# Early Wound Morbidity after Open Ventral Hernia (Repair with Biosynthetic or Polypropylene Mesh

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BACKGROUND:	Recently introduced slow-resorbing biosynthetic and non-resorbing macroporous poly-
	propylene meshes are being used in hernias with clean-contaminated and contaminated
	wounds. However, information about the use of biosynthetic meshes and their outcomes
	compared with polypropylene meshes in clean-contaminated and contaminated cases is
	lacking. Here we evaluate the use of biosynthetic mesh and polypropylene mesh in elective
	open ventral hernia repair (OVHR) and investigate differences in early wound morbidity after
	OVHR within clean-contaminated and contaminated cases.
STUDY DESIGN:	All elective, OVHR with biosynthetic mesh or uncoated polypropylene mesh from January
	2013 through October 2016 were identified within the Americas Hernia Society Quality
	Collaborative. Association of mesh type with 30-day wound events in clean-contaminated
	or contaminated wounds was investigated using a 1:3 propensity-matched analysis.
<b>RESULTS:</b>	Biosynthetic meshes were used in 8.5% (175 of 2,051) of elective OVHR, with the majority
	(57.1%) used in low-risk or comorbid clean cases. Propensity-matched analysis in clean-
	contaminated and contaminated cases showed no significant difference between biosyn-
	thetic mesh and polypropylene mesh groups for 30-day surgical site occurrences (20.7% vs
	16.7%; $p = 0.49$ ) or unplanned readmission (13.8% vs 9.8%; $p = 0.4$ ). However, surgical
	site infections (22.4% vs 10.9%; $p = 0.03$ ), surgical site occurrences requiring procedural
	intervention (24.1% vs 13.2%; $p = 0.049$ ), and reoperation rates (13.8% vs 4.0%;
	p = 0.009) were significantly higher in the biosynthetic group.
CONCLUSIONS:	Biosynthetic mesh appears to have higher rates of 30-day wound morbidity compared with
	polypropylene mesh in elective OVHR with clean-contaminated or contaminated wounds.
	Additional post-market analysis is needed to provide evidence defining best mesh choices,
	location, and surgical technique for repairing contaminated ventral hernias. (J Am Coll Surg
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Ventral hernia repair (VHR) is one of the most common surgical procedures performed worldwide.<sup>1</sup> Outcomes after VHR vary widely, depending on characteristics related to the hernia, the patient, and operative techniques. Ventral hernias have been grouped into various grades based on patient comorbidities and wound status as determined by CDC wound class.<sup>2,3</sup> Following that approach, ventral hernias are classified as grade I (low risk, clean),

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Abbreviations and Acronyms		
AHSQC	= Americas Hernia Society Quality Collaborative	
OVHR	= open ventral hernia repair	
SSI	= surgical site infection	
SSO	= surgical site occurrence	
SSOPI	= surgical site occurrences requiring procedural intervention	
VHR	= ventral hernia repair	

grade II (comorbid, clean), or grade III (contaminated). Grade III hernias are further classified into grade IIIa (clean-contaminated), IIIb (contaminated), and IIIc (dirty/infected) hernias. Such classification allows surgeons to ascertain repair outcomes and postoperative morbidity in these different hernia settings.<sup>4</sup>

Unfortunately, there is very little high-level evidence to guide surgical techniques in the different grades of hernias. Although mesh reinforcement is the gold standard in VHR and a multitude of mesh products are available for use,5 none of the currently available meshes are approved for use in the presence of infection or contamination<sup>6</sup> and mesh selection decisions are largely based on individual surgeon preference. In practice, synthetic meshes have mostly been used in clean cases (hernia grade I and II) due to the increased risk of infectious complications reported with conventional heavyweight microporous synthetic meshes in contaminated settings.7,8 Biologic meshes have been advocated for use in contaminated and, in particular, infected/dirty cases (hernia grade IIIc)9-11 due to their ability to clear bacteria and resist infection. However, mesh selection continues to be unclear in clean-contaminated and contaminated cases (hernia grade IIIa and IIIb).<sup>2,12</sup>

In the setting of declining reimbursements and costcontainment, there has been a shift in mesh indications and use patterns among surgeons.13-18 High-cost and poor long-term outcomes have tempered the enthusiasm around using biologic meshes.<sup>16,19,20</sup> Meanwhile, advances in biomaterial technologies5 and an improved understanding of the risk factors affecting wound outcomes in VHR<sup>3,21</sup> have led to a resurgence of interest in synthetic meshes and the development of the new class of slowly resorbing biosynthetic meshes. Recent evidence shows that macroporous polypropylene meshes, for example, Prolene Soft mesh (Ethicon, Inc) and Bard Soft Mesh (CR Bard, Inc), are safe and effective in cleancontaminated and contaminated cases in the shortterm.<sup>16,22,23</sup> In addition, early results using biosynthetic meshes, for example, Phasix (CR Bard, Inc), Gore Bio-A (WL Gore), and TIGR-Matrix (Novus Scientific),

also suggest that these meshes can be safe and effective in clean-contaminated and contaminated hernias.  $^{\rm 24\text{-}26}$ 

Barring these few reports investigating a particular mesh group in a specific patient population, there are no studies reporting the use of biosynthetic meshes and macroporous polypropylene meshes in different hernia grades, or comparing their outcomes in a well-matched population. The objectives of this study were therefore to evaluate use of biosynthetic mesh and macroporous polypropylene mesh in open VHR with different wound classes and hernia grades, and investigate differences in early wound morbidity after open VHR in a wellmatched group of clean-contaminated and contaminated cases using data from the Americas Hernia Society Quality Collaborative (AHSQC). We hypothesized that biosynthetic mesh use would be associated with improved 30-day outcomes compared with macroporous polypropylene mesh use in open clean-contaminated/ contaminated VHR.

#### METHODS

#### **Data source**

The AHSQC is a nationwide quality-improvement effort designed to improve the value of hernia care by monitoring surgical complications, operation outcomes, and patient quality of life after VHR. The AHSQC data registry is prospectively maintained and contains surgeon-entered, point-of-care data from preoperative, intraoperative, and 30-day postoperative phases of hernia care. At the time of this study, the AHSQC had data available from 181 academic, community, and academic-affiliated surgeons in a variety of clinical settings. Details about the AHSQC and registry structure, governance, and data assurance process have been reported previously.<sup>27</sup>

### Patients

All patients 18 years of age and older who underwent an elective open VHR (OVHR) with any resorbable biosynthetic mesh or uncoated polypropylene mesh placement from January 2013 through October 2016 were identified within the AHSQC. Patients included in this analysis underwent repairs of a midline incisional hernia with or without simultaneous repair of a parastomal hernia. Because the incidence of wound events is a primary end point of interest, only those patients who received prophylactic IV antibiotics within 1 hour before surgery and those with 30-day follow-up data available were included in this analysis. Patients who had a laparoscopic or robotic hernia repair, those who did not receive prophylactic IV antibiotics within 1 hour before surgical

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