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Mesh choice in ventral hernia repair: so many choices, so little time

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Abstract

BACKGROUND: Currently, >200 meshes are commercially available in the United States. To help guide appropriate mesh selection, the investigators examined the postsurgical experiences of all patients undergoing ventral hernia repair at their facility from 2008 to 2011 with ≥12 months of follow-up.

METHODS: A retrospective review of prospectively collected data was conducted. All returns (surgical readmission, office or emergency visit) for complications or recurrences were examined. The impact of demographics (age, gender, and body mass index [BMI]), risk factors (hernia grade, hernia size, concurrent and past bariatric surgery, concurrent and past organ transplantation, any concurrent surgery, and American Society of Anesthesiologists score), and prosthetic type (polypropylene, other synthetic, human acellular dermal matrix, non-cross-linked porcine-derived acellular dermal matrix, other biologic, or none) on the frequency of return was evaluated.

RESULTS: A total of 564 patients had 12 months of follow-up, and 417 patients had 18 months of follow-up. In a univariate regression analysis, study arm (biologic, synthetic, or primary repair), hernia grade, hernia size, past bariatric surgery, and American Society of Anesthesiologists score were significant predictors of recurrence ($P < .05$). Multivariate analysis, stepwise regression, and interaction tests identified three variables with significant predictive power: hernia grade, hernia size, and BMI. The adjusted odds ratios vs hernia grade 2 for surgical readmission were 2.6 (95% confidence interval [CI], 1.3 to 5.1) for grade 3 and 2.6 (95% CI, 1.1 to 6.4) for grade 4 at 12 months and 2.3 (95% CI, 1.1 to 4.6) for grade 3 and 4.2 (95% CI, 1.7 to 10.0) for grade 4 at 18 months. Large hernia size (adjusted odds ratio vs small size, 3.2; 95% CI, 1.6 to 6.2) and higher BMI (adjusted odds ratio for BMI ≥50 vs 30 to 34.99 kg/m^2, 5.7; 95% CI, 1.2 to 26.2) increased the likelihood of surgical readmission within 12 months.

CONCLUSIONS: The present data support the hypothesis that careful matching of patient characteristics to choice of prosthetic will minimize complications, readmissions, and the number of postoperative office visits.

Currently, >200 meshes for hernia repair are available in the United States. Increasing use of mesh for hernia repairs follows recent prospective studies reporting lower recurrence rates when mesh is used[1,2] and aggressive marketing of mesh products. The appropriate use of mesh in challenging patients may improve their anatomic and

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surgical outcomes, but there are no use recommendations or guidelines on the basis of peer-reviewed prospective studies. When making decisions on mesh selection for hernia repair, surgeons are left with only level 2 data, expert opinion, and their own experience.[3–5]

Techniques for repair of ventral hernias are not standardized and vary depending on hernia characteristics and surgeon preference. Mesh choices are based on personal preference and experience, hospital purchase protocols and contracts with buying groups, and recent visits by mesh manufacturing representatives.[6–8] Hernia location and size, the quality of the tissues, comorbidities, age, body mass index (BMI), and lifestyle should influence mesh selection data.[8] In an attempt to assist in decision making, the Ventral Hernia Working Group consolidated many of these characteristics and published a hernia grading system based on relative risk stratification and surgical site occurrence.[5]

There is a wide array of prosthetic implants available, each with its own advantages and disadvantages.[9] The ideal synthetic would be chemically inert, noncarcinogenic, noninflammatory, nonallergic, and resistant to mechanical strain and infection; would remain elastic and flexible in tissues; would contribute minimally to adhesion formation; would be rapidly incorporated; and would be inexpensive. When placed in the appropriate patient, synthetics have the advantage of being relatively inert and having adequate strength, of being available in a variety of sizes and shapes, and of being inexpensive. Polypropylene meshes have evolved from heavy weaves with little porosity to low-weight and medium-weight, monofilament, porous meshes. These "newer" polypropylene meshes are associated with a decrease in infection risk, less in vivo shrinkage, and less patient discomfort.[10,11] Concerns with the synthetic meshes include risk for adhesions and erosion into bowel, shrinkage or contraction with migration from fixation points, and dramatically increased risk for infection compared with native tissue repairs.[10] In an attempt to ameliorate some of these concerns, the synthetic meshes have been coated with materials such as titanium, collagen, omega-3 fatty acids, or hyaluronate and polyglycolic acid. The benefits of these coatings have yet to be confirmed in randomized or comparative studies.[12]

Biologic mesh products are collagen based and derived primarily from porcine, bovine, or human origin. They are available in a variety of matrix patterns, such as acellular non-cross-linked human and porcine dermal products, layered porcine intestinal submucosa, bovine fetal dermis composites, and bovine pericardium.[9,12,13] The biologics are reported to offer better performance in a contaminated field.[14–17] The only prospective human trial using a non-cross-linked porcine acellular dermal matrix in 80 patients with large complex contaminated and clean contaminated ventral hernia repairs reported that biologic grafts needed to be explanted despite being placed in contaminated fields. Nevertheless, some biologic meshes are more prone to dissolution in infected fields.[18,19] In addition to better tolerance in the face of contamination, the biologics, in general, have been reported to have lower risk for adhesions, seroma, and encapsulation, and less need for explantation, compared with the synthetics. Again, this is variable among the biologics. The more heavily cross-linked or processed the tissues are, the greater the inflammatory response, seroma, infection risk, and adhesion formation.[20,21]

The choice of substrate and variable processing procedures make the in vivo reactions dramatically different among various meshes. These products are marketed with virtually no prospective data and, in many cases, not even any retrospective data. The premarket testing of these products has not been tightly regulated, so the safety and effectiveness of each mesh type are often unknown.

To help guide appropriate mesh selection on the basis of patient and hernia characteristics, we examined the postsurgical experiences of all patients undergoing ventral hernia repair with $\geq$12 months of follow-up at our facility from 2008 to 2011. We identified the hernia and patient characteristics that were most closely related to procedure success or failure, as defined by complications and recurrences. This analysis provides guidance for optimizing surgical outcomes, cost-effectiveness, and safety in ventral hernia repair.

Methods

Patients undergoing ventral incisional hernia repair at our institution between April 1, 2008, and December 31, 2011, were identified retrospectively using the prospectively collected database. A patient's earliest ventral incisional hernia repair during this period was defined as the index event. For all identified patients, we collected data from available electronic records through February 29, 2012, on encounters with our health care system. Patients with $\geq$18 months of postsurgical follow-up were identified and are the primary focus of study results.

Data were collected from surgery department electronic records on initial and postoperative inpatient or outpatient visits for hernia-related surgery, along with emergency department visits and office visits. For hernia-related surgeries, electronic review of case records and manual review of operative notes were conducted to identify nature of the hernia, mesh used, implanted and/or removed (if any), whether the removed synthetic mesh was infected, hernia size, American Society of Anesthesiologists (ASA) score, wound class, concurrent procedures, serum glucose, serum albumin, and patient characteristics such as gender, age, and BMI. Hernia size was available in descriptive terms in some records; when measurements were available, size was classified as small ($<$50 cm^2), medium (50 to 150 cm^2), or large ($>$150 cm^2). If multiple hernias were repaired, classification was based on the largest individual hernia. Each index event was assigned a hernia grade of 1 to 4 according to the general parameters specified by the Ventral Hernia Working Group.[5]

Postsurgical encounters were classified as follows:

- Surgery: hernia-related surgery in the hospital inpatient or day surgery setting.
- Complication: a diagnosis code for ≥ 1 of the following conditions (within 18 months unless otherwise specified): abscess (90 days); adhesions; bowel obstruction or other gastrointestinal complication; complication of device, graft, or mesh; dehiscence; deep vein thrombosis or pulmonary embolism (90 days); enteritis or colitis (30 days); fistula (6 months); hematoma (14 days); infection (washout or debridement procedure, 18 months; pneumonia, 30 days, septicemia and all other infections, 90 days); peritonitis (30 days); postoperative complications in the hospital (index hospitalization); procedural complications (30 days); septicemia (90 days); seroma (90 days); skin or connective tissue (60 days); and wound complications (60 days).
- Hernia recurrence: recurrent hernia found at surgery, radiographic confirmation of recurrent hernia, or attending surgeon examination and documentation of presence of hernia.

Statistical analysis

Data are expressed as number of patients (percentage) for categorical variables and as mean ± SD for continuous variables. Comparisons of patient population characteristics among study arms were carried out using either chi-square tests or analysis of variance as appropriate. Stepwise regression analysis was used to investigate relationships between the frequency of return visits and the various patient demographics and risk factors. For significant variables, post hoc comparisons of means controlled the family-wise error rate at .05 using Tukey's procedure. Stepwise logistic regression was used to investigate the relationships between surgical readmission (yes or no) and the patient demographics and risk factors. Adjusted odds ratios with 95% confidence intervals are presented for significant variables. The stepwise models included the main effects and 2-way interactions. P values $<.05$ were considered statistically significant.

Data were gathered in Microsoft Excel 2007 and analyzed descriptively in Microsoft Access 2007 (Microsoft Corporation, Redmond, WA). All statistical analysis was carried out using SAS/STAT version 9.2 for Windows (SAS Institute Inc, Cary, NC).

Results

The study population consisted of a case series of 417 patients with 18 months of clinical follow-up. Table 1 illustrates patient characteristics by study arm. Table 2 provides odds ratios describing the relationship between type of repair and three variables: ASA score, hernia grade, and hernia size.

Patients receiving biologic mesh were more likely to have higher ASA scores, higher hernia grades, and larger hernia defects; they were also slightly older. Biologics were used much more often for complex repairs with contamination and large defects; synthetic were used most often for grade 2 hernias, irrespective of size; and primary repair was used for smaller defects in patients with hernia grades of 1 to 3.

Nine patients required removal of synthetic mesh. Five of the 9 patients in whom synthetic mesh was removed for infection had had hernias that were previously repaired with synthetic materials that had noted infections. The infected meshes removed were Parietex (Covidien, Mansfield, MA; 2 cases), polytetrafluoroethylene (1 case), and microporous polypropylene (2 cases). These events occurred a mean of 182 ± 213.7 days after the index hernia repair (range, 10 to 475 days). Infected mesh was not removed from any patients in this series whose index hernias were repaired with AlloDerm (LifeCell Corporation, Bridgewater, NJ), Strattice (LifeCell Corporation), macroporous polypropylene, or other biologics or absorbable synthetics. Noninfected Parietex (other synthetic) that had pulled away from fascia on all sides was removed in 1 patient. Noninfected meshes were removed from 3 patients whose hernias were subsequently repaired with biologics (2 with AlloDerm, 1 with another biologic), whose details follow. In the AlloDerm study arm, noninfected AlloDerm was fully or partially explanted 378 days after implantation in 1 patient and 231 days after implantation in another. AlloDerm was removed for laxity of the material. In the 3rd patient, whose index hernia was repaired with Permacol (Covidien) secondarily had Strattice implanted during repair of a recurrent hernia at 140 days after the index event and removed (noninfected) 133 days later in a subsequent recurrent hernia repair that was again repaired with Strattice. In the analysis of complications, removals of infected meshes were classified as complications of the device, graft, or mesh, with 1 exception. All removals of noninfected meshes occurred in the context of recurrent hernias or mesh diastasis and were classified in that category.

Patients receiving biologic mesh had a higher mortality rate (8.1%) compared with patients receiving either primary repair (3%) or synthetic mesh (2.6%), likely related to patient comorbidities and other risk factors contributing to their hernia grades. Table 2 illustrates the occurrence of complications by hernia grade. As would be expected, complication occurrences rose as hernia grade increased.

Statistical analyses using per patient rates of return for treatment of complications, additional surgical interventions, and routine follow-up visits, by hernia grade and study arm, showed that on average, patients with ventral hernias returned 3.5 times for additional treatments during the 18-month study period, 2.0 times for treatment of complications and additional hernia-related surgeries, and 1.5 times for routine visits. There was nearly a 3-fold increase in per patient return rates for grade 3 vs grade

Table 1 Patient population characteristics

Variable	Biologic mesh (n = 134)	Primary repair (n = 220)	Synthetic mesh (n = 61)	P
Age (y)	56 ± 13[a]	52 ± 14[b]	55 ± 13[ab]	.02*
Women	79 (59%)	128 (58%)	31 (51%)	NS†
Men	55 (41%)	92 (42%)	30 (49%)	
BMI (kg/m^2)	35 ± 11	34 ± 12	33 ± 8	NS*
BMI distribution (kg/m^2)				NS†
<30	51 (40%)	82 (39%)	25 (44%)	
30–34.99	29 (23%)	45 (22%)	11 (19%)	
35–39.99	15 (12%)	30 (14%)	9 (16%)	
40–49.99	25 (20%)	30 (14%)	11 (19%)	
≥50	8 (6%)	21 (10%)	1 (2%)	
ASA score				.0006†
1 (normal health)	0 (0%)	10 (6%)	3 (4%)	
2 (mild systemic disease)	37 (33%)	84 (41%)	31 (53%)	
3 (severe systemic disease)	86 (64%)	97 (48%)	20 (39%)	
4 (severe systemic disease, life threatening)	5 (3%)	12 (6%)	3 (4%)	
Hernia grade				<.0001†
1 (low risk)	7 (5%)	30 (14%)	10 (16%)	
2 (comorbid)	59 (44%)	94 (43%)	44 (72%)	
3 (potentially contaminated)	41 (31%)	81 (37%)	7 (11%)	
4 (infected)	27 (20%)	15 (7%)	0 (0%)	
Hernia size				<.0001†
Small	24 (18%)	181 (85%)	24 (41%)	
Medium	29 (22%)	19 (9%)	18 (31%)	
Large	81 (60%)	13 (96%)	17 (29%)	

Percentages were calculated on the basis of the number of patients for whom the particular data point was available. Patients receiving absorbable synthetic mesh were excluded from most analyses because of small numbers. For age, study arm means connected with the same superscript letters were not significantly different.

ASA = American Society of Anesthesiologists; BMI = body mass index.

*Analysis of variance comparing the means among the 3 study arms (biologic, primary repair, and synthetic).

†Chi-square test comparing the distributions of patient characteristics among the 3 study arms (biologic, primary repair, and synthetic).

2 patients. Grade 4 patients returned for hernia-related services at a slightly higher rate than grade 3 patients. Segmentation by type of repair and hernia grade revealed much higher return rates for grade 3 patients receiving synthetic mesh compared with similarly graded patients receiving biologics or undergoing primary repair with no mesh (12.6 returns vs 3.6 returns for patients receiving biologics and 1.9 returns for patients receiving primary repairs with no mesh). A univariate regression analysis suggested that type of repair, hernia grade, hernia size, past bariatric surgery, and ASA score were significant predictors of return rates ($P < .05$). However, multivariate analysis and stepwise regression identified two variables with significant predictive power: hernia grade and BMI.

Patients with higher hernia grades (3 or 4) were significantly more likely to have additional hernia-related surgeries than patients with grade 2 hernias (odds ratios, 2.3 and 4.2, respectively). The impact of BMI on surgical returns was significant until patients reached BMIs >40 kg/m^2. Patients with BMIs of 30 to 34.99 kg/m^2 were 2.5 times more likely to be admitted for additional hernia-related surgeries as those with BMIs <30 kg/m^2. Patients with BMIs of 35 to 39.99 kg/m^2 were 3.2 times more likely to be admitted for additional hernia-related surgeries as those with BMIs <30 kg/m^2. However, patients in higher BMI categories (>40 kg/m^2) were no more likely to be readmitted than patients with BMIs of 30 to 34.99 kg/m^2, although our sample contained relatively small numbers of patients in the highest BMI categories.

Only hernia grade was identified as a significant predictor in a multiple logistic regression model ($P = .0036$). Patients with grade 3 hernias were 2.3 times more likely to experience hernia recurrence than those with grade 2 hernias. Patients with grade 4 hernias were >4 times more likely to have hernia recurrence than those with grade 2 hernias. Adjusted odds ratios for grade 3 vs grade 2 and for grade 4 vs grade 2 were 2.3 (95% confidence interval, 1.2 to 4.7) and 4.4 (95% confidence interval, 1.9 to 10.3), respectively.

Comments

It is estimated that >200,000 hernia repairs are done in the United States on an annual basis.[22] Despite the large number of repairs performed annually, controversy still

Table 2 Patients experiencing occurrences of complications by hernia grade

Complication	Hernia grade			
	1	2	3	4
Abscess	0 (0%)	(1%)	0 (0%)	0 (0%)
Adhesions	0 (0%)	8 (4%)	13 (10%)	11 (26%)
Bowel obstruction/other GI complication	1 (2%)	17 (9%)	32 (25%)	17 (40%)
Complication of device/graft/mesh	3 (6%)	7 (4%)	7 (5%)	5 (12%)
Dehiscence	1 (2%)	9 (5%)	4 (3%)	11 (26%)
DVT/PE	1 (2%)	7 (4%)	8 (6%)	4 (9%)
Enteritis/colitis	0 (0%)	0 (0%)	2 (2%)	2 (5%)
Fistula	0 (0%)	2 (1%)	4 (3%)	9 (21%)
Hematoma	1 (2%)	1 (1%)	3 (2%)	2 (5%)
Hernia recurrence	5 (11%)	15 (8%)	20 (15%)	18 (42%)
Infection	4 (9%)	23 (12%)	28 (22%)	24 (56%)
Peritonitis	2 (4%)	2 (1%)	3 (2%)	4 (9%)
Pneumonia	2 (4%)	5 (3%)	6 (5%)	3 (7%)
In-hospital postoperative complication	0 (0%)	3 (2%)	2 (2%)	6 (14%)
Procedural complication	1 (2%)	1 (1%)	6 (5%)	5 (12%)
Septicemia	1 (2%)	1 (1%)	1 (1%)	5 (12%)
Seroma	1 (2%)	5 (3%)	10 (8%)	7 (16%)
Skin/connective tissue	1 (2%)	8 (4%)	6 (5%)	7 (16%)
Wound complications	1 (2%)	13 (7%)	13 (10%)	17 (40%)
Grand total	25 (52%)	128 (70%)	168 (131%)	157 (368%)

DVT = deep vein thrombosis; GI = gastrointestinal; PE = pulmonary embolism.

exists concerning the method of repair, the type of mesh to use, and preoperative preparation required.[12,23] The ability to accurately predict which patients are most likely to need subsequent hospital admission and to experience major complications or hernia recurrence would be of significant value. Using univariate regression analysis of variables from our institutional hernia database, study arm, hernia grade, hernia size, past bariatric surgery, and ASA score were shown to be significant predictors of need to return to the hospital ($P < .05$). Stepwise regression identified only 3 variables with significant predictive power: hernia grade, hernia size, and BMI.

The use of biologic matrix implant materials has reduced postoperative complications and return visits.[10,24] The reduction in postoperative visits and complications was confirmed in our institutional review. Among patients undergoing grade 3 hernia repairs, the mean number of return visits for reoperation or complications required for biologic implant material was 3.6, while patients receiving synthetic polymers required an average of 12.6 return visits. Consistent with our data is a recent multicenter prospective trial of 80 patients undergoing hernia repair in infected or contaminated fields (grades 3 and 4) that found no biologic matrix (Strattice) that was required to be explanted.[19]

Ongoing analysis of our institution's data will continue to shed light on factors predicting the success or failure of our current approaches. On the basis of our database experience, we strongly suggest that surgeons risk-stratify each hernia and choose mesh on the basis of this risk stratification.

In summary, considering mesh selections, synthetic mesh should be used when a patient is at low risk for infection (grade 1 or low-risk grade 2 as graded by the Ventral Hernia Working Group).[5] Biologics are clearly favored and supported in this database review and the current literature for contaminated and clean contaminated cases. High-risk clean cases (ie, morbid obesity, smoking, immune suppression, and history of previous infection) should be considered on an individual basis for the use of biologic mesh. In patients with increasing numbers of comorbidities or risk factors, surgeons should strongly consider biologics. The grading system proposed by Breuing et al[5] is a good first step in this risk stratification. Ongoing analysis and review of our institution's prospectively collected database will continue to shed light on factors predicting successes and failures of our current approaches.

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Discussion

Michael Moore, M.D., F.A.C.S. (Spokane, WA): When asked to review this article, my first thought was "great, I finally will have a map to guide me through all of the mesh options on the market." Alas, this would not be the case, but instead a much more interesting discussion is presented. This is a study delving into the surgical planning of particularly complex ventral hernia repairs. The authors summarize and promote a formal grading system of hernias. From this they strongly suggest that we should risk stratify each hernia and then choose a mesh based on this risk stratification. The question is whether this stratification is fruitful in their cohort of patients or any cohort.

The study is a retrospective design of a longitudinal series from a single institution. Factors left out of consideration include a few "holy grails" to surgeons. Namely, the type of repair, the specific operative technique, and the number of prior repairs the patient had undergone. The impact of these factors is not discussed. Are we to assume from the authors' viewpoint, that these issues may not have as much relevance in predicting outcomes? I was also quite surprised to find that 53% of the patients in the study underwent a primary tissue repair. How this clarifies the choice between mesh products is not made evident. In addition, the definition of size for the hernias (small being up to 7 $\times$ 7 cm) seems quite large, particularly for a primary repair. The authors' review of outcomes, using both a univariate regression analysis and multivariate analysis, defines hernia size, along with hernia grade and body mass index (BMI), to have significant statistical power in predicting complicating events. In light of this observation, is mesh truly indicated less than half the time?

I reflected on the choice of design using postoperative visits (of those patients that chose to follow up over 18 months) as the metric to define problems and I feel that it works quite well. Significant complications that should influence our operative planning would require several visits for resolution. Using this format, I think the authors demonstrate the significant role hernia grade has in predicting complications with synthetic verses biologic mesh products. So, in the end, my specific mesh brand questions remain unanswered; but the much more important directive for which category of mesh is nicely shown. In my heart of hearts, I already knew that it is up to each one of us to critically evaluate the new products coming down the road and review the best available data and not be swayed by the market hype that often accompanies these products.