Clinical Outcomes of Biologic Mesh: Where Do We Stand?

Hobart W. Harris, MD, MPH

KEYWORDS

• Allograft • Xenograft • Prosthetics • Efficacy

KEY POINTS

- The cumulative data regarding biologic mesh use on ventral hernias under contaminated conditions do not support the claim that they are better than synthetic mesh used under the same conditions.
- Most of the available data pertain to the use of human acellular dermal matrix to repair complex ventral hernias, a product that both experts in the field and manufacturers now agree is inadequate for this clinical application.
- The highly promoted and frequently discussed practice of placing biologic mesh in contaminated surgical fields is being done outside of the products' original intended use and, in some instances, equates to off-label use of a medical device.
- Biologic mesh use, even in noncontaminated conditions, is questionable when the reported results are viewed in light of the high costs.

INTRODUCTION

Ventral hernias occur after 11% to 23% of laparotomy incisions. With 4 to 5 million laparotomies performed annually in the United States, there are an estimated 400,000 ventral hernia repairs each year, making it one of the most common procedures performed by general surgeons and adding more than $8 billion to US health care costs. A permanent prosthetic mesh repair during a clean case in which there is no bacterial contamination is the standard of care, yielding the best long-term results and reducing the hernia recurrence rate by 50%.[1] The management of ventral hernias in the setting of bacterial contamination remains, however, a major clinical challenge because placing a permanent synthetic prosthetic into a contaminated field is generally thought to result in an unacceptably high rate of complications, including surgical site infection, enterocutaneous fistula, and recurrent hernia formation. Therefore, until recently, the standard of care for repairing a complex ventral hernia (eg, one that involves a compromised surgical field in which gastrointestinal, biliary, and/or genitourinary procedures are performed or frank infection is present) was a 2-stage procedure. In the

Disclosures: The author has nothing to disclose.
Department of Surgery, UCSF, 513 Parnassus Avenue, Room S-301, Box 0104, San Francisco, CA 94143-0104, USA
E-mail address: Hobart.Harris@ucsfmedctr.org

Surg Clin N Am 93 (2013) 1217–1225
http://dx.doi.org/10.1016/j.suc.2013.06.001 **surgical.theclinics.com**
0039-6109/13/$ – see front matter

first stage, the contaminated portion of the surgery is completed and the abdominal wall reconstructed using a temporary synthetic (absorbable) prosthetic. In the second stage, after approximately 6 to 12 months have elapsed and the wound contamination has been eliminated, the persistent ventral hernia is repaired using a permanent synthetic prosthetic. Although the 2-stage procedure is thought to reduce the risks of infection-related complications by avoiding placement of permanent prosthetic material into a contaminated wound, it unfortunately requires patients to undergo 2 separate operations, hospitalizations, and recovery periods, during which time they often cannot work and must endure a limited level of physical activity.

Several biomedical companies have recently introduced new biologic prosthetics (mesh) to address the clinical challenge of treating complex ventral hernias with a 1-stage repair. Because biologic mesh is derived from living tissue, these products are promoted as resisting infection and enabling wound healing in contaminated surgical fields. Currently, an intriguing variety of biologic meshes, derived from collagen-rich porcine, bovine, or human tissues, such as skin, intestinal submucosa, or pericardium, is available for the 1-stage repair of complex ventral hernias. These products are, however, expensive, and long-term outcome data are sparse. Furthermore, data are accumulating that question the overall clinical efficacy of such products, despite their intuitive appeal as more natural tissue replacements.

This article reviews currently available clinical data regarding the use of biologic mesh for the 1-stage repair of incisional hernias in the setting of wound contamination. Specifically, it attempts to answer the general question, "Should biologic mesh be used for incisional hernia repair?"

TYPES OF BIOLOGIC MESH

Biologic meshes derived from collagen-rich tissues of human (allograft) or animal (xenograft) origin were introduced into clinical practice in the 1990s.[2] Whereas synthetic prosthetics have been successfully used to reinforce the abdominal wall for more than a century, biologic meshes represent the newest effort to find the ideal material for hernia repair. In theory, biologic mesh provides a 3-D scaffold of extracellular matrix proteins that enables native cells to infiltrate and promotes neovascularization and the regeneration of healthy connective tissue that is resistant to infection. The biologic nature of the material is thought to provide an improved ability to reintegrate with surrounding tissues while reducing the risk of infection, erosion, extrusion, and rejection compared with the synthetic alternatives. Biologic meshes purportedly avoid some of the complications observed with the use of synthetic mesh, but, most importantly, biologic meshes can be deployed in the setting of wound contamination, a condition for which the use of synthetic mesh is generally discouraged.

More than a dozen different biologic meshes are currently available for abdominal wall reconstruction (**Table 1**). These products differ in their biologic source, processing to remove cellular components and reduce antigenicity, decontamination, size and thickness, amount of cross-linking, storage and handling characteristics, and costs. Although a detailed evaluation of these various differences is beyond the scope of this article, a brief discussion of cross-linking is warranted because it is frequently cited as a feature that has a critical impact on a prosthetic's clinical performance. Cross-links are covalent or ionic bonds that link one polymer chain to another, with a resultant increase in strength of the overall material. Cross-linking in the context of biologic mesh refers to bonds between extracellular matrix proteins, most commonly collagen fibers. Some degree of collagen cross-linking occurs naturally; yet, creating additional cross-links yields increased resistance to degradation by