and Prevention [CDC] wound classification, etc), the desired handling characteristics to optimize mesh placement, material costs, and the products available to the surgeon based on hospital material contracts.[1] In the same publication, Jin and Rosen[2] described the limited data available specifically when comparing the long-term outcomes of for synthetic to biologic mesh. It seemed that most mesh selections were based on surgeon's anecdotal experience. Clearly, prospective studies comparing clinical outcomes for the variety of meshes available is needed.[2] In that same issue, Earle and Mark[3] discussed the many variables of mesh designs, including the polymer used, fiber size, fiber strength, elasticity, pore size, density, and bioreactivity. These multiple variables do not allow for direct comparisons. Earle and Mark also stressed that, as more mesh types are being developed, surgeons must balance the uncertainty of long-term outcomes when introducing a new prosthetic against the more certain outcomes of existing products.[3] This challenge remains true a decade later.

The 2013 publication of the *Surgical Clinics of North America* on abdominal wall reconstruction further addressed the clinical outcomes of biologic mesh and the safety of prosthetic mesh repair in contaminated settings. The literature exploring the use of biologic grafts in infected and contaminated fields was disappointing. Preclinical animal studies failed to demonstrate consistent evidence of biological mesh remodeling and long-term clinical outcomes using biologics revealed higher than expected recurrence rates.[4] Alternatively, Carbonell and Cobb[5] cited a relatively low morbidity rate associated with the use of light weight and even heavy weight polypropylene mesh in clean-contaminated and contaminated fields. At that time, however, many surgeons remained reluctant to change their practice based on this literature owing to fears of complications, specifically wound and mesh infections, and using prosthetic mesh off-label in CDC class II and III wounds.

The *Surgical Clinics of North America* is dedicating another publication to abdominal wall reconstruction in 2018, and this article provides an update on biomaterial research. This article specifically reviews synthetic, biologic, and biosynthetic mesh research and concludes with thoughts about the future of mesh research. This update highlights research that has been conducted since the prior publication to guide surgeons to make evidence-based choices about biomaterial for ventral hernia repair that are most appropriate for their patients.

UPDATE ON SYNTHETIC MESH RESEARCH

Since Usher and associates[6] first introduced polypropylene prosthetics for incisional hernia in the late 1950s, synthetic mesh has been the predominate material used for hernia repair. Permanent synthetic meshes provide long-term mechanical support to the hernia defect and have been shown to reduce recurrence rates compared with sutured or primary repair. As the use of synthetic mesh became more commonplace, clinical outcomes studies have been conducted that directly impact the surgeon's decision making with regard to mesh selection. Although permanent synthetic meshes have been engineered for strength and durability, short- and long-term complications have been attributed to their use. As such, additional modification in fiber diameter and pore size to decrease the density of the material were implemented. These meshes are categorized into heavy weight, midweight, and light weight depending on the grams per square meter.[7] Studies before 2013 demonstrated an improved quality of life (QOL) with light weight mesh. However, Groene and

colleagues[8] published a study in 2016 from the International Hernia Mesh Registry database that analyzed both surgical and QOL outcomes after open ventral hernia repair with heavy weight, midweight, and light weight mesh. This multinational, multi-institutional, prospective registry captured QOL surveys at 1, 6, 12, 24, and 36 months. Of the 549 open ventral hernia repairs, patients with midweight meshes had fewer surgical site infections and shorter durations of stay. Recurrence rates were equal (6.1%) among the 3 types of mesh. Nevertheless, light weight mesh was associated with an overall worse QOL at 6 months and more pain at 1 year. Other studies have reported unfavorable consequences of using light weight mesh, specifically mesh fracturing.[9] Whether this finding is a consequence of technique or related to patient comorbidities is not known. However, the benefits of a reduced foreign body reaction owing to the decreased density of material do not seem to be offset by the physicomechanical properties of the mesh.

In the majority of clean-contaminated and contaminated ventral incisional hernia repairs over the past decade, biologic and more recently bioabsorbable synthetic mesh have been used to reduce the incidence of mesh infection and unplanned reoperation. Prospective, longitudinal trials have demonstrated a 2-year recurrence rate of 20% to 30% and 5-year recurrence rates more than 50%.[10] Owing to the disappointingly high recurrence rate and cost of the biomaterials ($2500-$25,000), surgeons began to use permanent synthetic mesh in CDC class II and III wounds. With this off-label use of synthetic mesh, there is now mounting evidence that certain synthetic meshes, particularly wide pore or light weight mesh, may serve as a viable option in contaminated settings.[11] In 2017, Majumder and colleagues[12] published a multicenter, retrospective review of patients undergoing open ventral hernia repair in clean-contaminated/contaminated fields using biologic and synthetic mesh. A total of 126 patients were analyzed with surgical site infections found to be less frequent in the synthetic group (12.3% vs 31.9%) and a lower rate of hernia recurrence in the synthetic group (8.9% vs 26.3%). The synthetic mesh used was most commonly polypropylene (91%), mostly midweight with a microporous design (92%), and placed in a sublay position. Despite recent studies like this, additional evidence will likely be needed to convince surgeons to use synthetic mesh selectively in clean-contaminated and contaminated fields. If one is to consider the total cost of care to manage wound infections, reoperations for ventral hernia recurrence, and so on, synthetic mesh may eventually prove to be superior to biologic reinforcement in select patient populations.

UPDATES IN BIOLOGIC MESH RESEARCH

Biologic mesh was introduced in hopes that the patient's immune cells would infiltrate the material to defend against the bacterial load in a contaminated case and eventually replace the biologic mesh with the host tissue (tissue remodeling). Preclinical evidence that some biologic meshes enabled revascularization of soft tissue repair sites and improved pathogen clearance in contaminated and infected surgical sites.[13,14] The molecular composition of biologic mesh impacts the biocompatibility and biodegradability.[15,16] One aspect of the manufacturing process of biologic mesh is the cross-linking process that results in the creation of bonds between collagen, which is believed to enhance the strength and durability of the mesh.[17,18] The histologic remodeling profile and biomechanical properties of biologic mesh in particular had not been examined until Cavallo and colleagues[19] compared cross-linked (Permacol) or non–cross-linked (Strattice) porcine dermis over a 1-year period in a porcine model of ventral hernia repair. They found that cross-linked mesh demonstrated significant improvement over time in every remodeling category except for scaffold degradation.

Remodeling characteristics of non–cross-linked mesh remained relatively unchanged over time except for fibrous encapsulation and neovascularization. Remodeling scores for non–cross-linked mesh were significantly higher after 1 month compared with non–cross-linked biologic mesh. The tensile strength and stiffness of both cross-linked and non–cross-linked graft tissue composites were greater than the tensile strength and stiffness of the native porcine abdominal wall in the very early postoperative period, but there was no difference in tensile strength or stiffness by the end of the study period (12 months). Researchers concluded that cross-linked biologic mesh reduces the early histologic remodeling profile but does not significantly impact the tensile strength or stiffness of the graft–tissue composites in the long term. Although limitations of biologic mesh exist, they still are being used. Basic science, translational, and clinical research should still be helpful in aiding the decision of which biologic mesh to use, and what technique to apply to optimize mesh integration and overall tissue remodeling to decrease hernia recurrence.

Since the last *Surgical Clinics of North America* update, additional clinical trials have been reported in patients undergoing ventral incisional hernia repair with biologic mesh. Huntington and colleagues[20] prospectively examined the cost and comparative effectiveness of different biologic meshes used for abdominal wall reconstruction at a tertiary hernia center over a 10-year study period. In their study, 223 patients underwent open ventral hernia repair with either Alloderm Regenerative Tissue Matrix (Allergan, Dublin, Ireland), AlloMax Surgical Graft (Bard Davol, Warwick, RI), Flex HD Acellular Dermis (MTF/Ethicon, Inc., Somerville, NJ), Strattice Reconstructive Tissue Matrix (Allergan) or Xenmatrix Surgical Graft (Bard Davol). Their hernia defects were on average 257 $\pm$ 245 cm^2 with a mesh size of 384 cm^2. Of the patients studied, 31% had an infection at the time of operation and 28% had a mesh infection at the time of the operation. Hernia recurrence rates varied significantly by mesh type: 35% Alloderm, 34.5% AlloMax, 37% Flex HDTM, 14.7% Strattice, and 59.1% Xenmatrix over a mean follow-up of 18.2 months. Although 36.6% had postoperative wound infections, the rate of mesh infections requiring explantation was less than 1%.[19] Clearly, the choice of biologic mesh affects the long-term postoperative outcomes in ventral hernia repair and clinical outcome studies such as this can also aid a surgeon in which biologic mesh to choose. Abdelfatah and colleagues[21] published their results regarding long term outcomes with the use of porcine acellular dermal matrix for patients at high risk of infection. After a mean follow-up more than 5 years in 59 of 65 patients, they reported the need to explant mesh owing to infection and hernia recurrence of 25% and 66%, respectively. Patients who had grossly infected wounds had a 100% hernia recurrence rate. Owing to the unreliability of short- and long-term outcomes in patients with infected wounds, biologic mesh should not be used routinely with the expectations of a successful outcome. Several clinical studies have demonstrated that biologic meshes do not necessarily need to be removed when infected and can be managed with serial washout and negative pressure and/or passive dressings. The issue of high-risk patients has also altered mesh selection in patient with class I wounds through multiple grading scales evaluating the risk of surgical site occurrence related to patient comorbidities.

Preclinical and clinical trials, risk stratification, hernia grading, and aggressive marketing have contributed to an increase in demand for biologic mesh over the past decade.[14,22] This push has contributed to an increasing cost of care for the complex ventral incisional hernia patient. There is a lack of level 1 evidence that biologic mesh provides superior outcomes. This controversy continues more than 15 years after their introduction into hernia care.

UPDATE IN BIOSYNTHETIC AND SYNTHETIC ABSORBABLE MESH RESEARCH

The long-term absorbable synthetic materials, termed biosynthetic mesh, are relatively new to surgeons performing abdominal wall reconstruction and were not a focus in the *Surgical Clinics of North America* publication in 2013. Because of its breakdown via hydrolysis, biosynthetic mesh is believed to offer a unique advantage when challenged with bacterial colonization during complex abdominal wall reconstruction.[21] Using biodegradable polymers instead of xenogeneic or allogeneic tissue, biosynthetics provide a temporary scaffold for the deposition of the proteins and cells necessary for tissue ingrowth, neovascularization, and host integration. A variety of absorbable synthetic/biosynthetic meshes are now available and have emerged as a less costly and potentially effective alternative to biologic meshes. One type, GORE BIO-A Tissue Reinforcement (W. L. Gore & Associates, Newark, DE), is a biosynthetic mesh composed of a bioabsorbable polyglycolide-trimethylene carbonate copolymer. This polymer is gradually absorbed by the body within 6 to 7 months.[21] The COBRA (Complex Open Bioabsorbable Reconstruction of the Abdominal Wall) study published by Jin and Rosen[2] in 2017 was a multicenter prospective longitudinal study evaluating the performance of GORE BIO-A for reinforcement of the midline fascial closure in the single staged repair of contaminated ventral incisional hernias. Patients included had a clean-contaminated or contaminated wounds, a hernia defect at least 9 cm, and GORE BIO-A in a sublay, retrorectus, or intraperitoneal position (with at least a 4-cm overlap) with primary fascial closure (n = 104). Concomitant procedures in this cohort typically included enterocutaneous fistula takedown or infected mesh removal. Over a 24-month follow-up period (with 84% completing the study), hernia recurrence rate was 17% by physical examination. Although 29 patients (28%) experienced wound-related complications, no patients required mesh explantation. QOL and return to function significantly improved from baseline for these patients, illustrating that biosynthetic absorbable mesh showed efficacy in several patient-centered metrics. In similar groups of patients, this particular biosynthetic should provide an alternative to biologic and permanent meshes in complex hernia repairs.[10]

A different biosynthetic mesh, Phasix (Bard Davol) and its counterpart Phasix ST (Bard Davol), were evaluated by Scott and colleagues[23] assessing its mechanical and histologic properties. Phasix is composed of poly-4-hydroxybutyrate and Phasix ST composed of poly-4-hydroxybutyrate and an absorbable separate coating made of hydrogel to reduce adhesions. These novel biosynthetic meshes were compared with a partially absorbable permanent synthetic mesh, Ventralight ST (Bard Davol), and a biologic derived dermal mesh, Strattice. In this porcine model, mesh was placed as a sublay repair. Mechanical testing revealed Phasix ST and Phasix demonstrated comparable mechanical and histologic properties to Ventralight ST at 12 and 24 weeks. In addition, the results suggested that fully absorbable meshes with longer term resorption profiles may provide improved mechanical and histologic properties compared with biologically derived scaffolds and serve as a cost-effective alternative for complicated abdominal wall reconstruction cases. There are no prospective comparative studies regarding these devices at the time of this publication to suggest which clinical scenario is suited for their use. Further study is necessary to determine this.

TIGR Matrix (Novus Scientific, Singapore) is an alternative long-term absorbable synthetic mesh. Consisting of a slow-absorbing fiber made of lactide and trimethylene carbonate and a fast-absorbing fiber made of glycolide, lactide, and trimethylene carbonate, this device is designed to fully resorb in 3 years as per the manufacturer

description. There are some limited animal models comparing the use of TIGR Matrix with biologic meshes, Gore BIO-A, and polypropylene, which showed no clear benefit to the use of absorbable meshes in large abdominal wall hernias in rabbits.[24] There is also a single-arm clinical trial in which 40 primary inguinal hernias were repaired with TIGR Matrix with favorable short-term and long-term outcomes.[25] As is likely true with all resorbable meshes, further study in terms of comparative trials are needed to further elucidate their potential context for use.

UPDATE IN HYBRID MESH RESEARCH

More recent iterations of innovative devices include hybrid meshes, which consist of a class of meshes best described by the hybrid use of both biologic components and synthetic components. In theory, the biological components of the meshes are meant to protect the synthetic mesh devices from their surrounding environments. An example of such a device is Zenapro Hybrid Hernia Repair Device (Cook Medical, Bloomington, IN), a combination of extracellular matrix and large pore polypropylene mesh. Similarly to other innovative mesh devices, there are very few human studies—1 to date—that describe its use, and none are comparative head-to-head trials with other devices. The aforementioned study is a 12-month single arm study in 63 patients with Ventral Hernia Working Group Grade 1 and 2 hernias.[26] Likely, the follow-up time frame is too short to make any true conclusion regarding hernia recurrence rates. Further study is needed to determine any potential use for these types of devices, because their biologic component certainly will increase the cost of production, which begs further proof of concept in the opinion of these authors.

FUTURE OF MESH RESEARCH

The best mesh for patients still depends on multiple factors, including wound contamination, patient comorbidities, and surgical technique. Although uncertainty about clinical decision making related to mesh selection remains, the development of additional synthetic, biologic, and biosynthetic meshes continues including novel technologies. For instance, Grafmiller and colleagues[27] investigated a polymer that provides controlled release of an antibiotic in a linear fashion over a 45-day period and found that vancomycin drug-releasing polymers in the form of microspheres adequately cleared a bacterial burden of *Staphylococcus aureus* and prevented mesh infection in a rat model. Poppas and colleagues[28] developed a novel nonbiodegradable hydrogel coated polypropylene mesh and found that it led to a significant decrease in foreign body reaction, oxidative stress, and apoptosis compared with uncoated polypropylene in a rat model. Last, Klinger and colleagues[29] created a model for a "living mesh" with decellularized porcine small intestinal submucosa as a scaffold for human adipose-derived stem cells and analyzed the neovascularization and tensile strength in a rat ventral hernia model. The clinical gap these novel technologies could ultimately cover is to be determined. Nonetheless, innovation in biomaterial development will likely lead to improved patient outcomes. As these clinical studies are completed to evaluate novel technologies, data registries such as the American Hernia Society Quality Collaborative will have a significant role. The American Hernia Society Quality Collaborative was formed in 2013 by hernia surgeons in private practice and academic medical centers using the concepts of continuous quality improvement to improve clinical outcomes, to improve efficiencies of care, and to optimize costs. The patient-centered data collection platform provides ongoing, real-time performance feedback to clinicians in a setting of collaborative learning.[30] The American Hernia Society Quality Collaborative will hopefully provide a mechanism for long-term outcomes

research and postmarket surveillance of new products to aid surgeons who perform ventral incisional hernia repair or abdominal wall reconstruction to select the mesh most appropriate and effective for their patients.

SUMMARY

Since the *Surgical Clinics of North America* publication in 2013, clinical research focusing on the use of biologic and synthetic mesh has brought more, but still limited, clarity to the efficacy of these materials as well as their limitations in particular clinical scenarios. Evidence to support the use of biosynthetic meshes, as an alternative to biologic mesh, in CDC class II and III wounds is intriguing. The use of synthetic mesh in these patients is even more disruptive as the accountability to increasing cost of care increases. It will be important that over the next 5 to 10 years of biomaterial research focuses on patient-centered outcomes and value-based metrics. Surgeon-led initiatives such as the American Hernia Society Quality Collaborative should transform the surgeons' capacity to make evidence-based decision regarding biomaterial selection for abdominal wall reconstruction.

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