The American Journal of Surgery 223 (2021) 375–379

Contents lists available at ScienceDirect

The American Journal of Surgery

journal homepage: www.americanjournalofsurgery.com

Original Research Article

Biologic mesh is non-inferior to synthetic mesh in CDC class 1 & 2 open abdominal wall reconstruction

Jenny M. Shao [a], Sullivan A. Ayuso [b], Eva B. Deerenberg [c], Sharbel A. Elhage [b], Tanu Prasad [b], Paul D. Colavita [b], Vedra A. Augenstein [b], B. Todd Heniford [b, *]

[a] Department of Gastrointestinal Surgery, University of Pennsylvania, Philadelphia, PA, 19107, USA
[b] Gastrointestinal and Minimally Invasive Surgery, Department of Surgery, Carolinas Medical Center, Charlotte, NC, 28204, USA
[c] Department of Surgery, Franciscus Gasthuis en Vlietland, Rotterdam, the Netherlands

ARTICLE INFO

Article history:
Received 11 February 2021
Received in revised form
29 April 2021
Accepted 15 May 2021

Podium Presentation at the American College of Surgeons, 2020

Keywords:
Abdominal wall reconstruction
Hernia
Biologic mesh
Synthetic mesh
CDC wound class

ABSTRACT

Background: Biologic mesh has historically been used in contaminated abdominal wall reconstructions (AWRs). No study has compared outcomes of biologic and synthetic in clean and clean-contaminated hernia ventral hernia repair.

Methods: A prospective AWR database identified patients undergoing open, preperitoneal AWR with biologic mesh in CDC class 1 and 2 wounds. Using propensity score matching, a matched cohort of patients with synthetic mesh was created. The objective was to assess recurrence rates and postoperative complications.

Results: Fifty-eight patients were matched in each group. Patient in the biologic group had higher rates of immunosuppression, history of transplantation, and inflammatory bowel disease ($p \leq 0.05$). Operative variables were comparable for biologic vs synthetic, including defect size (230.5 ± 135.4 vs 268.7 ± 194.5 cm^2, $p = 0.62$), but the synthetic mesh group had larger meshes placed (575.6 ± 247.0 vs 898.8 ± 246.0 cm^2 $p < 0.0001$). Wound infections (15.5% vs 8.9%, $p = 0.28$) were equivalent, and recurrence rates (1.7% vs 3.4%, $p = 1.00$) were similar on follow up (19.3 ± 23.3 vs 23.3 ± 29.7 months, $p = 0.56$).

Conclusions: In matched, lower risk, complex AWR patients with large hernia defects, biologic and synthetic meshes have equal outcomes.

Introduction

Over 350,000 ventral hernia repairs are performed each year in the United States.[1] Studies demonstrate the incidence of hernia is 12.5% (range: 0–35.6%) following laparotomy, which leads to a considerable toll on patient quality of life and finances.[2,3] Most hernia repairs utilize mesh, which can decrease hernia recurrence rates by more than three-fold compared to primary suture repairs.[4] Even with very small defects, measuring no greater than 6 cm, long-term follow up demonstrates a reduction in recurrence by 50%.[4] Optimal mesh type for hernia repair is a controversial topic, and surgeons must consider the different mesh characteristics such as strength, tissue ingrowth, contracture, infectability, and cost.[5–8]

Meshes can be classified into two broad categories: synthetic and biologic. Since the introduction of synthetic mesh in the 1890s, which were initially comprised of multifilament sutures such as silk, surgeons have been developing algorithms for the optimal mesh.[9] Synthetic mesh is often permanent and is usually favored in clean or clean-contaminated cases, although this is also controversial.[10] Synthetics generally induce a more robust inflammatory reaction, which is greater in microporous vs macroporous mesh.[11] Synthetics have the advantage of being inert, with increased tensile strength and decreased upfront cost compared to biologic mesh.[11]

Biologic meshes come from many tissue sources, including porcine, bovine, and human, and may be processed in ways that significantly alter their tissue characteristics.[12,13] Biologics may revascularize after implantation, which allows for incorporation

* Corresponding author. Gastrointestinal and Minimally Invasive Surgery, Department of Surgery, 1025 Morehead Medical Drive Suite 300, Charlotte, NC, 28204, USA.
E-mail address: todd.heniford@gmail.com (B.T. Heniford).

https://doi.org/10.1016/j.amjsurg.2021.05.019
0002-9610/

into native tissues and a possible reduction in complications.[14,15] Given these potential advantages, biologic mesh has been reported to be a more safe choice to use in complex operations when there is a higher risk for infection, especially for patients who have fistulas, chronic infection, or an ostomy.[16–20] While some tend to pool various biologic meshes as a single unit when reporting outcomes, there does appear to be variation in outcomes according to mesh type.[16]

Breuling et al., in the Ventral Hernia Working Group guidelines, encouraged the reduction of bioburden in hernia repair and advocated for biologic mesh use in patients who are high risk for infection.[21] Many studies detailing the implantation of biologic mesh demonstrate higher recurrence rates and wound complications, but these are typically conducted in a contaminated operative field or include patients who require a bridged repair, which invariably lead to increased post-surgical complications and hernia repair failure.[22–24] There have been few studies examining the durability and efficacy of biologic meshes in clean or clean-contaminated fields.[25,26] Of the existing studies in the literature, there are no studies that directly compare the outcomes between synthetic and biologic mesh by wound types in a matched study. The authors hypothesized that in patients undergoing complex open ventral hernia repair (OVHR) with similar wound classes, risk factors, and fascial defect closure without bridging, biologic and synthetic mesh would result in similar recurrence rates and wound complications. The importance of this study is to demonstrate the feasibility and non-inferiority of biologic mesh versus synthetic mesh, which has been called into question.

Methods

Patient selection

In an Institutional Review Board approved study, a prospectively maintained hernia database was queried for patients undergoing an OVHR from July 2010 to February 2020. All patients in this study were over the age of 18 and underwent abdominal wall reconstruction at a tertiary hernia referral center (Carolinas Medical Center in Charlotte, NC). The surgeries were performed by four surgeons with fellowship-training and experience in abdominal wall reconstruction. Inclusion criteria consisted of patients undergoing an OVHR with a Center for Disease Control (CDC) wound classification of 1 or 2, defined as clean (1) or clean-contaminated (2).[27] Patients with concomitant panniculectomy (CP) were included despite the recognized heterogeneity of this patient population. CP is frequently performed at this institution and has an increased wound complication rate that is primarily driven by superficial wound breakdown rather than wound infection.[28]

Patients were separated into two groups based on mesh type—synthetic or biologic. All synthetic meshes used were permanent mid weight large pore polypropylene and all biologic meshes used were a single brand of acellular porcine dermal matrix (Strattice™, Allergan, Blanchburg, NJ, USA). Due to a previous comparative study showing superior results when compared to other biologics, only acellular porcine dermal matrix meshes were included.[16] All patients matching the inclusion criteria underwent propensity score matching for: CDC wound classification, defect size, BMI, and number of comorbidities. Primary outcome assessed was hernia recurrence rate verified on physical exam or radiographic imaging. Secondary outcomes included wound complications, length of stay, and overall charges. Wound complications that were reported included superficial and deep wound infection, seroma, and mesh infection. The cost of the mesh was included in the total hospital charges but not operative charges.

Pre-habilitation of patients

Perioperative management of patients was consistent by the surgeons. Patients who are overweight are encouraged to lose weight through exercise and a ketogenic diet. Although there is no BMI cutoff, target BMI is set to <35 kg/m^2 if possible. Smoking cessation is required at least one month prior to their scheduled operations, and frequently smoking cessation is confirmed with a urine cotinine test.[29] Diabetic patients have a target HgbA1C of 7.2 g/dL or less. If there significant loss of domain noted on physical exam and abdominal imaging, patients are considered for preoperative injection of botulinum A toxin to help with rectus medialization and closure.[30]

Data analysis

Data were analyzed using the SAS® program version 9.4 (SAS, Cary, NC, USA) and standard statistical methods. Descriptive statistics included means and standard deviations for continuous variables or counts and percentages for categorical variables. For continuous variables, comparisons were made between groups using t tests and Wilcoxon–Mann–Whitney tests. For categorical variables, Chi square and Fisher's exact tests were used to compare between groups. All tests were two-tailed with a $p \leq 0.05$ considered statistically significant.

Results

Patient characteristics

After propensity score matching, 116 patients were identified: 58 patients each in the biologic and synthetic mesh cohorts. Complete patient characteristics are listed in Table 1. Patients were well-matched in baseline characteristics with no differences ($p > 0.05$) noted between biologic and synthetic groups in age (56.9 vs 57.7), BMI (34.5 vs 34.2 kg/m^2), incidence of diabetes (43.1% vs 46.6%), smoking history (29.3% vs 20.7%), ASA class, and average number of comorbidities reported (5.7 vs 5.0), respectively. Both groups had similar breakdown of CDC wound classes ($p = 0.27$), with the majority of patients in CDC wound Class 1 (72.4% vs 81.0%) and fewer in CDC wound Class 2 (27.6% vs 19.0%) for both cohorts. Of note, the biologic mesh group had a higher incidence of patients with other co-morbidities, such as chronic steroids (13.8% vs 1.8%), cirrhosis (13.8% vs 0%), history of solid organ transplantation (8.6%

Table 1
Patient characteristics.

	Biologic	Synthetic	p-value
N	58 (50%)	58 (50%)	
Age (Years)	56.9 ± 12.5	57.7 ± 10.0	0.85
Gender (Female)	56.9%	48.3%	0.35
BMI (kg/m^2)	34.5 ± 8.5	34.2 ± 8.4	0.76
Diabetes	43.1%	46.6%	0.71
Smoking History	29.3%	20.7%	0.28
Immunosuppression	13.8%	1.8%	**0.02**
Number of Comorbidities	5.7 ± 3.0	5.0 ± 2.2	0.30
CDC Wound Class			0.27
Class 1	72.4%	81.0%	
Class 2	27.6%	19.0%	
ASA Class			0.60
I	0%	0%	
II	22.4%	30.4%	
III	72.4%	66.1%	
IV	5.2%	3.6%	
V	0%	0%	
Hernia Defect Size (cm^2)	230.5 ± 135.4	268.7 ± 194.5	0.62

vs 0%), and inflammatory bowel disease (3.4% vs 0%), $p \leq 0.05$. Hernia defect sizes were well-matched with the average defect size for biologic mesh measuring 230.5 cm^2 compared to 268.7 cm^2 for patients in the synthetic mesh cohort ($p = 0.62$).

Operative details

Operatively, both the biologic and synthetic groups underwent comparable operations ($p > 0.05$) with similar operative time (180.7 vs 191.4 min), estimated blood loss (129.8 vs 134.0 mL), need for preoperative botulinum A (27% vs 22.2%), components separation (46.6% vs 63.8%), concomitant panniculectomy (43.1% vs 39.7%), and layer within the abdominal wall in which the mesh was placed (Table 2). Fascial defect closure was achieved in almost all patients in both cohorts, only 2 patients did not have fascial closure in the synthetic mesh group (3.7%). The average mesh size used in the synthetic group was almost double the size of the mesh used in the biologic group (575.6 vs 898.8 cm^2, $p < 0.01$). Operative charges were higher in the biologic group ($17,364 vs $14,591, $p = 0.04$).

Hernia outcomes

At an average follow up time of 19.3 vs 23.3 months for biologic and synthetic meshes respectively ($p = 0.56$), the hernia recurrence rates were similar between the two groups with one recurrence noted in the biologic mesh group (1.7%) and two recurrences seen in the synthetic mesh group ($p = 1.00$) (Table 3). Lengths of stay were not significantly different between the two groups ($p = 0.09$), with similar 30-day readmission rates ($p = 0.14$). Rates of wound complications between the biologic and synthetic cohorts were similar ($p > 0.05$) for incidence of seroma formation (12.1% vs 20.0%), hematoma (5.2% vs 3.6%), and wound infection (15.5% vs 8.9%). Incidence of intraabdominal abscess and mesh infections were also similar between the two cohorts ($p > 0.05$), with 3.5% of patients in each cohort developing a mesh infection. In each group, there were 9 patients (15.5%) who required a return trip to the operating room ($p = 1.00$), and 6 patients (10.3%) who required percutaneous drain placement for seroma or abscess formation. Both patients who developed synthetic mesh infection were treated with complete mesh excision.

Discussion

In a propensity matched cohort of patients undergoing complex open AWR with CDC wound Class 1 and 2 with biologic and synthetic mesh, hernia recurrence rates and overall wound related complications were similar. Biologic and synthetic mesh performed similarly in complex cases demonstrating that the durability of biologic mesh is similar to synthetic. The incidence of wound complications and overall length of stay were comparable between the two groups despite a significant increase in patients with cirrhosis, a history of solid organ transplantation, inflammatory bowel disease, and chronic steroid use in the biologic mesh group. The biologic mesh group had a higher overall operative cost.

Table 2
Operative details.

	Biologic	Synthetic	p-value
Operative Time (min)	180.7 ± 55.6	191.4 ± 72.0	0.64
Estimated Blood Loss (mL)	129.8 ± 108.0	134.0 ± 207.3	0.38
Preoperative Botox Injection	27.0%	22.2%	0.66
Component Separation	46.6%	63.8%	0.06
Fascial Defect Closure	100%	96.3%	0.14
Panniculectomy	43.1%	39.7%	0.71
Mesh Size (cm^2)	575.6 ± 247.0	898.8 ± 246.0	**<0.01**
Mesh Placement			0.19
Preperitoneal	87.9%	94.8%	
Intraperitoneal	3.5%	3.5%	
Retrorectus	6.9%	0%	
Operative Charges	$17,364 ± 7740	$14,591 ± 7500	**0.04**

Table 3
Hernia outcomes.

	Biologic	Synthetic	p-value
Hernia Recurrence	1.7%	3.4%	1.00
Length of Stay (LOS)	7.7 ± 5.0	7.1 ± 7.3	0.09
30-Day Readmission Rates	15.5%	6.9%	0.14
Wound Infection	15.5%	8.9%	0.28
Seroma	12.1%	20.0%	0.25
Hematoma	5.2%	3.6%	0.69
Intraabdominal Abscess	6.9%	3.6%	0.43
Mesh Infection	3.5%	3.5%	0.97
Follow Up Time (Months)	19.3 ± 23.3	23.3 ± 29.7	0.56
Total Hospital Charges	$109,807 ± 39,628	$74,478 ± 66,376	**<0.01**

The true recurrence and wound complication rates for patients undergoing complex abdominal wall reconstruction in clean or clean-contaminated wounds is not well defined. This is the largest study comparing biologic and synthetic mesh in a matched cohort with similar wound classes and risk factors, which demonstrates that wound occurrences and hernia recurrence rates are not different at an average follow up of one and a half to two years. This is similarly seen in a study by Kanitra et al. which demonstrated 25% recurrence rates and 10% wound complication rate, in CDC Class 1 and 2 hernia repairs using biologic mesh (which was similar to their outcomes using synthetic mesh).[25] A meta-analysis by Darehzereshki et al. demonstrated that in all CDC classes, biologic mesh use yielded a comparable recurrence rate to synthetic mesh, yet had a lower rate of wound complications.[26] While more evidence is still forthcoming, these studies appear to demonstrate the need for investigation of the use of biologic mesh in patients and wound classes beyond the typical setting of complex, contaminated abdominal wall reconstructions.[17–19,31]

Although biologic mesh is associated with a higher cost, expanding the indications for usage in select high risk patients may be beneficial as results of its durability in this study is encouraging. High risk patients who have multiple comorbidities including obesity, diabetes, prior history of infection, cirrhosis, smoking history, malignancy, chronic immunosuppression, or enterotomy at the time of surgery have a higher risk for developing post-operative infections, and could be safely managed with a biologic mesh.[17–19,32] As an example, patients who have undergone previous transplant not only have an increased risk of wound complications, but they also have a higher reported hernia recurrence rates up to 77%.[33] The authors recently described a case series of liver transplant patients with large hernia defects who underwent incisional undergoing hernia repair with biologic mesh, with a 17.7% wound complication rate and no recurrences at a mean follow-up of 21.6 ± 11.6 months.[34] In the present study, the comparable wound complication rates between the groups was impressive considering the biologic group was higher risk given their increased immunosuppression and other comorbidities.

Not all “high-risk” patients are equivalent and should be considered in two groups: modifiable and non-modifiable. It is appropriate for patients with modifiable risk factors, such as diabetics, smoking, and obesity, to be considered to undergo prehabilitation by encouraging weight loss, smoking cessation, and diabetes management.[35] Other efforts, such as “no-touch” mesh placement and the use of an incisional vacuum-assisted closure (VAC) device are being used in the perioperative period to attempt to further reduce hernia repair complications.[36,37] Intraoperatively,

fascial closure is associated with a decrease in recurrence and wound complications.[23,24] With this in mind, patients with significant loss of domain may undergo botulinum toxin injections to help achieve fascial closure.[30,38] Patients with non-modifiable risk factors, such as chronically immunosuppressed patients and those with a history of previous prosthetic infection, might be considered for implantation of a biologic mesh. All of these decisions are made in an effort to avoid the need for reoperation and entrance into the "vicious cycle" of hernia repair.[39]

Although this study demonstrates the increased cost of biologic mesh in comparison to synthetic mesh, there is more information that should be considered. The impact of biologic mesh on wound healing and wound-related complications needs further and directed study, but the current data demonstrates equal wound complication rates despite the biologic group being more immunosuppressed and comorbid.[40] Prior work has demonstrated the additional cost of a wound infection averages approximately $65,200 with $20,200 in follow up costs.[35] Synthetic mesh infection, which can cost upward of $82,800 with an additional $63,400 in follow up costs, has been reported to present at a mean time of 26.9 months following mesh placement.[35,41] Our study does not have adequate follow-up to capture all of the mesh infections that may occur following hernia repair. While there is evidence to suggest that mesh salvage can be an appropriate treatment strategy for synthetic mesh infection, this data comes predominantly from case studies with short follow-up.[41,42] Data from this institution suggests an 84% mesh salvage failure rate after being treated with an average of 11 months of antibiotics and treatment typically involves complete mesh excision.[43] A study by Chung et al. indicated a 70% failure rate when only partial mesh excision is performed.[44]

While this study demonstrates similar recurrence rates with moderate length of follow up, long term recurrence rates are yet to be determined. There may be some concern regarding hernia recurrence rates with longer follow-up of biologic mesh materials, but most data related to long-term follow up with biologic mesh is mostly confined to use in the contaminated setting.[45] For instance, in patients with CDC Class 2 and 3 wounds, Rosen et al. reported a midline recurrence rate of 14% with 24-month follow-up.[14] In that study, almost all of the reported recurrences happened within the first 15 months, which is less than the minimum follow-up reported in the biologic group in this study of 19 months.[14] Other studies have also demonstrated excellent recurrence rates, ranging from 8.3% to 9.1%, in complex repairs with fascial closure and a porcine dermal matrix.[46]

The main limitation of the study is the lack of longer term follow up to assess important outcomes such as hernia recurrence and mesh infection. By following these patients for several years could help to determine if the upfront costs of biologic mesh are worthwhile. A study with a more direct focus on cost-analysis, readmissions, reoperations, and management of wound and mesh complications would be of benefit.

Conclusions

In a tertiary referral hernia center, complex abdominal wall reconstruction with biologic and synthetic mesh resulted in similar hernia recurrence, wound complication rates, and length of stay. Costs were higher in the biologic mesh group. This initial increase in cost for a biologic mesh repair could potentially be offset by a reduction in mesh-related complications, but randomization with long-term follow up may be needed. Determining the specific patient factors and applying long term follow-up will be needed to support this concept.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Declaration of competing interest

Financial disclosure statement: Dr. Heniford receives surgical research/education grants as well as honoraria for speaking from Allergan and W.L. Gore. Dr. Augenstein receives speaking honoraria from Medtronic, Allergan, Intuitive, Acelity, and Bard. Dr. Colavita is a consultant on a research protocol for Becton Dickinson. Dr. Shao has a research grant from the Intuitive Foundation. Dr. Deerenberg receives speaking honorarium from Medtronic. Drs. Ayuso, Elhage and Ms. Prasad have nothing to disclose.

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