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# Special REPORT

JUNE 2010

*New Evidence-based  
Recommendations for*

## The Grading and Technique of Repair of Incisional Ventral Hernias

*This supplement represents a condensed version of the following publication: The Ventral Hernia Working Group. Incisional ventral hernias: review of the literature and recommendations regarding the grading and technique of repair [published online ahead of print March 22, 2010]. Surgery. doi: 10.1016/j.surg.2010.01.008.*

*The Ventral Hernia Working Group was recently established to evaluate new technologies and techniques for ventral hernia repair. In September 2008, the group met for a 2-day summit with the goal of creating a grading system to guide surgeons in the assessment of patients with incisional ventral hernias with regard to risk for surgical site occurrences such as infection. The group also proposed evidence-based recommendations regarding the approach to advanced surgical techniques for the repair of incisional ventral hernia. This report reviews the grading system and recommendations proposed by the Ventral Hernia Working Group.*

### Introduction

An estimated 250,000 ventral hernia repairs are performed each year in the United States, making this procedure one of the most common challenges facing general surgeons.<sup>1</sup> Although the indications for repair of incisional ventral hernias are well accepted, controversies persist regarding the technique of repair, the reinforcement of repairs, and what type of repair material should be used, if any. There is also ongoing debate regarding the

most important end point in ventral hernia repair: surgical site occurrence (SSO) or hernia recurrence. No guidelines for the repair of ventral hernias have yet been established in the literature.

To address these gaps, the Ventral Hernia Working Group (VHWG) was established to evaluate new technologies and techniques for ventral hernia repair. The VHWG consists of 8 surgeons (4 general and 4 plastic) with extensive experience in abdominal wall reconstruction. The group met for a 2-day summit in

#### ACKNOWLEDGMENTS

Funding for the Ventral Hernia Working Group was provided by LifeCell Corporation, Branchburg, New Jersey. Editorial support was provided by Medisys Health Communications, High Bridge, New Jersey. Writing assistance was provided by Joshua Kilbridge of Kilbridge Associates, San Francisco, California.

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2008 for the purpose of creating a grading system to guide surgeons in the assessment of patients with incisional ventral hernias with regard to risk for SSO, particularly infection. The group also proposed evidence-based recommendations regarding the approach to advanced surgical techniques for the repair of incisional ventral hernia.

An extensive literature search was performed to identify existing best practices in each core area in ventral hernia repair. Articles were graded based on level of evidence in accordance with established methods.<sup>2,3</sup> The recently published recommendations of the VHWG<sup>4</sup> include evidence-based options for the evaluation of patients according to risk for SSO and the selection of surgical techniques and appropriate reinforcement material (Tables 1 and 2).<sup>5-25</sup> The purpose of this report is to review the clinical challenge of repairing incisional ventral hernia and describe the recommendations and grading system proposed by the VHWG.

## Background

Numerous advanced techniques and technologies have been developed for the repair of ventral hernias. Nevertheless, recurrence rates remain unacceptably high. This shortcoming is best illustrated by the pivotal, prospective, randomized trial by Luijendijk et al, which reported that nearly half of all primary repairs and one-fourth of ventral herniorrhaphies reinforced with synthetic mesh fail within 3 years.<sup>7</sup> Furthermore, each reoperation for ventral hernia carries an increased risk for recurrence,

as illustrated by a retrospective cohort study of a hospital discharge database, which found progressively shorter intervals between each additional hernia repair.<sup>26</sup> Within 5 years of the initial herniorrhaphy, 12.3% of patients required at least one subsequent reoperation; the length of time between reoperations was progressively shorter after each additional hernia repair.

The seminal study by Luijendijk et al clearly demonstrated the utility of prosthetic reinforcement of ventral hernia repairs.<sup>5</sup> Indeed, the overriding recommendation of the VHWG (Table 1) is to reinforce all ventral hernia repairs with appropriate repair material. Another major advance in ventral herniorrhaphy was introduced by Ramirez et al in 1990.<sup>27</sup> These authors described the use of local tissue transfer to create a tension-free closure of the midline. Synthetic repair material has been combined with this component separation technique to further reinforce ventral hernia repair and reduce the rate of recurrence.<sup>5</sup> Unfortunately, synthetic mesh is associated with complications such as the formation of enterocutaneous fistulae and infection of the prosthesis.<sup>25,28-30</sup> More recently, biologic repair materials were introduced as a potential solution to the twin complications of recurrence and SSO. However, no consensus has been published regarding the indications, technique of use, and risks for SSO and recurrence with these novel materials.

## Surgical Site Occurrences

Common SSOs following ventral herniorrhaphy include infection, seroma, wound dehiscence, and the formation of enterocutaneous fistulae. Infection is a particularly common and troubling

**Table 1. Ventral Hernia Working Group's Recommendations for Technique of Repair of Incisional Ventral Hernias**

Recommendation	Strength of Recommendation	Level of Evidence	Evidence
1. Reinforcement recommended for repair of all incisional ventral hernias	1	A/B	Burger et al <sup>5</sup> Espinosa-de-los-Monteros et al <sup>6</sup> Luijendijk et al <sup>7</sup>
2. Centralize and reapproximate rectus muscles when feasible under physiologic tension	1	C	de Vries Reilingh et al <sup>8</sup> Espinosa-de-los-Monteros et al <sup>6</sup> Kolker et al <sup>9</sup> VHWG opinion
3. Reduce bioburden prior to repair	1	B	Mangram et al <sup>10</sup> VHWG opinion
4. Placement of repair material: underlay is the recommended technique for the placement of appropriate repair material for open and laparoscopic repairs; overlay placement of repair material should be considered only when complete fascia-to-fascia repair has been achieved	2	B	Awad et al <sup>11</sup> Espinosa-de-los-Monteros et al <sup>6</sup> Korenkov et al <sup>12</sup> VHWG opinion
5. In the setting of gross, uncontrolled contamination, it is appropriate to consider delayed repair	1	C	VHWG opinion

Based on references 5-12.

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complication that can increase the risk for hernia recurrence.<sup>31</sup> Ventral herniorrhaphy is associated with a higher risk for infection than are other clean surgical procedures; published rates of infection following ventral hernia repair range from 4% to 16%, compared with 1.5% following other procedures.<sup>7,13,14,18,32</sup> Additionally, a history of previous wound infection increases the risk for new infection. One study of patients undergoing ventral hernia repair reported that 41% of those with previous wound infection developed a new infection, compared with 12% of those with no history of wound infection ( $P < 0.05$ ).<sup>18</sup>

Other factors that increase the risk for wound infection include the presence of comorbidities. For example, analyses of the National Surgical Quality Improvement Program (NSQIP) database have identified corticosteroid use, smoking, coronary artery disease, chronic obstructive pulmonary disease, low preoperative serum albumin levels, prolonged operative time, and use of absorbable synthetic mesh (likely a surrogate for more complex procedures) as significant independent predictors of wound infection.<sup>13,14</sup> Other studies have identified age, obesity, altered immune response, and nutritional status as predictors of infection.<sup>10,15</sup>

### Permanent Synthetic Mesh and SSO

The development of synthetic repair material was a major advance in hernia repair. The advantages of synthetic mesh,

which include reduced recurrence rates, ease of use, and relatively low cost, have made these products the most commonly used repair material for the reinforcement of ventral hernias.<sup>1</sup> However, several significant disadvantages are commonly reported in association with synthetic mesh, including increased risk for visceral adhesions to the repair site, erosion into the bowel leading to formation of enterocutaneous fistulae and/or bowel obstruction, extrusion of the repair material, and infection.<sup>19,25,28,33-35</sup> Infected synthetic repair material often necessitates surgical removal, leaving a contaminated field and a hernia deficit larger than the original and still in need of repair with reinforcement.<sup>8,16,21,23,24,36</sup> Options for reinforcement following the removal of infected synthetic mesh are limited, as reimplantation of synthetic repair material into contaminated fields leads to a high rate of reinfection.<sup>37</sup>

### Biologic Repair Materials and SSO

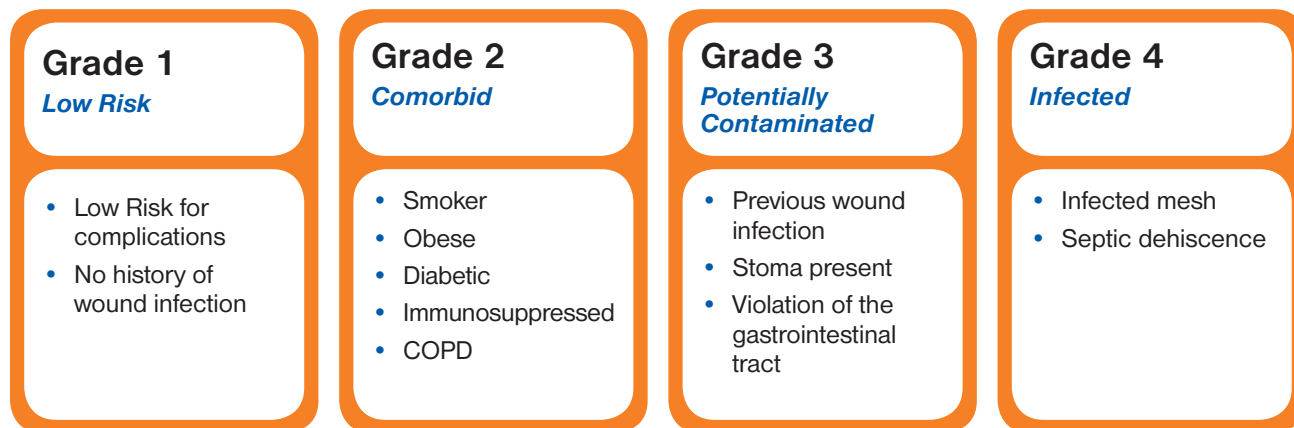
Biologic repair materials comprise a broad and expanding class. Some biologic repair material does not inhibit the body's ability to fight infection and does not require removal when exposed or infected.<sup>20,22,38,39</sup> Certain biologic prostheses have documented support for revascularization post implantation. This clinical aspect has been demonstrated in vitro and in animal models.<sup>41</sup> One recent animal study, for example, found that a human acellular dermal matrix was significantly superior

**Table 2. Recommendations of the Ventral Hernia Working Group (VHWG) for Choice of Repair Material For Incisional Ventral Hernias, by Grade**

Recommendation		Strength of Recommendation	Level of Evidence	Evidence
Grade 1	Choice of repair material by surgeon preference and patient factors	1	C	VHWG opinion
Grade 2	Increased risk for surgical site occurrence suggests additive risk for permanent synthetic repair material, and potential advantage for appropriate biologic reinforcement	1	B	Dunne et al <sup>13</sup> Finan et al <sup>14</sup> Pessaux et al <sup>15</sup> Petersen et al <sup>16</sup> VHWG opinion
Grade 3	Permanent synthetic repair material generally not recommended; potential advantage to biologic repair material	1	B	Diaz et al <sup>17</sup> Houck et al <sup>18</sup> Jones et al <sup>19</sup> Kim et al <sup>20</sup>
Grade 4	Permanent synthetic repair material not recommended; biologic repair material should be considered	1	A	Diaz et al <sup>17</sup> Jones et al <sup>19</sup> Kim et al <sup>20</sup> Paton et al <sup>21</sup> Patton et al <sup>22</sup> Sczcerba et al <sup>23</sup> van't Riet et al <sup>24</sup> Voyles et al <sup>25</sup>

Based on references 13-25.

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**Figure 1. Hernia grading system: assessment of risk for surgical site occurrences.**

Note: Wound infection defined as being contained within the skin or subcutaneous tissue (superficial), or involving the muscle and/or fascia (deep).

**COPD**, chronic obstructive pulmonary disease

Based on references 4 and 14.

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to polytetrafluoroethylene in the clearance of *Staphylococcus aureus* inoculate ( $P=0.002$ ).<sup>42</sup> Preclinical studies also suggest that some biologic repair materials can be placed in direct contact with the bowel.<sup>34</sup>

Clinical studies in high-risk patients with incisional ventral hernia reinforce these preclinical findings. Investigators have described the nonsurgical management of biologic prostheses, even in the setting of frank infection, and some biologic materials have been used successfully in the repair of large contaminated and/or irradiated abdominal wall defects, even when placed directly over the bowel.<sup>17,20,22,38,39</sup>

### The VHWG Grading System

The VHWG recently proposed a SSO risk grading system to help surgeons stratify patient risk for developing postoperative complications (Figure 1).<sup>4</sup> The rationale for developing this grading system was based on the complex considerations that surgeons face when selecting among synthetic and biologic repair materials for the reinforcement of ventral hernias. The grading system was designed as a memorable and simple-to-use framework for the assessment of SSO based on characteristics of the individual patient and hernia defect.

The system consists of 4 grades (Figure 1), ranging from low (eg, healthy patients with uncomplicated wounds) to high risk (eg, patients with multiple comorbidities and uncontrolled infection). Because each grade represents a wide range of risk and patient types, assessment of risk for SSO will continue to rely to some degree on individual surgeon judgment and experience.

Grade 1 (low risk) encompasses patients who have no comorbidities, no history of wound infection, and no evidence of contamination. Grade 2 (comorbid) includes patients who have comorbidities that increase the risk for surgical site infection. However, this category does not include patients who have

evidence of wound contamination or active infection. Because comorbidities are common among patients with incisional ventral hernia, grade 2 represents a broad swath of patients. As described above, comorbidities have been associated with an increased risk for infection following hernia repair.<sup>10,13-15</sup> Even a single comorbidity may increase the risk for postoperative infection by as much as 4-fold.<sup>14</sup> However, the relative contribution of different comorbidities or clusters of comorbidities to infection risk remains unknown, and only minimal data have been published describing the point at which a characteristic should be considered a comorbidity (eg, how recent a history of infection, how much smoking, what degree of malnutrition, how much corticosteroid use). Until more definitive data become available, surgeons will have to rely on their clinical judgment when evaluating grade 2 patients on risk for SSO.

Grade 3 (potentially contaminated) is a higher-risk group that includes patients who have evidence of contamination of the wound, such as the presence of a nearby stoma, violation of the gastrointestinal tract, or history of wound infection. Grade 4 (infected) patients are at highest risk for SSO. Features that suggest grade 4 include active infection, particularly infected synthetic mesh, and septic dehiscence.

The grading system is based on risk factors for SSO. It does not consider risk for recurrence. Based on the results of the literature review, the VHWG concluded that data describing risk for recurrence were too limited to support a reliable grading system; furthermore, it was felt that including risk for recurrence would overly complicate the tool. The grading system also does not include other features of hernia repair, such as the size or complexity of the defect or the proposed technique of repair. Therefore, a hernia with infected mesh would be considered grade 4 because of the presence of active infection, no matter the size of the defect; similarly, a relatively large hernia in an otherwise healthy individual may be considered grade 1 if there are no comorbidities or signs of contamination.

## VHWG Approach to the Technique for the Repair of Incisional Ventral Hernias

In addition to the SSO grading system, the VHWG proposed evidence-based recommendations regarding approaches to the repair of incisional ventral hernias (Table 1). These recommendations were offered in the belief that the use of advanced surgical techniques and materials could reduce the risks for recurrence and SSO such as infection.

Overall principles for the approach to ventral hernia repair suggested by the VHWG are outlined in Table 3.<sup>4</sup> These principles include optimization of the patient, preparation of the wound, centralization and reapproximation of the rectus muscles along the midline to the extent possible, and the use of appropriate prosthetic repair material to reinforce the closure.

### Selection and Use of Prosthetic Repair Material

Specific recommendations regarding the selection of repair material by risk for SSO are outlined in Table 2. The VHWG recommends that biologic repair materials with specific characteristics (see below) are preferred over synthetic mesh for use in infected fields and should be strongly considered when contamination is suspected. The increased risk associated with comorbidities described in grade 2 suggests that some patients in this category will develop an SSO such as infection. Based on this reasoning and the finding that biologic repair materials may facilitate management of infection without necessitating removal, the VHWG suggests that there may be potential advantages to some biologic repair materials for the reinforcement of hernia repairs in patients considered to be grade 2. The selection of repair material for patients in grade 2 depends on choice of technique (eg, open vs laparoscopic) and the balance of benefits and risks. It should be noted that no controlled clinical studies have been published to date comparing biologic and synthetic repair materials in this patient population.

Although the VHWG does not make any recommendation regarding choice of specific repair materials, certain features of synthetic and biologic prostheses should be considered. Important characteristics include adequate strength, ease of handling during procedures, ability to resist bowel adhesions when placed in contact with the bowel, and reduced risk for infection through support for tissue incorporation and revascularization.

### Synthetic Repair Materials

Synthetic meshes include macroporous, microporous, and composite materials.<sup>12,43</sup> Macroporous meshes employ large-sized pores that allow for ingrowth of scar tissue. Because of this characteristic, macroporous meshes have been associated with the formation of bowel adhesions and obstructions and enterocutaneous fistulae when placed in contact with abdominal viscera.<sup>44,45</sup> Microporous meshes avoid this problem through a smaller pore size that does not allow for tissue ingrowth. However, the microporous structure may lead to encapsulation and the persistence of bacteria, increasing the risk for infection. A wide variety of composite materials are now available that combine macroporous and microporous mesh on alternate sides.<sup>46</sup> Antiadhesive coatings also have been developed for synthetic meshes to reduce risk for adhesion formation.<sup>47,48</sup> New, light-weight meshes also are now available and have been used in

**Table 3. Principles for the Repair of Incisional Ventral Hernias**

<b>Optimize patient condition</b>
Nutritional status
Blood sugar levels
Smoking cessation
<b>Prepare wound</b>
Reduce bioburden
Take down adhesions, fistulae
<b>Reapproximate midline to the extent possible using component separation when appropriate</b>
<b>Use appropriate reinforcement material</b>
Consider biologic repair material in patients at increased risk for surgical site occurrences

Based on reference 4.

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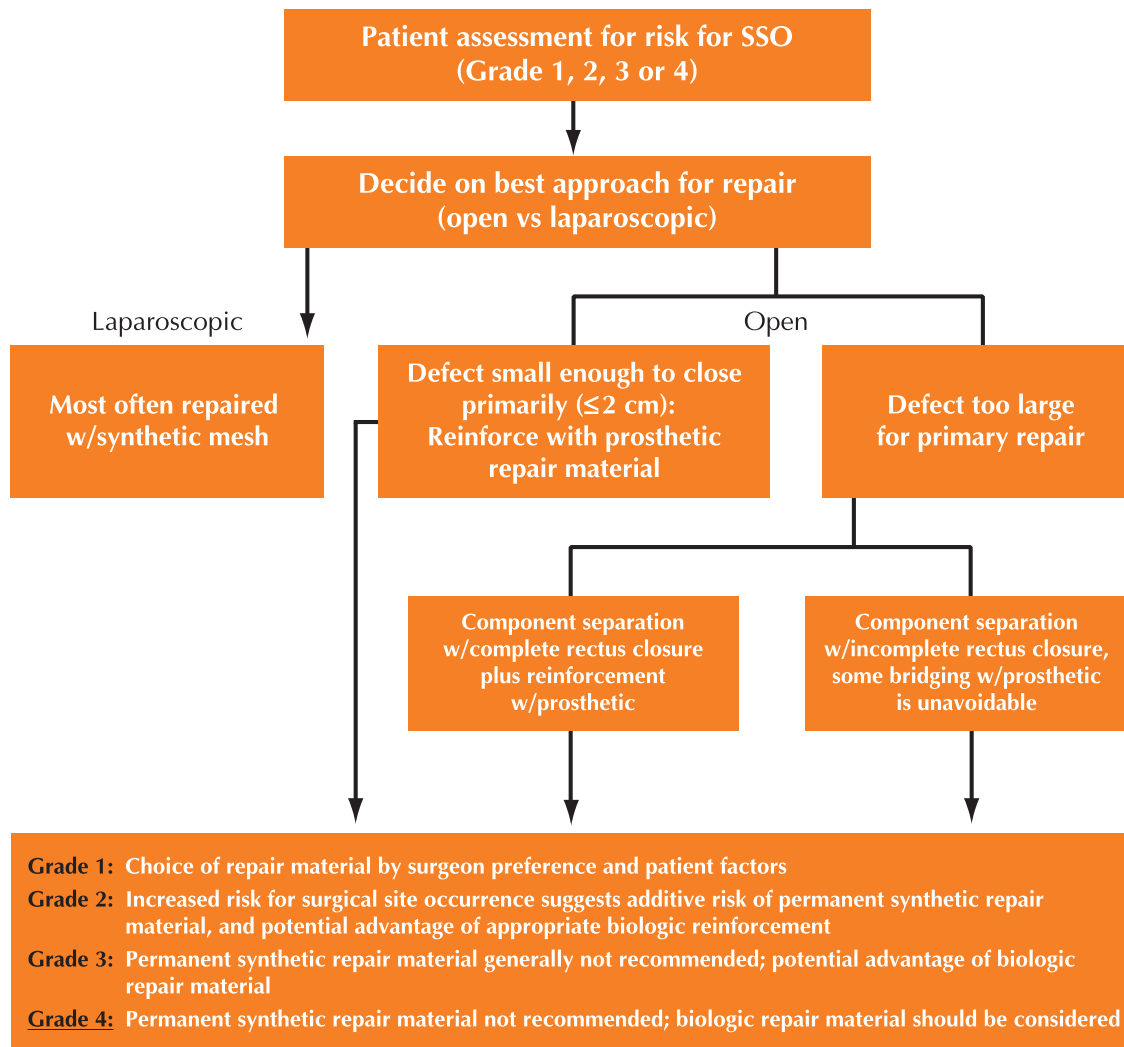
both open and laparoscopic hernia repairs.<sup>49</sup> Prospective data are lacking regarding the clinical benefits of these prostheses for ventral hernia repair, and no comparative clinical data are currently available.

### Biologic Repair Materials

The class of biologic repair materials has grown in number and diversity since its inception in the late 1990s. However, only some biologic prostheses have demonstrated successful use in the setting of contamination and infection. Certain specific characteristics are thought to contribute to successful use in these settings, whereas other biologic materials are contraindicated. Key features noted by the VHWG include intact extracellular matrix and the ability to support tissue regeneration through revascularization and cell repopulation in a clinically relevant time frame.

Investigators have proposed that some biologic repair materials can tolerate infection, possibly related to the ingrowth of cells and vasculature.<sup>50</sup> As indicated by Milton et al<sup>42</sup> and Holton et al,<sup>50</sup> neovascularization reported in studies with some biologic repair materials may allow these materials to better resist infection when placed in a potentially contaminated field. Conversely, a number of animal studies have shown that altering the extracellular matrix through suboptimal processing and/or crosslinking may have a negative impact on host response to the repair material.<sup>51,52</sup>

Host response to repair materials is thought to be critical. Positive recognition (ie, recognition of the prosthesis as "self") leads to regeneration and integration of the repair material into host tissue. Negative recognition (ie, recognition of the prosthesis as foreign) may lead to resorption or encapsulation.<sup>51,53</sup> Studies in a nonhuman primate model of abdominal wall repair have demonstrated resorption and encapsulation with several biologic repair materials.<sup>51</sup> Investigators suggested that the lack



**Figure 2. Algorithm for repair of incisional ventral hernia.**

SSO, surgical site occurrence

Based on reference 4.

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of integration and tissue regeneration with these materials may account for poor initial wound healing. In the same nonhuman primate model, the integration of a non-crosslinked, intact biologic repair material into native tissue has been demonstrated.

Results from clinical studies also describe remodeling and revascularization of certain biologic repair materials.<sup>54,55</sup> For example, biopsies of an implanted biologic repair material in one study showed similar cell density, vasculature, and collagen orientation to that of normal abdominal fascial tissue.<sup>54</sup> Other investigators reported revascularization and cellular repopulation in an explanted biologic repair material used to reinforce an irradiated, contaminated abdominal wall repair site more than 1 year after implantation.<sup>55</sup>

It must be emphasized that no comparative trials have been performed to date evaluating different biologic repair materials in incisional hernia repair. Differentiating between products

must be based on early findings with a limited number of available prostheses. Similar animal and clinical studies are awaited for the majority of biologic prostheses.

### Treatment Algorithm

The VHWG proposed an algorithm for the treatment of incisional ventral hernias (Figure 2).<sup>4</sup> The first step in this algorithm is patient assessment, which begins with evaluation of risk factors and size of the defect. Risk for SSO is assessed using the grading system described above. Very small defects ( $\leq 2$  cm) may be suitable for primary repair, but larger defects (ie, where the fascia does not meet without undue tension) should be reduced as much as possible. The VHWG noted that most defects too large for primary repair likely can be closed with component separation and reinforced with prosthetic repair

material. For the rare cases in which component separation is not feasible or is insufficient to fully reduce the defect, bridging the defect with prosthetic repair material may be considered.

## Summary

The repair of incisional ventral hernias is a common and challenging problem for surgeons. Recurrence and SSO frequently complicate hernia repair, and the dearth of high-quality evidence and published guidelines force surgeons to rely largely on clinical judgment. In an effort to guide surgeons in the selection of techniques and materials, the VHWG has produced a set of evidence-based recommendations, a treatment algorithm, and a grading system for risk for SSO. This effort was based on best available evidence and led by thought leaders in the field. It is hoped that these recommendations will serve to assist surgeons and stimulate discussion and research.

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