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Outcomes of Biosynthetic and Synthetic Mesh in Ventral Hernia Repair

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Background: The introduction of mesh for reinforcement of ventral hernia repair (VHR) led to a significant reduction in hernia recurrence rates. However, it remains controversial whether synthetic or biologic mesh leads to superior outcomes. Recently, hybrid mesh consisting of reinforced biosynthetic ovine rumen (RBOR) has been developed and aims to combine the advantages of biologic and synthetic mesh; however, outcomes after VHR with RBOR have not yet been compared with the standard of care.

Methods: We performed a retrospective analysis on 109 patients, who underwent VHR with RBOR (n = 50) or synthetic polypropylene mesh (n = 59). Demographic characteristics, comorbidities, postoperative complications, and recurrence rates were analyzed and compared between the groups. Multivariate logistic regression models were fit to assess associations of mesh type with overall complications and surgical site occurrence (SSO).

Results: Patients who underwent VHR with RBOR were older (mean age 63.7 versus 58.8 years, $P = 0.02$) and had a higher rate of renal disease (28.0 versus 10.2%, $P = 0.01$) compared with patients with synthetic mesh. Despite an unfavorable risk profile, patients with RBOR had lower rates of SSO (16.0 versus 30.5%, $P = 0.12$) and similar hernia recurrence rates (4.0 versus 6.78%, $P = 0.68$) compared with patients with synthetic mesh. The use of synthetic mesh was significantly associated with higher odds for overall complications (3.78, $P < 0.05$) and SSO (3.87, $P < 0.05$).

Conclusion: Compared with synthetic polypropylene mesh, the use of RBOR for VHR mitigates SSO while maintaining low hernia recurrence rates at 30-month follow-up.
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INTRODUCTION

Ventral hernia repair (VHR) is one of the most commonly performed surgical procedures costing the US healthcare system more than $3.2 billion annually.[1] The prevalence of VHR continues to rise steadily, with approximately half a million procedures performed each year.[2] The introduction of prosthetic materials in the form of nonabsorbable synthetic meshes has led to a significant reduction in hernia recurrence rates compared with primary suture repair.[3,4] Synthetic meshes, typically composed of a polypropylene substrate, currently represent the standard of care for VHR. These meshes are robust and cost effective; however, they have been shown to induce a prolonged inflammatory and fibrotic response at the site of implantation, with potential consequences of abdominal stiffness, pain, adhesions, fistula formation, and surgical site infection.[5–8] In addition, polypropylene meshes eventually undergo contraction of the mesh and surrounding tissues.[9] This host response to synthetic foreign materials, termed the foreign body response, has been well described and likely contributes to the complications associated with synthetic mesh.[10]

For these reasons, biologic meshes were developed with the rationale that they may be able to minimize the foreign body response, improve biocompatibility, and be less susceptible to infections related to contamination of the operative field.[6] Several commercially available biologic meshes are derived from a variety of different species,

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including porcine, bovine, and ovine sources, among others.[11,12] The most commonly reported drawbacks of biologic meshes relate to their high cost and elevated risk of hernia recurrence.[1]

Since both biologic and synthetic substrate materials have a unique set of advantages and drawbacks respectively, hybrid meshes were recently developed, such as biologic decellularized ovine rumen reinforced with synthetic interwoven propylene [reinforced biosynthetic ovine rumen (RBOR)]. This reinforced tissue matrix attempts to combine the benefits of biologic material and polymer reinforcement to provide a more physiologic hernia repair when compared with mesh products composed of just synthetic polymer materials. The synthetic component of this mesh is thought to confer increased long-term strength and load-sharing capacity, while the biologic ovine rumen aims to promote tissue integration, minimize foreign body response, and reduce potential infection by shielding the synthetic component.[13]

So far, postoperative outcomes after VHR with biosynthetic mesh have not been directly compared with VHR with synthetic mesh, which is the current standard of care. Here, we compared postoperative complications and hernia recurrence rates between patients who had undergone VHR with RBOR and synthetic polypropylene mesh at Stanford University Medical Center.

Takeaways

Question: There are minimal data comparing outcomes after ventral hernia repair (VHR) between biosynthetic and synthetic mesh.

Findings: Our data suggest that reinforced biologic mesh decreases hernia recurrence rates and surgical site occurrences compared with synthetic meshes.

Meaning: Biosynthetic mesh may lead to improved outcomes after VHR compared with the standard of care. Our data provide important insights for preoperative surgical planning and counseling of patients undergoing VHR.

Table 1. Patient Demographics and Comorbidities

	RBOR (n = 50)	Synthetic (n = 59)	
	Reinforced Biologic Ovine Rumen	Polypropylene	*P*
Age (SD)	63.7 (9.51)	58.8 (11.9)	**0.020**
BMI (SD)	30.3 (4.31)	28.7 (5.01)	0.080
Tobacco use	5 (10.0%)	5 (8.47%)	0.900
Diabetes	16 (32.0%)	15 (25.4%)	0.586
CAD	6 (12.0%)	16 (27.1%)	0.085
Renal disease	14 (28.0%)	6 (10.2%)	**0.018**
History of radiation	5 (10.0%)	13 (22.0%)	0.154
Previous abdominal surgery	50 (100%)	51 (86.4%)	**0.007**
Revision mesh surgery	20 (40.0%)	16 (27.1%)	0.222
Incarcerated	2 (4.00%)	6 (10.2%)	0.285
Component separation	10 (20.0%)	6 (10.2%)	0.241
Enterocutaneous fistula	2 (4.00%)	5 (8.47%)	0.449

Boldface values indicate $P < 0.05$.

METHODS

Patients

We performed a retrospective analysis on 109 patients who underwent VHR with RBOR (Ovitex, TELABio, Malvern, Pa.) (n = 50) or synthetic mesh (n = 59) at Stanford University Medical Center between 2002 and 2021. A total of four surgeons performed the hernia repair procedures for these patients. The synthetic mesh products used were Prolene (Johnson & Johnson, New Brunswick, N.J., n = 29), Parietex (Medtronic, Dublin, Ireland, n = 15), and Physiomesh (Ethicon, Raritan, N.J., n = 15). The study protocol was approved by the institutional review board at Stanford University. Patients who met the following inclusion criteria were included in the study: 18 years of age or older, open VHR operated on between 2002 and 2021, and implantation of RBOR or Prolene mesh. Exclusion criteria were the presence of umbilical hernias or multiple ventral hernias, combinations of multiple mesh types, active abdominal infection, concomitant procedures in addition to VHR, and laparoscopic repair.

Data Acquisition

Demographic and baseline characteristics of the patients were analyzed by comparing age, gender, BMI, smoking activity, and medical comorbidities between the groups (Table 1). Surgical characteristics, including modified ventral hernia working group (MVHWG) classification, hernia defect size, and mean length of follow-up (in person), were compared between the groups.[14] Hernia defect size was obtained from preoperative CT scans by measuring the greatest fascial defect diameter on the sagittal and transverse planes. Mesh placement techniques, such as overlay, bridging, and preperitoneal underlay, were compared between the groups. (**See table, Supplemental Digital Content 1**, which displays hernia etiology and mesh placement, **http://links.lww.com/PRSGO/C302**.)

The overlay technique refers to a mesh placement overlying the anterior rectus fasica. The bridging technique involves mesh placement between the edges of the fascia to bridge the defect. The underlay technique involves mesh placement on the underside of the defect or inside the fascia. Postoperative complications included hernia recurrence, hematoma, seroma, wound complication, abdominal infection, and fistula. Wound complications included skin necrosis, prolonged wound healing (>14 days), and wound dehiscence. Surgical site occurrence (SSO) was defined as the occurrence of either hematoma, seroma, wound complication, or fistula.

Statistical Analysis

Continuous variables were compared between the groups using Student's *t* test. Categorical variables were

compared using the chi-square test. Odds ratios (ORs) and 95% confidence intervals (CIs) were calculated using multivariate logistic regression analysis. All variables that had a significant univariate test at P less than 0.1 were included in the multivariate analysis. The goodness of fit of the logistic regression models was examined by calculating the area under the receiver operating characteristic (ROC) curve. Statistical significance was set at P less than 0.05. All statistical tests were two-tailed. Data are presented as mean ± standard deviation (SD). Statistical analysis was performed in R (version 4.0, www.r-project.org).[15]

RESULTS

Baseline Characteristics

A total of 109 patients met inclusion criteria. Of these, 50 patients had undergone VHR with RBOR, and 59 patients had undergone VHR with synthetic mesh (Table 1). There were no statistically significant differences in BMI, tobacco use, diabetes, coronary artery disease (CAD), use of component separation [anterior (40%) or transverses abdominal release (60%)], and history of radiation between the groups. However, patients who had received RBOR were significantly older (mean age 63.7 years versus 58.8 years, P = 0.02) and had a higher incidence of renal disease (28% versus 10.2%, P = 0.02) compared with patients who had received synthetic mesh. In addition, all patients who underwent VHR with RBOR had undergone prior abdominal surgery compared with only 86.4% of patients who received synthetic mesh (P = 0.01). These differences in baseline characteristics were adjusted for in the final analysis using a multivariate logistic regression model.

There were no significant differences in hernia grade as defined by the MVHWG classification between the two groups.[14] Of the patients in our cohort with MVHWG grade 3, all were classified as clean contaminated by CDC wound classification. Furthermore, there were no significant differences among patients in RBOR and synthetic mesh groups for hernia defect size (153 cm^2 versus 129 cm^2, P = 0.096), and the mean follow-up time was not significantly different between the two groups (29.0 months versus 34.3 months, P = 0.054). (Table 2; **see table, Supplemental Digital Content 1 http://links.lww.com/PRSGO/C302**.)

Table 2. Surgical Characteristics

	RBOR (n = 50)	Synthetic (n = 59)	
	Reinforced Biologic Ovine Rumen	Polypropylene	*P*
Modified ventral hernia working group classification, n (%)			
Grade 1	13 (26.0)	17 (28.8)	0.673
Grade 2	32 (64.0)	39 (66.1)	
Grade 3	5 (10.0)	3 (5.08)	
Defect size (cm^2)			
Mean (SD)	153 (52.2)	129 (51.9)	0.096
Mean follow-up (SD), months (min, max)	29.0±11.1 (10.2, 55.5)	34.3±16.9 (7.4, 60.3)	0.054

SD, standard deviation.

Postoperative Complications

Although patients who underwent VHR with RBOR were older and had a higher rate of renal disease and prior abdominal surgery compared with patients who underwent VHR with synthetic mesh, this did not translate into higher complication or recurrence rates. No significant differences in postoperative hematoma, seroma, wound complications, or abdominal infections were found between the groups. Fewer fistulas were found in patients with RBOR compared with patients with synthetic mesh (0% versus 6.8%, P = 0.04); however, the total number of patients with this complication was low (n = 4). None of the patients who developed fistulas postoperatively had presented with fistulas in the preoperative setting. Hernia recurrence occurred in 4% of patients with RBOR and 6.8% of patients with synthetic mesh without significant differences between the groups (P = 0.69). (Table 3; **see table, Supplemental Digital Content 2**, which displays postoperative complications in synthetic mesh types, **http://links.lww.com/PRSGO/C303**.)

To adjust for differences in baseline characteristics between the two groups and determine the impact of mesh type on overall complications and SSO, we constructed multivariate logistic regression models. Patients who had received synthetic mesh were found to have a significantly higher odds for development of overall complications (OR, 3.78, P < 0.05) and SSO (OR, 3.87, P < 0.05) compared with patients with RBOR. None of the covariables had a significant association with overall complications or SSO in multivariable logistic regression analysis (Tables 4, 5). ROC analysis was performed to determine

Table 3. Postoperative Complications

	RBOR (n = 50)	Synthetic (n = 59)	
	Reinforced Biologic Ovine Rumen, n (%)	Polypropylene, n (%)	*P*
Overall complications	9 (18.0)	19 (32.2)	0.141
Recurrence	2 (4.00)	4 (6.78)	0.685
Hematoma	2 (4.00)	5 (8.47)	0.449
Seroma	7 (14.0)	11 (18.6)	0.695
Wound complication	4 (8.00)	9 (15.3)	0.385
Abdominal infection	1 (2.00)	5 (8.47)	0.215
Fistula	0 (0.00)	4 (6.8)	0.040

Table 4. Logistic Regression for Overall Complications

	OR (95% CI)	*P*
Mesh type		
RBOR	Ref.	Ref.
Polypropylene	3.78 (1.2–13.6)	**0.027**
Placement		
Overlay	Ref.	Ref.
Bridging	0.603 (0.05–8.13)	0.703
Preperitoneal underlay	0.644 (0.23–1.83)	0.407
Overlay and preperitoneal underlay	5.26 (0.21–13.7)	0.318
Follow-up	1.00 (0.97–1.03)	0.915
Age	0.972 (0.93–1.02)	0.197
BMI	1.10 (0.99–1.23)	0.071
CAD	1.37 (0.42–4.49)	0.601
Previous abdominal surgery	3.01 (0.31–8.63)	0.338
Renal disease	2.15 (0.62–7.34)	0.225

Table 5. Logistic Regression for SSO

Variable	OR (95% CI)	*P*
Mesh type		
RBOR	Ref.	Ref.
Polypropylene	3.87 (1.23–13.5)	**0.025**
Placement		
Overlay	Ref.	Ref.
Bridging	0.717 (0.03–9.10)	0.802
Preperitoneal underlay	0.695 (0.24–1.97)	0.496
Overlay and preperitoneal underlay	6.02 (0.19–18.2)	0.246
Follow-up	0.998 (0.97–1.03)	0.927
Age	0.985 (0.94–1.03)	0.484
BMI	1.06 (0.96–1.18)	0.273
CAD	0.997 (0.28–3.25)	0.995
Previous abdominal surgery	3.09 (0.45–6.22)	0.321
Renal disease	1.76 (0.49–6.06)	0.373

the goodness of fit of the models, which yielded an area under the ROC curve of 0.69 for overall complications and 0.67 for SSO (Fig. 1).

DISCUSSION

The introduction of mesh to reinforce the abdominal wall in VHR has significantly reduced hernia recurrence rates, leading to its use in over 80% of hernia repairs currently performed in the United States.[16] However, data related to long-term outcomes after implantation of synthetic versus biologic mesh for VHR remain equivocal. A randomized trial of 253 patients showed that synthetic mesh significantly reduced the risk of hernia recurrence compared with biologic mesh in patients undergoing repair of clean-contaminated and contaminated ventral hernias.[1] However, another study of 725 patients who underwent abdominal wall reconstruction with porcine- or bovine-derived biologic mesh showed durable long-term outcomes with low recurrence rates that were comparable to those observed using synthetic mesh.[17]

Recently, hybrid mesh devices were developed with the aim of addressing the limitations of purely synthetic and biologic meshes. These biosynthetic meshes combine biologic materials with a permanent prosthetic support material to provide a durable abdominal wall support while minimizing foreign body reaction and allowing for native tissue ingrowth.[18] Preclinical studies have shown that reinforced biologic scaffolds display biomimetic proprieties, support cellular adhesion, and maintain their native architecture over the long term, allowing for organized collagen deposition and tissue remodeling. Furthermore, they have been shown to be less prone to stretch compared with purely biologic scaffolds.[19] The currently available

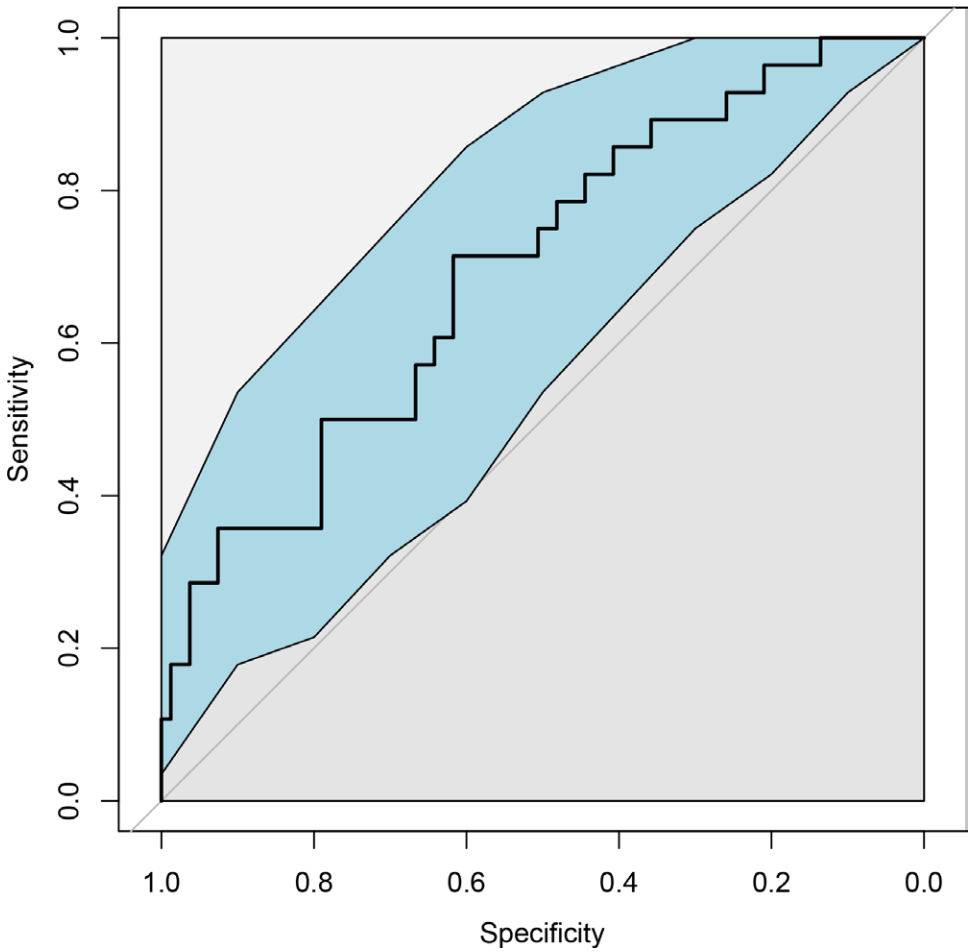

Fig. 1. ROC plot.

hybrid meshes used in abdominal wall reconstruction include Gore's Synecore (polytetrafluorethylene fibers combined with a bioabsorbable copolymer scaffold composed of polyglycolic acid and trimethylene carbonate), Cook Medical's Zenapro (polypropylene mesh sandwiched between layers of porcine small intestinal submucosa), and TELA Bio's Ovitex (ovine rumen reinforced with interwoven propylene). A prospective study of contaminated ventral hernias repaired with Synecore mesh noted a 17% hernia recurrence rate in a population of mainly complex contaminated (77%) cases. In a population of predominantly clean (92.1%) cases, a recurrence rate of 7.3% was found after VHR with Zenapro mesh.[20] A 12-month interim analysis of an ongoing prospective, single-arm study evaluating outcomes after VHR with Ovitex RBOR showed a recurrence rate of 2.7% in a population of largely clean (81%) cases.[21]

Clinically, the strongest evidence for use of biologic mesh devices in VHR exists in patients with complex and contaminated (MVHWG grade III) defects.[17] Our group previously compared outcomes after VHR with different types of porcine- and bovine-derived biologic meshes as well as RBOR and found lower rates of recurrence and postoperative complications in patients who received RBOR compared with other biologic mesh types.[22] In patients with contaminated defects (grade III), Parker et al[23] found that outcomes after VHR with RBOR were comparable to those in patients with grade II defects that had undergone repair with synthetic mesh.

Whether hybrid meshes show benefits for the repair of low-to-intermediate risk patients (grades I and II) compared with synthetic mesh has not yet been investigated. Here, we compared postoperative outcomes after VHR with RBOR or synthetic mesh. Both patient cohorts had comparable defect sizes and mostly intermediate (grade II) and low risk (grade I) hernias; however, patients who received RBOR were older and had a higher rate of renal disease. Nevertheless, patients with RBOR had lower rates of SSO, while recurrence rates were comparable in both groups (4% versus 6%).

When adjusting for possible confounders using multivariate logistic regression analysis, synthetic mesh was found to be associated with a higher odds for development of SSO and overall complications. Mesh infection, extrusion, and enterocutaneous fistula formation are challenging surgical problems that can result from implantation of synthetic mesh and usually require revision surgery, involving removal of the infected mesh.[24] These complications are likely related to an inflammatory foreign body response to implanted synthetic mesh, which is why these devices are usually avoided for VHR in contaminated fields at many centers.[10] Our study demonstrates that hybrid biosynthetic mesh can reduce these complications also in low-to-intermediate risk patient populations undergoing VHR, while providing a durable reinforcement of the abdominal wall and low recurrence rates.

Limitations of our study are related to its retrospective nature and limited sample size. Hence, the significant difference in postoperative fistula formation between the groups may be related to a low sample size and warrants further investigation. Additionally, there is a five-month mean follow-up difference between the two cohorts, which may contribute to the difference in hernia recurrence observed, although the difference was not significant. However, our study is the first to compare outcomes after VHR with RBOR or synthetic mesh in low-to-intermediate risk patient cohorts with comparable defect sizes. Our data provide important insights for preoperative surgical planning and counseling of patients undergoing VHR. We show that the use of biosynthetic mesh reduces SSO with low hernia recurrence rates compared with patients treated with synthetic mesh. Future studies should aim to prospectively compare the efficacy of hybrid biosynthetic mesh to synthetic mesh in a prospective randomized fashion.

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