Early Clinical Outcomes of a Novel Antibiotic-Coated, Non-Crosslinked Porcine Acellular Dermal Graft after Complex Abdominal Wall Reconstruction

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BACKGROUND: Non-crosslinked porcine acellular dermal grafts (NCPADG) are currently the mainstay biomaterial for abdominal wall reconstruction (AWR) in complex hernia patients. We report early clinical outcomes using a novel rifampin/minocycline-coated NCPADG for AWR.

STUDY DESIGN: A multi-institutional retrospective review was performed of patients who underwent ventral hernia repair using XenMatrix AB Surgical Graft (CR Bard, Inc [Davol]). Patient demographics, hernia and procedure characteristics, and surgical site occurrences/postoperative complications were reviewed up to 6 months after AWR.

RESULTS: Seventy-four patients underwent AWR using XenMatrix AB Surgical Graft. Open AWR was performed in 52 patients (70.3%), and 22 patients (29.7%) underwent laparoscopic VHR. Median hernia size/area was 66.0 cm^2 (range 9.4 to 294.5 cm^2). Sixteen patients (21.6%) had previous wound infections, and 16 patients (21.6%) had violation of the gastrointestinal tract during hernia repair. The most common locations of NCPADG placement were within the intraperitoneal (32.4%) and onlay (21.6%) positions, respectively. Median hospital length of stay was 4 days. Within 30 days after AWR, 6 (8.1%) patients were readmitted, postoperative seroma formation developed in 4 (5.4%) patients, 1 patient required percutaneous drainage, and surgical site infections developed in 5 (6.8%) patients. At 6 months follow-up, hernia recurrence had developed in 4 (5.4%) patients.

CONCLUSIONS: Data suggest that use of a novel rifampin/minocycline-coated NCPADG was associated with a low rate of postoperative surgical site occurrences/postoperative complications during the first 30 days of follow-up in complex AWR patients. In addition, data suggest a low rate of hernia recurrence at 6-month follow-up. Additional study is warranted to determine whether early antimicrobial protection of the device translates into longer-term protection of the repair. (J Am Coll Surg 2016;223:581−586. © 2016 by the American College of Surgeons. Published by Elsevier Inc. All rights reserved.)

Innovation in biomaterial processing and hernia repair technology has led to the development of biologically derived scaffolds from human or animal tissue sources. The widespread use of biologic grafts for abdominal wall reconstruction has been driven in part by the potential for permanent synthetic mesh complications, including chronic infection, bowel erosion, enterocutaneous fistula formation, and need for reoperation.[1]

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Abbreviations and Acronyms

AWR = abdominal wall reconstruction
NCPADG = non-crosslinked porcine acellular dermal graft
VHR = ventral hernia repair
VHWG = Ventral Hernia Working Group
XenAB = XenMatrix AB

Biologic grafts are typically derived from human, porcine, or bovine sources and are prepared through a variety of processing techniques (crosslinked and non-crosslinked) and sterilization techniques (radiation, ethylene gas sterilization, or aseptic methods).[1] Collagen matrices from biologic platforms provide areas for tissue integration and collagen regeneration.[1] Collagen ingrowth and neovascularization would, in theory, allow delivery of macrophages and antibiotics to resist bacterial proliferation.[1] Ideally, biologic graft materials would serve the function of abdominal wall reinforcement with a reduced risk of chronic permanent synthetic mesh infection.

A more recent technologic development has allowed incorporation of antibiotics into polymer coatings, which can be applied directly to mesh materials, allowing for prolonged release of antibiotic agents over time.[2,3] Application of antibiotics to the mesh material has been shown to decrease microorganism adhesion, biofilm formation, and periprosthetic bacterial growth.[3] In vivo studies have confirmed decreased rates of wound infection using antibiotic polymer-coated mesh materials at 2 and 4 weeks after implantation.[4]

Recently introduced to the market, XenMatrix AB Surgical Graft (XenAB; CR Bard, Inc. [Davol]) is a non-crosslinked porcine acellular dermal graft (NCPADG) with a tyrosine polymer coating containing the antibiotics rifampin and minocycline (Fig. 1). Preclinical test results have demonstrated inhibited colonization by MRSA, *Escherichia coli*, and other bacteria, which serves to protect the graft before neovascularization and provides protection from biofilm formation.[5,6] Here we describe early clinical outcomes using XenAB NCPADG for ventral hernia repair (VHR). The primary goal of this review was to determine whether the antibiotic coating elicited any negative effects on the patients or the hernia repair.

METHODS

Approval for this study was obtained from the IRB of each of the 5 participating clinical sites. All procedures performed in this study that involved human participants were conducted in accordance with the ethical standards of the Institutional Research Committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. For this retrospective study, informed consent for research participants was waived and privacy rights of human subjects were carefully observed.

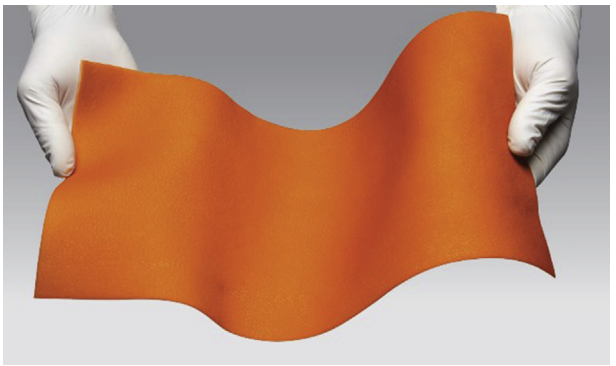

Figure 1. XenMatrix AB Surgical Graft is an antibacterial coated, non-crosslinked porcine acellular dermal graft. The polymer coating contains a combination of rifampin and minocycline. (From: CR Bard Inc [Davol], with permission.)

Data were retrospectively collected on patients who underwent open or laparoscopic abdominal wall hernia repair using XenAB. Five sites contributed to patient accrual, including Carolinas Medical Center, Charlotte, NC; Thomas Jefferson University Hospital, Philadelphia, PA; Oklahoma University Medical Center, Oklahoma City, OK; Presbyterian Hospital/St Luke's, Denver, CO; and Jersey Shore Medical Center, Neptune, NJ. Study inclusion criteria were as follows: aged 18 years or older, presence of a ventral hernia requiring open or laparoscopic repair, use of XenAB, and at least 30 days of postoperative follow-up. Exclusion criteria included placement of an inlay graft with edge to edge suturing, life expectancy <2 years at the time of surgery; contraindication for placement of graft as outlined by the device instructions for use; incomplete removal of any existing mesh from an earlier repair in the same area; defined collagen disorder; known sensitivity to porcine products; intact permanent mesh adjacent to the hernia site to be repaired; peritonitis at the time of surgery; presence of cirrhosis or ascites; clinically significant kidney disease, including requirement for hemodialysis or peritoneal dialysis; American Society of Anesthesiology classification of IV or V; known infection by human immunodeficiency virus; pregnant or breastfeeding status or plans to become pregnant during the study period; and a history of allergy or hypersensitivity to tetracyclines or rifamycins.

Demographic, operative, perioperative, and postoperative data were collected for each patient at each