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Special REPORT

H.E.R.N.I.A.: Hernia Experts Roundtable and New Innovations Assembly

Importance of Mesh Selection in Complex Hernia Repair

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In January 2015, W. L. Gore & Associates, Inc., hosted the Hernia Experts Roundtable and New Innovations Assembly (H.E.R.N.I.A.) in Miami Beach, Florida. Leaders in hernia repair and high-volume hernia surgeons from around the United States met to discuss issues related to management of patients with ventral hernias.

The aim of this symposium was to outline evidence-based practices regarding patient risk management, wound classification, mesh materials, and surgical techniques. The symposium included discussion of costs and value in hernia repair, and how they influence clinical decision making. Course director Brent D. Matthews, MD, FACS, Chair of Surgery at the Carolinas Medical Center in Charlotte, North Carolina, said that the field of hernia repair is changing rapidly as the health care system shifts from a volume-based system to a value-based one. As a result, there is now unprecedented focus on optimizing the entire care process for the ventral hernia patient.

"The preoperative risk assessment and comorbidity management before surgery is as important as the decision making about what kind of technique you are going to use and what kind of material you are going to use," Dr. Matthews said. "Ultimately you can do a great operation, pick the right technique and the right material but still have adverse events because the patient has comorbidities that you haven't managed.

"As an overall message, there are a lot of options for how to manage a hernia. But the challenge is to make sure that you do the right thing for the right patient and your patient ultimately has to participate in defining what that is."

Introduction

Approximately 350,000 ventral hernias are repaired in the United States annually.[1] Despite the volume, wide variation exists in management, which cannot be explained by differences in patient or hernia characteristics.[1] Researchers have attributed the disparities in practice to a lack of robust evidence and supporting guidelines for care.[1,2] The available evidence consists largely of level II to IV recommendations.[3] As a result, practice patterns for ventral hernia repair (VHR) often are driven primarily by individual surgeon and/or patient preference and are reflected in suboptimal and varied outcomes.

Surgical decisions greatly affect the health care resources used for patients. In a 2013 study, researchers reported that 15% of patients accessed the top 50% of inpatient resources associated with VHR in 2009.[4] From the study: "The decisions made by surgeons have a direct impact on this relationship, because initiating an operative procedure results in consumption of resources unlike many other patient–provider relationships in medicine. The challenge in appropriate delivery of these resources is maximizing value for patients and health systems by improving outcomes and minimizing costs."[4]

Mesh Materials: The Evidence

No single mesh is ideally suited for every patient. Each mesh carries its own risks and benefits. The challenge for surgeons is to select the most appropriate mesh for the most appropriate patient, and to do so in a matter that offers the greatest value. For that reason, it is critical that surgeons understand the composition, costs, and supporting evidence for meshes.

Synthetic Mesh

In a recent report, Brown and Finch stated that the original logic behind using a synthetic mesh product was "very simple: the mesh was a material that could be used to reinforce the abdominal wall with the formation of scar tissue."[5] In time, some surgeons reported that the heavyweight design of early meshes, intended to provide strength and induce maximal fibrosis, led to pain and difficulty in movement. By the late 1990s, herniologists favored lightweight materials, believing that they were incorporated better and caused less pain.[5] Today, however, clinicians widely accept that mesh porosity is as important as weight.[5] A series of studies on mesh performance completed in Germany using rabbit models, showed that large pores lead to less mesh surface, thereby reducing adhesive potential.[6]

"If we can minimize weight and, more importantly, widen the pores, we can minimize scarplate formation and inflammatory response. The concept of bridging fibrosis was born out of this," said William S. Cobb, MD, FACS, Associate

Professor of Clinical Surgery in the Greenville Health System in Greenville, South Carolina.

Today, permanent synthetic meshes are constructed from materials such as polypropylene, polyester, and expanded polytetrafluoroethylene, used in combination or with other materials.[5] The type of mesh alters soft tissue ingrowth with meshes with larger pores associated with increased soft tissue development.[5] Mesh weight also influences elasticity. Studies report about a 20% to 35% elasticity at 16 N/cm for lightweight meshes and half of this elasticity for heavyweight materials.[5,7] Mesh fibers may be monofilament, multifilament, or patches. Multifilament meshes may be the most prone to infection. In vivo studies found multifilament meshes promote the persistence of bacteria in the implant bed.[8]

Biologic Mesh

The use of biologic mesh has grown considerably in recent years in response to the need for a better option for contaminated hernias. Currently available biologic meshes come from human, porcine, or bovine sources, and may be produced from acellular dermis, fetal dermis, small intestine submucosa, and pericardium.[9] No large prospective randomized trials have been conducted to compare different biologics head-to-head, nor examine their utility in different wound classes. As a result, the ideal role of biologic mesh in hernia repair is still evolving. This uncertainty is reflected in practice patterns: According to a survey of more than 200 practicing surgeons, surgeons use biologic mesh in various wound classifications despite a lack of level 1 evidence.[10] The most commonly reported influences for use were personal experience (45%), published research (28.3%), and product availability (17.2%).[10]

Scott Roth, MD, FACS, Professor of Surgery and Chief of Gastrointestinal Surgery at the University of Kentucky College of Medicine in Lexington, Kentucky, noted that surgeons should consider multiple factors when using a biologic mesh in a patient with a ventral hernia. "When deciding whether to use a biologic mesh or not, you've got to review cost, both short- and long-term; hernia recurrence rate, which is the greatest cost to the patient; complications including mesh infection, migration, [and] erosion; and individual characteristics whether it be the CDC [Centers for Disease Control and Prevention] wound classification, Ventral Hernia Working Group classification, or the Ventral Hernia Risk Score."

The strongest evidence supporting a role for biologic mesh in VHR suggests it may have some clinical advantages in contaminated fields. The RICH (Repair of Infected or Contaminated Hernias) study, a prospective, multicenter single-arm trial, found use of the non-crosslinked porcine mesh STRATTICE® Reconstructive Matrix (LifeCell) in repair of contaminated ventral hernias in high-risk patients allowed for successful, single-stage reconstruction in more than 70% of patients, with a 28% recurrence rate by the 2-year post-surgery mark.[11]

In a 2014 study, investigators reviewed retrospectively collected data from 359 consecutive abdominal wall reconstructions with an acellular dermal matrix (ADM).[12] At a mean follow-up of 28.1 months, clean wounds (n=171) required fewer reoperations than combined contaminated (n=188) wounds (2.3% vs 11.2%, P=0.001) and trended toward experiencing fewer surgical site occurrences (19.9% vs 28.7%, P=0.052). There were no significant differences between clean and contaminated cases in 30-day surgical site infections (SSIs; 8.8% vs 8%), hernia recurrences (9.9% vs 10.1%), and mesh removal (1.2% vs 1.1%) rates.[12] Study authors concluded that these data support the use of ADM rather than synthetic mesh for complex abdominal wall reconstruction in the setting of wound contamination.[12]

In another series, Brahmbhatt and colleagues reviewed a series of patients who underwent repair with lightweight mesh in contaminated fields (n=39), and compared the outcomes with those patients who underwent biologic mesh repair in contaminated fields (n=38).[13] Biologic meshes were associated with lower rates of mesh explantation (0% vs 5.1%, P=0.24) and hernia recurrence (0% vs 7.7%, P=0.24) at a median follow-up of 15 months.[13] The researchers stated that their results suggest lightweight mesh may not be strong enough for lasting repairs in contaminated settings and may lack the ability to tolerate bacterial contamination compared with biologic mesh.[13]

Conversely, some published reports are less supportive of biologic mesh in contaminated cases. A 2013 report found that published reviews tend to favor use of these meshes but cumulative data does not support the claim that biologic mesh is better.[14] A retrospective review of 128 patients who underwent single-stage VHR in contaminated fields with biologic mesh showed 31.3% developed a hernia recurrence at a mean follow-up of 21.7 months.[15] A case series from 2013 concluded that synthetic mesh has a role in contaminated VHR. Among 100 patients who underwent open VHR with polypropylene mesh—most in the retrorectus position—in clean-contaminated and contaminated fields,[16] surgical site occurrences were reported in 26.2% of clean-contaminated cases and 34% of contaminated cases. With a mean follow-up of 10.8 months, 7 patients developed recurrence and 4 required mesh removal.[16]

Biologic mesh must be considered in terms of cost, according to Dr. Roth; he and his colleagues studied the costs associated with complex abdominal wall hernia repair at their facility, analyzing cost data on consecutive open VHRs over 3 years. They found that the hospital experienced a median net financial loss of $8,370 with a median contribution margin for cases using biologic mesh of –$4,560.[17]

Biosynthetic Mesh

Biosynthetic meshes are a newer class of materials: They aim to provide a stable scaffold for tissue remodeling but fully dissolve into tissue over time. At present, 5 biosynthetic meshes are available: VICRYL® Mesh (Ethicon Endo-Surgery, Inc.), TIGR® Resorbable Matrix (Novus Scientific), PHASIX Mesh (Davol Inc.), SERI Surgical Scaffold (Allergan), and GORE® BIO-A® Tissue Reinforcement.

Made with absorbable material,[18] VICRYL® Mesh degrades in vivo through hydrolysis and is fully absorbed by 3 months[19]; its quick absorption profile may make it less than ideal for

hernia repair. PHASIX Mesh is fabricated from a poly-4-hydroxybutyrate (P4HB), a naturally derived, fully absorbable polymer.[20] In porcine models, scaffolds derived from the P4HB material degraded slowly, maintaining support at the repair site over a 52-week period.[19] TIGR® Matrix is knitted from 2 synthetic resorbable fibers. The first, a copolymer of glycolide, lactide, and trimethylene carbonate, loses most mechanical strength at approximately 2 weeks and is fully absorbed in 4 months. The second, a copolymer of lactide and trimethylene carbonate, absorbs over 3 years.[21] The dual-fiber design provides strength in the acute wound-healing phase and facilitates mechanical stimulation of new tissue.

GORE® BIO-A® Tissue Reinforcement has the most clinical evidence of newer-generation biosynthetic mesh products. Made from polyglycolic acid and trimethylene carbonate, its scaffold is designed for tissue ingrowth and absorbs over 6 to 7 months.[22] A multicenter, prospective trial, COBRA (Complex Open Bioabsorbable Reconstruction of the Abdominal Wall), examined GORE® BIO-A® Tissue Reinforcement in complex VHR. The trial was designed to assess 2-year outcomes after use of a biosynthetic mesh to reinforce the midline fascial closure in single-stage, open, clean-contaminated and contaminated VHR. Investigators enrolled 104 adult patients with nonurgent hernia defects of at least 9 cm^2 and a clean-contaminated or contaminated operative field.[23]

Results from an interim 1-year analysis showed 9.7% hernia recurrence, 18% infection, and 5% seroma rates.[23] To date, no infected biosynthetic meshes required explantation from the study population. Factors not associated with recurrence included obesity, defect size, number of previous hernia repairs, smoking, and diabetes. Surveys showed patients' quality of life and physical health were significantly higher at 6 and 12 months.[23] Positive final results from the COBRA trial have been presented at the 1st World Conference on Abdominal Wall Hernia Surgery in Milan, Italy.[24]

"Is there a value in biosynthetic products? I think there probably is," said Garth Jacobsen, MD, Director of the UCSD Hernia Center at the University of California, San Diego School of Medicine in San Diego. "They can serve as a scaffold for tissue regeneration. Clinical data say, yes, they are safe for use in contaminated fields. They are definitely cheaper than normal biologics, but also more expensive than lightweight macroporous mesh. Specifically when compared with biologics, the value of positive performance may be there for biosynthetic meshes."

Wound Classification

Wound classification has emerged as one of the challenging issues in hernia repair. Lack of a universally accepted classification system for wounds has led to erroneous risk evaluation of patients, incomparable series in the literature, and deficient methods of evaluating the quality of surgical outcomes.

The CDC's wound classification system is the predominant grading schema used in the United States. Created more than 15 years ago, the CDC system rates the degree of contamination of a surgical wound at the time of operation on a scale of 1 to 4 with 4 being the most severely infected or dirty wounds.[25] Studies have shown that the CDC wound classification system does not adequately estimate risk for infection. In a study based on 15,289 patients in the National Surgical Quality Improvement Program (NSQIP) database, wound classification was a significant predictor of overall complications, reoperation, and mortality, but not an adequate predictor of SSIs.[26]

Dr. Matthews said the CDC system fails to account for the complexities of today's hernia patients. "In the US, the typical hernia patient that shows up in 2015 is very different from the typical patient who showed up in 1999. If you consider the increase in obesity and obesity-associated conditions, and the increase in diabetes, our patients have changed significantly," he said. "These comorbidities change the risk for undergoing the types of operations these patients are having, whether it's a straightforward ventral hernia repair or a complex abdominal wall reconstruction."

The outdated CDC classification system was the impetus for the Ventral Hernia Working Group schema in 2010, which stratified patients into a 4-tier system based on risk for developing an SSI.[27] This system, however, has been criticized as inaccurate for predicting SSIs and occurrences.[28] At present, several groups are working on models to better stratify the risk for SSIs and occurrences in VHR. Most recently, surgeons from the University of Pennsylvania published an internally validated risk model for open repairs using the American College of Surgeons NSQIP database, which stratifies patients in 5 groups based on risk factors related to operative time and degree of wound contamination.[29]

"I think we're going to move further and further away from the CDC system of wound classification as it relates to the hernia patient," Dr. Matthews said. "Data, analytics, and informatics will become more a part of the risk stratification process. This is something surgeons must be aware of, particularly as sites like Hospital Compare or other groups use classification systems to judge the risk for patients having a surgical site occurrence. It's becoming increasingly important that we have a basic understanding of wound classification because if the data going into a system has some liability, what comes out of it is not good data."

Optimizing Patients for Surgery

In recent years, prehabilitation has emerged as a method for better preparing patients for VHR, thereby reducing risk for developing an SSI and/or hernia recurrence. The rise of prehabilitation stems from a broader shift in health care that has payors, physicians, patients, and policymakers prioritizing issues like value and outcomes, Dr. Matthews said. "Surgeons are becoming more focused on the prehabilitation of patients before surgery and much of that is being pushed because of a change in our health care system from a volume-based system to a value-based system," he said.

Very few studies have examined specifically at how preoperative changes affect outcomes in VHR. However, it is intuitive that patients benefit from interventions that reduce their surgical risk. Clinical optimization, especially for recurrent hernia

Table. H.E.R.N.I.A.: Hernia Experts Roundtable and New Innovations Assembly[a] Statements on Clinical Decision Making in Complex Ventral Hernia Repair Based on a Presentation by Matthew Goldblatt, MD, FACS

Type of Wound	Expert Consensus Repair Recommendations
Clean	<2 cm, nonobese patient: primary repair >2 cm, obese or recurrent hernia after abdominal wall reconstruction: laparoscopic repair with mesh
Contaminated	Open, rectorectus repair with biosynthetic mesh
Contaminated (with enterotomy)	Complete lysis of adhesions, 2- to 3-d rest on antibiotics, laparoscopic VHR or open rectorectus repair with biosynthetic mesh
Infected	Infected mesh with pus: mesh removal, VAC, and washout Enterocutaneous fistula, malnutrition: resection of bowel if needed. If significant infection or sepsis, consider primary fascial closure, staging the repair with a temporary closure, or placing a bridging non-permanent with planned recurrence in 6-12 mo

VAC, vacuum-assisted closure; **VHR,** ventral hernia repair

[a] The H.E.R.N.I.A.: Hernia Experts Roundtable and New Innovations Assembly was sponsored by W. L. Gore & Associates, Inc., makers of GORE® BIO-A® Tissue Reinforcement.

patients, is integral to creating a safe, lasting repair, according to Dr. Jacobsen. "You might not get patients fully where you want before surgery but if they are fully invested in that process of optimizing, then maybe you can go to the operating room with them," he said. "This is your one and only chance to intervene so clinical optimization is really essential to outcomes."

Interventions shown to benefit VHR patients include the following:

Weight loss: Obesity predisposes patients to incisional herniation and increases incidence of recurrence after VHR, according to H.E.R.N.I.A. panelists. Several panelists said that they refer obese patients with hernias to dietitians or bariatric surgeons before an elective hernia repair.

Smoking cessation: Smoking increases hernia recurrence 4-fold; drives inflammation; decreases collagen deposition; and contributes to pain, infection risk, and cardiovascular complications, according to H.E.R.N.I.A. panelists who recommend patients quit smoking at least 4 weeks before surgery, but offered mixed opinions on nicotine-replacement products. Most said they permitted these products but several surgeons expressed concern that the products skew laboratory tests and/or negatively influence wound healing.

Diabetes mellitus: For individuals with diabetes, blood glucose levels should be well controlled, although less strict than previously believed, in the range of 140 to 160 mg/dL or glycosylated hemoglobin A_{1c} levels below 8%, according to the panelists.

Malnutrition: Patients who are malnourished may have a reduced ability to heal from surgery and face higher risks for postoperative wound infection. H.E.R.N.I.A. panelists recommend oral or enteral dietary supplementation with arginine, omega-3 fatty acids, and nucleotides, known as immunonutrition, for malnourished patients.

Skin preparation: A 2010 randomized trial suggested that chlorhexidine/alcohol is superior to other skin preparations in prevention of SSIs. However, other skin preparations in the study did not include alcohol.[30] Although some debate remains about chlorhexidine versus povidone-iodine

(the active ingredient in Betadine®), evidence suggests that isopropyl alcohol is the key ingredient in an effective skin preparation, and iodine-based preparations in alcohol are equivalent, perhaps superior, to chlorhexidine.[31]

Carbohydrate loading: The value of carbohydrate loading in hernia repair is difficult to assess because it often is evaluated as part of a broader enhanced recovery after surgery protocol. That said, evidence from other surgical fields shows a benefit: A randomized trial showed preoperative administration of oral carbohydrate leads to a significantly reduced postoperative hospital stay when compared with consuming water preoperatively, with a trend to earlier return of gut function (not significant).[32]

Guy Voeller, Professor of Surgery at the University of Tennessee Health Science Center in Memphis, recommended surgeons use the free Carolinas Equation for Determining Associated Risks (CEDAR) application. CEDAR calculates a patient's likelihood for wound complications and the associated costs from a VHR. It also demonstrates how patients can reduce that risk by changing behaviors such as smoking.[33] "We have our patients go through it in our office," he said. "They can see the cost, the follow-up charges, and become more educated on how certain behaviors add to their risk."

Evidence-Based Approaches to Hernia Repair

The current standard for evidence-based medicine is randomized controlled trials (RCT) or meta-analyses. Unfortunately, in hernia surgery, comparison of RCTs and meta-analyses are rarely able to confirm any significant effect of a specific procedure.[34]

Experts at H.E.R.N.I.A. agreed that evidence supports a laparoscopic approach to VHR in patients with clean wounds. In one study using Nationwide Inpatient Sample data, patients who underwent laparoscopic VHR with mesh had fewer complications, shorter hospital length of stay, lower hospital charges, more frequent routine discharge, and decreased mortality compared with patients who underwent open repair.[35] Another study showed that laparoscopic VHR is associated with decreased length of stay and infection rates, although laparoscopic surgery accounted for only 17% of hernia repair operations.[36]

"Even in my practice, the majority of my repairs are open and I helped develop laparoscopic repair," Dr. Voeller said. "But if we're truly interested in evidence-based medicine and reducing surgical site infections, we need to look at doing more of repairs laparoscopically. I'm not talking about complicated repairs but the kind of things we encounter in the community."

At H.E.R.N.I.A., Matthew Goldblatt, MD, FACS, Associate Professor in the Department of Surgery at Froedtert & Medical College of Wisconsin in Milwaukee, Wisconsin, presented a flowchart for clinical decision making using evidence-based approaches to hernia repair. He recommended performing a laparoscopic repair using mesh in patients when a clean wound is present, a hernia defect is greater than 2 cm, when patients are obese, or when patients have experienced a hernia recurrence after abdominal wall reconstruction. In patients with contaminated wounds, evidence supports an open, retrorectus repair with a biosynthetic mesh (Table).

Conclusion

Surgery is shifting away from reliance on RCTs and beginning to look toward complex systems science to improve the quality of health care, said Bruce Ramshaw, MD, FACS, Co-Director of Advanced Hernia Solutions in Daytona Beach, Florida. Increasingly, surgeons and organizations will have to rely on quality collaboratives, local data collection, and continuous quality improvement to improve value in patient care.

"This is about looking at data in a different way. We need to define what factors matter to produce outcomes and define our value-based outcomes. The health care system today is too complex to fit into principles of reductionist science," Dr. Ramshaw said. "We can't use the same static algorithms we used in the past. Otherwise, we'll get worse and worse. But if we continue to collect data and adapt new algorithms, we'll get better and better. The new algorithms include care coordination, building a team, defining the context of care, measuring value, and using data to attempt to improve value.

"Ultimately, we will all have to work together because there's no one place that's going to get it figured out. Only by sharing information and ideas will we all get better," he added.

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