PRS GLOBAL OPEN

ORIGINAL ARTICLE
Reconstructive

Reinforced Biologic Mesh Reduces Postoperative Complications Compared to Biologic Mesh after Ventral Hernia Repair

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Background: The use of biologic mesh to reinforce the abdominal wall in ventral hernia repair has been proposed as a viable alternative to synthetic mesh, particularly for high-risk patients and in contaminated settings. However, a comparison of clinical outcomes between the currently available biologic mesh types has yet to be performed.
Methods: We performed a retrospective analysis of 141 patients who had undergone ventral hernia repair with biologic mesh, including noncross-linked porcine ADM (NC-PADM) (n = 51), cross-linked porcine ADM (C-PADM) (n = 17), reinforced biologic ovine rumen (RBOR) (n = 36), and bovine ADM (BADM) (n = 37) at the Stanford University Medical Center between 2002 and 2020. Postoperative donor site complications and rates of hernia recurrence were compared between patients with different biologic mesh types.
Results: Abdominal complications occurred in 47.1% of patients with NC-PADM, 52.9% of patients with C-PADM, 16.7% of patients with RBOR, and 43.2% of patients with BADM ($P = 0.015$). Relative risk for overall complications was higher in patients who had received NC-PADM (RR = 2.64, $P = 0.0182$), C-PADM (RR = 3.19, $P = 0.0127$), and BADM (RR = 2.11, $P = 0.0773$) compared with those who had received RBOR. Furthermore, relative risk for hernia recurrence was also higher in all other mesh types compared with RBOR.
Conclusion: Our data indicate that RBOR decreases abdominal complications and recurrence rates after ventral hernia repair compared with NC-PADM, C-PADM, and BADM. (*Plast Reconstr Surg Glob Open 2022;10:e4083; doi: 10.1097/GOX.0000000000004083; Published online 7 February 2022.*)

INTRODUCTION

Ventral hernias represent a common complication of abdominal wall surgery and have an incidence of approximately 11%–20%.[1] The prevalence of ventral hernia repairs (VHRs) continues to rise steadily, with more than 400,000 surgeries performed each year in the United States.[2] Direct surgical repair can have a failure rate of up to 50%, but the introduction of prosthetic materials in the form of nonabsorbable synthetic meshes has led to a significant reduction in hernia recurrence rates.[3]

Currently, synthetic meshes represent the standard of care for VHR. The main advantage of synthetic meshes lies their robust strength as well as cost; however, this mesh type has been shown to be prone to surgical site infections, abdominal adhesions, fistula formation, and abdominal stiffness.[2] Biologic meshes were developed with the goal of overcoming these challenges and more recently have been recommended primarily for use in situations where contamination is high with an increased concern for infection.[4] These meshes are derived from biological sources such as human dermal allografts, bovine or porcine skin, or ovine rumen. Biologic meshes are thought to be better able to both incorporate into the native tissue and be less susceptible to infections related to contamination of the operative field.[5]

Several different biologic mesh types have been developed and are currently being utilized for hernia repair. They can be derived from a variety of different species, encompassing porcine, bovine, and ovine sources, among

others. Examples include noncross-linked porcine ADM (NC-PADM), cross-linked porcine dermal biologic mesh (C-PADM), and fetal bovine ADM (BADM).[6,7] Recently, a hybrid biologic and synthetic (biosynthetic) mesh has been developed, which is composed of both biologic and synthetic components. This mesh consists of ovine rumen reinforced with interwoven propylene [reinforced biologic ovine rumen (RBOR)]. The synthetic component of this mesh is thought to confer increased long-term strength and an improved load-sharing capability, whereas the biologic ovine rumen component aims to promote tissue integration and minimize foreign body response (Fig. 1).[8]

Despite the variety of biologic meshes that are currently available for clinical use, there is a paucity of data comparing postoperative outcomes after VHR with different types of biologic mesh. Here, we compared postoperative complications and hernia recurrence rates between patients who had undergone VHR with NC-PADM, C-PADM, BADM, and RBOR at the Stanford University Medical Center.

METHODS

Patients

We performed a retrospective study on 141 patients who underwent VHR with biologic mesh, including noncross-linked porcine ADM (NC-PADM: Strattice, LifeCell Corp., Branchburg, N.J.) (n = 51), cross-linked porcine ADM (C-PADM: Permacol, Covidien, Dublin, Ireland) (n = 17),

Takeaways

Question: Despite the variety of biologic meshes that are currently available for clinical use, there is a paucity of data comparing postoperative outcomes after ventral hernia repair with different types of biologic mesh.

Findings: Our data indicate that a reinforced biologic mesh decreases abdominal complications and recurrence rates after ventral hernia repair compared to commonly implanted biologic mesh types.

Meaning: Utilizing reinforced biologic meshes for VHR may lead to improved outcomes relative to current biologic mesh types.

RBOR (Ovitex, TELABio, Malvern, Pa.) (n = 36), or bovine ADM (BADM: Surgimend, Integra LifeSciences, Billerica, Mass.) (n = 37) at the Stanford University Medical Center between 2002 and 2020. The study protocol was approved by the institutional review board of Stanford University. Patients who met the following inclusion criteria were included in the study: more than 18 years of age, VHR operated between 2002 and 2020, and implantation of biologic mesh or reinforced biologic mesh. Exclusion criteria were the presence of umbilical hernias, implantation of synthetic mesh, combinations of multiple mesh types, laparoscopic repair, and active abdominal infection.
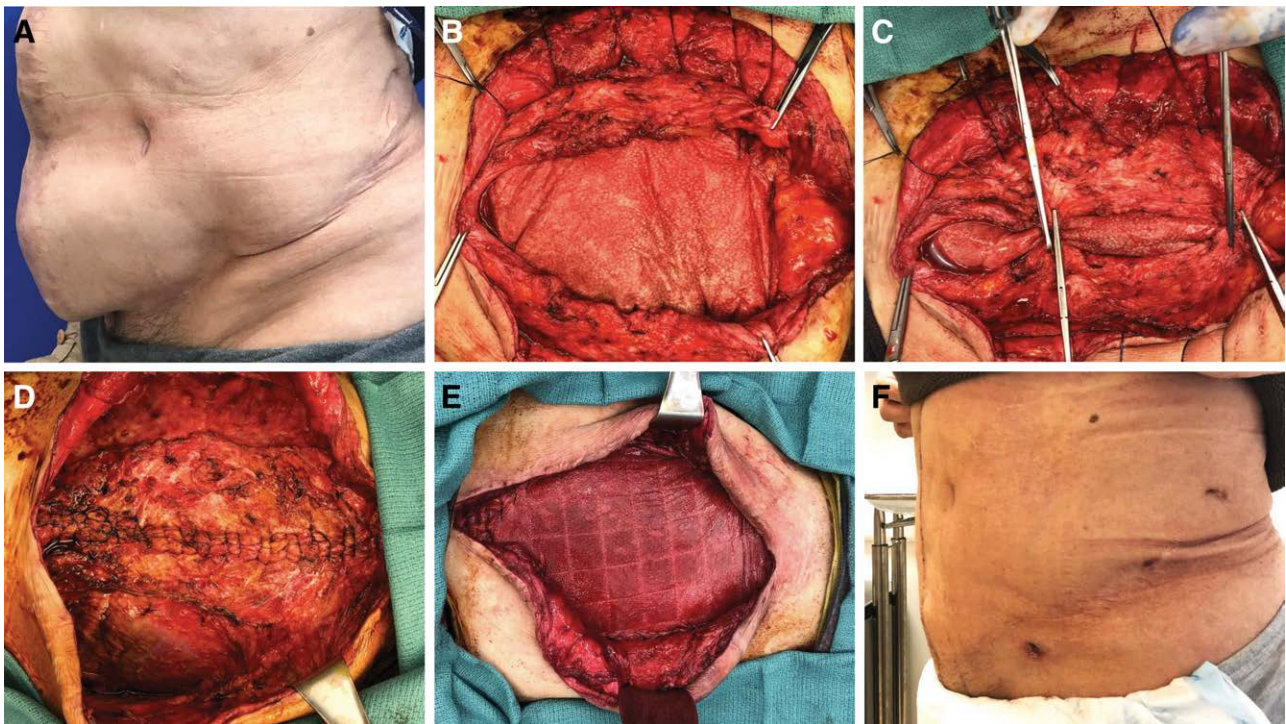
Fig. 1. Complex ventral hernia repair with reinforced biologic mesh. A 72-year-old female patient had been suffering from a ventral hernia for several years (A). She had a history of multiple previous abdominal surgeries including an open cholecystectomy and an abdominoplasty. Left and right-sided component separation was performed followed by midline closure. An underlay RBOR mesh was placed to reinforce the abdominal wall closure (B). Once completed, the incision was closed in the midline (C and D). A second RBOR mesh was placed in an on-lay position for additional support, and the incision was closed in multiple layers (E). Her wounds healed well without complications. At postoperative week 10, her abdominal wall reconstruction was stable without residual hernia or bulging (F).

DATA ACQUISITION

Demographic and baseline characteristics of the patients were analyzed by recording age, gender, BMI, smoking activity, and comorbidities such as diabetes, liver, or kidney disease. Surgical characteristics including degree of defect contamination (clean, clean-contaminated, and contaminated), modified ventral hernia working group classification (grades 1, 2, and 3), hernia defect size, and median length of follow-up were compared between the groups.[9] Hernia defect size was obtained via preoperative computed tomography scans by measuring the greatest fascial defect diameter on the sagittal and transverse planes. Hernia characteristics such as type of hernia (ventral/incisional, parastomal or combined ventral, and parastomal) and etiology (abdominal surgery and idiopathic) were compared between the groups as well.

Mesh placement techniques, which were based on clinical decision making, such as overlay, inlay, preperitoneal/intraperitoneal underlay, and retrorectus were analyzed and compared between the groups. Postoperative complications included hernia recurrence, hematoma, seroma, minor and major wound complication, abdominal infection, or fistula. Minor wound complications included skin necrosis, delayed wound healing, and dehiscence, with no revision surgery required. Major wound complications were defined as any wound complication requiring revision surgery.

Statistical Analysis

The Chi-square test was used to compare categorical variables using Prism 8 (GraphPad). Relative risk was estimated using modified Poisson regression analysis with robust error variance in R.[10] All potential covariates were assessed. Covariates that affected relative risk for any mesh by more than 10% were kept in the final model. Statistical significance was set at a *P* value less than 0.05. All statistical tests were two-tailed.

RESULTS

Baseline Characteristics

A total of 141 patients met the criteria for inclusion into the study. Of these, 51 patients had undergone abdominal wall repair with NC-PADM, 17 with C-PADM, 36 with RBOR, and 37 with BADM (Table 1). There were no statistically significant differences in demographic characteristics among patients with respect to age, BMI, tobacco use, diabetes, coronary artery disease, renal disease, liver disease, or history of radiation. When comparing patients with different mesh types, we found that patients who received C-PADM had higher incidence of incarceration (29.4%), and those with BADM had higher incidence of component separation (54.1%) compared to patients that had received other mesh types. These differences in baseline characteristics were adjusted for in the final analysis using modified Poisson regression analysis.

There were no statistically significant differences in degree of defect contamination among patients with different mesh types, which encompassed clean, clean-contaminated, and contaminated wounds. Furthermore, there were no significant differences in the grade of ventral hernias, as measured using the modified ventral hernia working group classification (grades 1, 2, and 3). This was also the case among patients for hernia defect size, the presence of a concomitant procedure, and median follow-up time (Table 2).

There were no statistically significant differences in hernia types between patients with different mesh types, which included ventral incisional, parastomal, as well as combined ventral incisional and parastomal. This was similarly true for hernia etiology between patients, which included abdominal surgery and idiopathic presentation. All patients underwent repair using an open approach (Table 3).

Postoperative Complications

Overall, complications occurred less often in patients that had undergone reconstruction with RBOR, compared to patients that had received C-PADM, NC-PADM, and BADM (16.7% versus 52.9%, 47.1%, 43.2%) (*P* = 0.015). Rates of recurrence were lower in patients that had received RBOR and NC-PADM compared to patients that had received C-PADM and BADM (2.78% and 13.7% versus 29.4% and 24.3%) (*P* = 0.022) (Table 4). No significant differences in minor wound complications, abdominal infection, hematoma, seroma, or fistula formation were found among patients with different mesh types.

We further compared abdominal complications among patients with different mesh types using modified Poisson regression analysis, adjusting for differences in baseline

Table 1. Patient Demographics and Comorbidities

	NC-PADM (n = 51)	C-PADM (n = 17)	RBOR (n = 36)	BADM (n = 37)	*P*
Age (SD)	57.8 (14.1)	55.3 (10.6)	63.4 (10.4)	59.6 (15.2)	0.367
BMI (SD)	32.2 (9.30)	29.7 (6.98)	30.9 (4.04)	29.8 (5.88)	0.741
Tobacco use	7 (13.7%)	3 (17.6%)	5 (13.9%)	3 (8.11%)	0.761
Diabetes	17 (33.3%)	2 (11.8%)	13 (36.1%)	11 (29.7%)	0.314
CAD	11 (21.6%)	2 (11.8%)	6 (16.7%)	6 (16.2%)	0.797
Renal disease	16 (31.3%)	1 (5.88%)	12 (33.3%)	10 (27.0%)	0.174
Liver disease	12 (23.5%)	2 (11.8%)	10 (27.8%)	5 (13.5%)	0.340
History of radiation	4 (7.84%)	0 (0.00%)	5 (13.9%)	2 (5.41%)	0.520
Ostomy	17 (33.3%)	7 (41.2%)	6 (16.7%)	11 (29.7%)	0.226
Previous abdominal surgery	49 (98.0%)	17 (100%)	36 (100%)	36 (97.3%)	0.819
Revision mesh surgery	24 (47.1%)	3 (17.6%)	15 (41.7%)	14 (37.8%)	0.194
Incarcerated	6 (11.8%)	5 (29.4%)	2 (5.56%)	2 (5.71%)	0.038
Component separation	16 (31.4%)	8 (47.1%)	8 (22.2%)	20 (54.1%)	0.024
Enterocutaneous fistula	11 (21.6%)	2 (11.8%)	2 (5.56%)	4 (10.8%)	0.167

Table 2. Surgical Characteristics

	NC-PADM (n = 51)	C-PADM (n = 17)	RBOR (n = 36)	BADM (n = 37)	P
Wound classification					0.776
Clean	31 (61.3%)	13 (76.5%)	22 (61.1%)	21 (55.9%)	
Clean-contaminated	13 (24.7%)	3 (17.7%)	10 (28.4%)	13 (35.9%)	
Contaminated	7 (14%)	1 (5.8%)	4 (11.1%)	3 (8.2%)	
Modified ventral hernia working group classification					0.159
Grade 1	9 (17%)	3 (17.6%)	12 (33.4%)	15 (40.0%)	
Grade 2	40 (78.7%)	12 (70.6%)	21 (58.3%)	19 (51.4%)	
Grade 3	2 (4.3%)	2 (11.8%)	3 (8.3%)	3 (8.6%)	
Defect size (cm²)					
Mean (SD)	130.2 (78.3)	222.2 (111.2)	153.6 (64.8)	230.5 (120.4)	0.067
Concomitant procedure	11 (21.8)	2 (14.2)	8 (22.2)	7 (18.2)	0.815
Median follow-up, mo (SD)	34.6 (15.2)	58.4 (19.4)	28.6 (12.1)	37.5 (17.5)	0.073

Table 3. Hernia Type and Etiology

	NC-PADM (n = 51)	C-PADM (n = 17)	RBOR (n = 36)	BADM (n = 37)	P
Hernia type					0.245
Ventral incisional	42 (84.0%)	16 (94.1%)	33 (91.7%)	32 (86.5%)	
Parastomal	7 (14.0%)	1 (5.88%)	2 (2.56%)	1 (2.70%)	
Ventral incisional and parastomal	1 (2.00%)	0 (0.00%)	1 (2.78%)	4 (10.8%)	
Etiology					0.962
Abdominal surgery	47 (92.1%)	16 (94.1%)	34 (97.1%)	35 (94.6%)	
Idiopathic	4 (7.9%)	1 (5.88%)	2 (2.86%)	2 (5.41%)	

characteristics. Relative risk for overall complications was higher in patients who had received NC-PADM (RR = 2.64, P = 0.0182), C-PADM (RR = 3.19, P = 0.0127), and BADM (RR = 2.11, P = 0.0773), compared with patients who had received RBOR mesh. There were no significant differences in overall complications with respect to the position of mesh placement (Table 5). Relative risk for hernia recurrence was higher in all other mesh types compared to RBOR, with BADM (RR = 6.15, P = 0.0729) trending toward significance (Table 6).

DISCUSSION

The introduction of biologic mesh for complex abdominal wall repair has led to improved postoperative patient outcomes, particularly in the context of patients with increased risk of infection and mesh exposure in the setting of contaminated wounds.[4,11] However, data related to clinical outcomes among the various types of biologic mesh used in abdominal wall repair are limited. A prospective study of 223 patients comparing outcomes post randomization of five biologic mesh products showed increased odds of recurrence for human acellular dermal matrices compared with noncross-linked porcine ADM.[12] Another study showed that noncross-linked porcine biologics were less likely to be explanted but had higher recurrence rates compared to cross-linked porcine biologics. Cross-linked porcine biologics showed higher infection and explanation rates relative to other biologic mesh types.[13]

Reinforced biologic mesh, which combines both biologic and synthetic materials, is a more recent addition surgical option for hernia repair. Sheets of extracellular matrix derived from biologic sources are combined in a variety of thicknesses and reinforced using a synthetic thread.[14] In preclinical studies, the biological performance of this hybrid mesh type has shown that reinforced biologic mesh invokes less of an inflammatory response and promotes better wound healing than synthetic meshes.[14] Furthermore, reinforced biologic meshes are better able to maintain their structural integrity and repair geometry compared to biologic meshes.[14] A 12-month follow-up analysis of an ongoing prospective, single-arm study (BRAVO) evaluating the clinical outcomes of ventral hernias repaired with RBOR showed that just two of 76 enrolled patients experienced hernia recurrence, both of which were adjacent to the original repair. An additional study compared two cohorts of patients undergoing VHR with RBOR or synthetic mesh. Although RBOR was preferentially utilized in higher-risk patients, this reinforced biologic mesh performed similarly to synthetic meshes with respect to surgical site occurrence and hernia recurrence. Additionally, patients receiving RBOR who developed surgical site occurrence were significantly less likely to have hernia recurrence than those who received synthetic mesh.[15]

Table 4. Postoperative Complications

	NC-PADM (n = 51)	C-PADM (n = 17)	RBOR (n = 36)	BADM (n = 37)	P
Overall complications	24 (47.1%)	9 (52.9%)	6 (16.7%)	16 (43.2%)	0.015
Recurrence	7 (13.7%)	5 (29.4%)	1 (2.78%)	9 (24.3%)	0.022
Hematoma	6 (12.5%)	1 (5.88%)	1 (2.78%)	6 (16.2%)	0.276
Seroma	6 (12.5%)	3 (17.6%)	5 (13.9%)	5 (13.5%)	0.943
Minor wound complication	7 (14.6%)	5 (29.4%)	2 (5.56%)	7 (18.9%)	0.120
Major wound complication	11 (22.9%)	1 (5.88%)	1 (2.78%)	10 (27.0%)	0.016
Abdominal infection	6 (12.5%)	2 (11.8%)	1 (2.78%)	2 (5.41%)	0.385
Fistula	2 (4.17%)	3 (17.6%)	0 (0.00%)	3 (8.11%)	0.165

Table 5. Modified Poisson Regression for Overall Complications

Mesh type	RR (95% CI)	P
RBOR	Ref.	Ref.
NC-PADM	2.64 (1.17–5.90)	0.0182
C-PADM	3.19 (1.28–7.92)	0.0127
BADM	2.11 (0.92–4.86)	0.0773
Placement		
Overlay	Ref.	Ref.
Bridging	1.17 (0.63–2.17)	0.6149
Preperitoneal underlay	0.88 (0.48–1.62)	0.6880
Intraperitoneal underlay	1.38 (0.74–2.56)	0.3153
Overlay and preperitoneal underlay	1.36 (0.37–5.10)	0.6456
Unknown	1.31 (0.86–2.02)	0.2102
Incarcerated	0.70 (0.36–1.34)	0.2780
Component separation	1.53 (1.10–2.16)	0.1408

CI, confidence interval; RR, relative risk.

Table 6. Modified Poisson Regression for Hernia Recurrence

Mesh type	RR (95% CI)	P
RBOR	Ref.	Ref.
NC-PADM	3.51 (0.479–25.8)	0.2165
C-PADM	5.31 (0.632–44.6)	0.1242
BADM	6.15 (0.845–44.7)	0.0729
Placement		
Overlay	Ref.	Ref.
Bridging	1.33 (0.487–3.63)	0.5772
Preperitoneal underlay	1.93 (0.732–5.10)	0.1834
Intraperitoneal underlay	0.956 (0.334–2.74)	0.9338
Unknown	1.93 (0.954–3.89)	0.0674
Incarcerated	1.60 (0.793–3.24)	0.1893
Component separation	1.55 (0.861–2.78)	0.1445

CI, confidence interval; RR, relative risk.

In our study, we compared postoperative abdominal complications among patients who had undergone VHR with biologic mesh placement using RBOR, NC-PADM, C-PADM, and BADM. We found that patients who had received RBOR experienced lower hernia recurrence and significantly lower overall complications compared with patients with other biologic mesh types. In this study, we are the first to preliminarily compare reinforced biologic to other biologic meshes for VHR, as well as to report the relative benefit of RBOR over purely biologic mesh types in VHR. The results of our study support the findings of the BRAVO study, and additionally demonstrate that the use of a hybrid reinforced mesh like RBOR may confer increased benefit to patients undergoing VHR compared to purely biologic mesh types.[16,17] The low rate of complications and hernia recurrence highlights the potential of reinforced biologic tissue matrices to improve outcomes in hernia repairs.

Limitations of our study include its retrospective nature and a relatively small sample size in each subgroup. As biologic mesh has proven to be particularly beneficial in the setting of complicated VHR, each subgroup included patients who had received prior hernia repairs. However, to analyze postoperative outcomes and recurrence rates with statistical robustness, we adjusted for differences in baseline characteristics using Poisson regression. Additionally, the presence of incarcerated hernia in a subset of our patients may have introduced a degree of outcome bias; however, the overall incidence of incarceration was low.

This is the first exploratory study to statistically compare postoperative complications and rates of hernia recurrence among four biologic mesh types in a sizeable patient cohort. This study provides valuable information for preoperative surgical planning and counseling of patients undergoing abdominal wall repair with biologic mesh implantation. Future studies should aim to prospectively compare the impact of biologic mesh type on postoperative complications in a randomized fashion.

CONCLUSIONS

Our data indicate that in patients undergoing abdominal wall repair, RBOR mesh decreases overall complications and hernia recurrence compared to those receiving NC-PADM, C-PADM, and BADM. Utilizing reinforced biologic meshes for VHR may lead to improved outcomes relative to current biologic mesh types.

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