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ORIGINAL ARTICLE

Complex ventral hernia repair with a human acellular dermal matrix

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Abstract
Purpose The ideal approach to complex ventral hernia repair is frequently debated. Differences in processing techniques among biologic materials may impact hernia repair outcomes. This study evaluates the outcomes of hernia repair with a terminally sterilized human acellular dermal matrix (TS-HADM) (AlloMax® Surgical Graft, by C. R. Bard/Davol, Inc., Warwick, RI, USA) treated with low-dose gamma irradiation.
Methods A single-arm multi-center retrospective observational study of patients undergoing hernia repair with TS-HADM was performed. Data analyses were exploratory only; no formal hypothesis testing was pre-specified.
Results Seventy-eight patients (43F, 35M) underwent incisional hernia repair with a TS-HADM. Mean follow-up was 20.5 months. Preoperative characteristics include age of 56.6 ± 11.1 years, BMI 36.7 ± 9.9 kg/m^2, and mean hernia defect size 187 cm^2. Sixty-five patients underwent component separation technique (CST) with a reinforcing graft. Overall, 21.8 % developed recurrences. Recurrences occurred in 15 % of patients repaired with CST. Major wound complications occurred in 31 % of patients overall. Based upon CDC surgical wound classification, major wound complications were seen in 26, 40, 56, and 50 % of Class 1, 2, 3, and 4 wounds, respectively. No grafts required removal.
Conclusions Hernia recurrences are not uncommon following complex abdominal wall reconstruction. Improved outcomes are seen when a TS-HADM is utilized as reinforcement to primary fascial closure.

Keywords Component separation · Human acellular dermal matrix · Biologic mesh · Ventral hernia

Introduction

Abdominal operations are among some of the most commonly performed surgical procedures with an estimate of 4–5 million laparotomies performed annually in the United States [1]. Although there is considerable interest in hernia prophylaxis, the incidence of incisional hernia formation following laparotomy remains significant with a reported incidence as high as 20 % [2, 3]. The majority of incisional hernias may be successfully repaired utilizing synthetic mesh materials with a reasonable recurrence rate [1, 4, 5]. However, a proportion of those patients undergoing incisional hernia repair will develop recurrences and complications [4, 5]. Prosthetic mesh-related complications including mesh infections, extrusions, and enterocutaneous fistulas, although rare, are a significant burden to the health care system [6]. The management of these complications and complex recurrent incisional hernias has become an increasing challenge for surgeons and patients alike owing to the increase in both morbidity and recurrences among this group.

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The use of human acellular dermal matrices (HADMs) for the repair of complex incisional hernias has been reported extensively [7–13]. Initial reports demonstrated early successes; however, subsequent reports revealed hernia recurrence rates approaching 100 % when these materials were utilized to bridge hernia defects [7]. HADMs are most commonly utilized during hernia procedures in which there is contamination, infection, or an increased risk for postoperative wound complications [14]. HADMs appear to be safe when placed into high-risk and contaminated wounds [10, 11, 13]. In general, the presence of contamination or infection has been considered a contraindication to the utilization of synthetic mesh materials. Accordingly, HADMs provide surgeons with an alternative hernia repair strategy when a synthetic mesh is not appropriate and alternative strategies such as flaps or tissue transfers would have otherwise been required. When utilized as reinforcement to a component separation hernia repair, HADMs have been shown to reduce recurrences [15], although this remains an area of controversy [16]. Although all HADMs originate as donated human tissue, processing techniques differ which may impact material properties, host responses, and ultimately surgical outcomes [17–19].

In this study, we evaluate the outcomes of patients undergoing complex ventral hernia repair utilizing a terminally sterilized human acellular dermal matrix, AlloMax™ Surgical Graft (TS-HADM). Sterilization of the graft occurs by means of low-dose gamma irradiation. Prior studies have demonstrated the efficacy of TS-HADM in the repair of paraesophageal hernias [20], but outcomes following abdominal wall hernia repair have not been reported.

Methods

After obtaining Institutional Review Board approval, a single-arm, multi-center, observational study of patients who had previously undergone hernia repair with a TS-HADM was performed. Patients who had undergone ventral hernia repair with a TS-HADM a minimum of 9 months prior to study enrollment were included. Consented patients underwent review of medical records for risk factors for hernia recurrence, procedural details, complications, and recurrences. Patients without evidence of hernia recurrence following record review were prospectively evaluated for hernia recurrence by means of a physical examination. Patients with documented evidence of hernia recurrence by imaging or prior physical examination were not required to complete a further physical examination.

Patients were enrolled at four medical centers including: Barnes Jewish St. Peters Hospital, St Peters, MO; St. Francis Hospital, Tulsa, OK; Winthrop University Hospital, Mineola, NY; and University of Kentucky, Lexington, KY. Only those patients, at least 18 years of age, who had undergone a ventral hernia repair with the TS-HADM were included in the study group. Medical records were reviewed for risk factors for hernia recurrence including cancer, infection, obesity, history of prior hernia, immunosuppression, smoking, malnutrition, diabetes mellitus, anemia, liver disease, pulmonary disease, and prior abdominal surgery.

Hernia repairs were stratified by the Centers for Disease Control and Prevention (CDC) surgical wound classification which includes Class 1 (clean), Class 2 (clean-contaminated), Class 3 (contaminated) and Class 4 (dirty-infected). Operative details were obtained including operative date and time, procedure type (use of component separation, graft location, buttressed or bridging repair, recurrent or primary), suture type, defect size, graft size, number of grafts utilized, degree of fascial closure/bridging, skin closure, hernia wound classification, antibiotic use, and serum albumin level. Patients were considered to have an onlay repair if any graft was placed in a location ventral to the fascial closure, whereas non-onlay repairs include retro-rectus, preperitoneal, and intraperitoneal grafts.

Hernia recurrence was defined as any patient in whom the medical record documented a recurrent bulge by means of physical examination or radiographic studies or alternatively patients in whom a recurrent hernia was detected upon physical examination. Subsets of patient complications were defined as minor, major skin and soft tissue complications, seroma or hematoma. Minor complications were defined as cellulitis, epidermolysis, lymphedema, ecchymosis or erythema. Major skin and soft tissue complications include superficial wound infection, abdominal abscess, non-healing wounds, surgical site infections, postoperative wound infections, abdominal wall necrosis, and infected hematomas. Seromas and hematomas include only uninfected collections of fluid or blood, respectively.

Statistical analysis methods

Data from all investigational sites were pooled and summarized. Numerical data such as age, BMI, hernia defect size were reported as Mean ± SD; while categorical data such as wound complication rate, recurrence rate were reported as count and percentages. There was no preplanned formal hypothesis for testing. For exploratory purpose, univariate Chi-square test was used to compare the rate of wound complications and recurrence rates among group of subjects classified based on preoperative Center for Disease Control hernia wound classification.

Table 1 Preoperative characteristics

Comorbid conditions	*n* (%)
Current smoker	14 (17.9)
Prior abdominal infection	38 (48.7)
Prior mesh infection	17 (21.8)
Anemia	13 (16.7)
Cancer	17 (21.8)
Diabetes mellitus	26 (33.3)
Immunosuppression	9 (11.5)
Hepatic disease	4 (5.1)
Pulmonary disease	18 (23.1)
Malnutrition	2 (2.6)
Obesity	63 (80.8)
Recurrent hernia	50 (64.1)
Preoperative albumin <3.4 mg/dl	3 (3.8)

Results

Seventy-eight patients were identified who underwent ventral or incisional hernia repair with a TS-HADM. Repairs were performed between 2007 and 2010. There were 43 female and 35 male patients with a mean age of 56.6 ± 11.1 years (range 33–85), and a mean body mass index of 36.7 ± 9.9 kg/m^2 (range 22–89). Mean follow-up was 622 days (range 274–1,529 days). Forty-seven patients (64 %) underwent repair for a recurrent hernia. Among recurrent hernia repairs, the mean number of prior repairs was 2.1 ± 1.5 procedures. Preoperative patient co-morbidities included smoking, diabetes mellitus, anemia, cancer, pulmonary disease, hepatic disease, immunosuppression, malnutrition, obesity, and hypoalbuminemia (Table 1). Patients' preoperative Center for Disease Control (CDC) wound classification was Class 1 ($n = 53$, 72 %), Class 2 ($n = 10$, 14 %), Class 3 ($n = 9$, 12 %), and Class 4 ($n = 2$, 3 %).

Seventy-one patients underwent hernia repair with primary defect closure and placement of a TS-HADM graft as a reinforcement, of which 65 patients underwent a component separation procedure. Five patients underwent placement of a graft as a bridge (Table 2). In two patients, it was unclear whether the graft was used as a reinforcement or bridge. Surgical grafts were placed as either an onlay, retromuscular or preperitoneal underlay, intraperitoneal underlay or utilized a combination of underlay and overlay techniques. The mean hernia defect size measured intraoperatively was 178 ± 156 cm^2, whereas the mean graft size was 348 ± 296 cm^2. Hernia recurrences were seen in 17 patients (21.8 %) and were detected by either physical examination ($n = 9$) and/or radiologic imaging ($n = 9$). Recurrent hernias occurred less frequently among those patients who underwent hernia repair with a reinforcing mesh than other techniques. Fewer recurrences were also seen in those with underlay TS-HADM placement (retromuscular, preperitoneal or intraperitoneal) versus onlay placement, although not significant (6/33 vs. 11/45, $p = 0.508$).

Table 2 Operative details and hernia recurrence rates

Graft position	*n* (%)	Recurrence rate *n* (%)
Onlay	45 (58)	11 (24)
Non-onlay	33 (42)	6 (18)[a]
Hernia repair technique		
Component separation with reinforcing graft	65 (83)	10 (15)
Defect closure with Reinforcing graft	6 (8)	2 (33)
Bridging graft	5 (7)	4 (80)[b]

[a] Onlay/not onlay $p = 0.508$ (univariate)

[b] Bridging/reinforcing $p = 0.0005$ (univariate)

Table 3 Wound complications by graft location

Complications	Onlay graft ($n = 45$) (%)	Non-onlay graft ($n = 33$) (%)
Minor wound complications	11 (24.4)	5 (16)
Major wound complications	16 (35.5)	8 (24)
Seroma	18 (40)	5 (21)
Hematoma	1 (2.2)	3 (9)

Table 4 Major wound complications and hernia recurrences by CDC wound classification

CDC wound class	Major wound complications *n* (%)*	Recurrence *n* (%)**
Class 1/clean	14 (26)	13 (25)
Class 2/clean-contaminated	4 (40)	2 (20)
Class 3/contaminated	5 (56)	0 (0)
Class 4/dirty or infected	1 (50)	0 (0)

* $p = 0.068$ (univariate)

** $p = 0.082$ (univariate)

Wound complications were seen in patients who underwent repair with TS-HADM utilizing both onlay and underlay techniques. The incidence of postoperative seroma was 40 % in the overlay group, while 21 % of underlay repairs (including bilayer grafts) developed postoperative seromas (Table 3). There was a trend toward increased postoperative major wound complications associated with increasing CDC surgical wound classification, and no significant impact of CDC wound class upon recurrences (Table 4).

Discussion

Hernia repair remains as one of the most commonly performed operations in the United States with an increasing

number of incisional hernia repairs annually [21]. Despite best practices, hernia recurrences remain a significant challenge. The use of prosthetic materials has decreased the incidence of hernia recurrence [1, 4] although there are clearly unique complications related to the utilization of synthetic materials for hernia repair [6]. Many techniques for hernia repair have evolved in an attempt to both minimize hernia recurrences and reduce perioperative complications. This study evaluates the results of hernia repairs performed at four institutions utilizing a TS-HADM. Although the total number of hernia repairs at these four institutions was not evaluated, the number of patients included in this study represents a minority of all ventral hernias that were performed at these institutions and the authors believe that synthetic mesh should be utilized for the overwhelming majority of hernia repairs.

The component separation technique for hernia repair was described as a unique technique for the management of complex abdominal wall hernias in situations in which prosthetic material was felt to be not appropriate or feasible [22]. Although the initial description of component separation did not involve the placement of a reinforcing prosthetic material, the practice of reinforcing the midline closure following component separation, in an attempt to further reduce the risk of recurrence, has been reported [15, 16, 23]. The ideal prosthetic material for reinforcement of the abdominal wall is an area of tremendous controversy. Espinosa-de-Los-Monteros described a 13 % reduction in the risk of hernia recurrences when component separation hernia repairs were reinforced with a HADM [15]. A more recent report by Ko et al., however, demonstrated a reduced rate of hernia recurrence among those patients who underwent reinforcement with a polypropylene mesh compared to a HADM [16, 24]. In our series, the recurrence rate for patients who underwent component separation with TS-HADM reinforcement was 15 % with a mean follow-up of 20.5 months. This recurrence rate is similar to other reports of reinforced component separation repairs with either synthetic mesh or biologic grafts [16, 23, 24].

In this study, the majority of patients were considered to be at increased risk of wound complications and recurrence due to their pre-existing comorbid conditions. Nearly one-third of the study population experienced a major wound complication in this study. Despite this significant incidence of wound complications, there were no patients in this study who required graft removal. In a study of 545 component separation operations reported by Sailes et al. [23], there was an increased incidence of mesh infections seen with synthetic meshes compared with biologic grafts. Although synthetic mesh infections may be treated non-operatively, postoperative synthetic mesh infections are a source of additional morbidity and may necessitate mesh removal [25]. On the contrary, placement of a biologic graft at the time of a component separation is unlikely to result in the need for graft explant even in the presence of a postoperative infectious complication [8]. The ideal prosthetic for reinforcement of contaminated hernias, whether biologic or synthetic, remains an area of tremendous debate. It also represents an area in need of further investigation to clarify both the advantages and drawbacks of each material in a complex, contaminated or high-risk hernia repair. In this study population, the risk of hernia recurrence was similar across patients all CDC wound classes. This finding is somewhat counterintuitive, but patient selection was retrospective in this study, and definitive conclusions about comparative outcomes cannot be made. Nevertheless, just as major wound complications were increased with increasing CDC wound class, the authors would anticipate that recurrence rates would be increased among patients with higher wound classes.

The utilization of biologic materials in patients with risk factors for wound complications without active infection or contamination at the time of surgery remains an area of great debate. Known risk factors for postoperative skin and soft tissue infections following surgical procedures include diabetes, smoking, malnutrition, immunosuppression, obesity, staphylococcus aureus colonization in the nares, and remote body site infections [26–28]. Despite best practices, wound complications in high-risk populations remain problematic. There is little evidence to suggest that biologic grafts are superior to synthetic mesh in high-risk patients undergoing hernia repair [24]. As a result, operative decisions are often predicated upon local practice patterns and experience. As this study represents a prospective evaluation of previously operated patients, it is difficult to fully understand the rationale for the use of a biologic group for all patients. At the time of the study, biologic meshes were not uncommonly utilized in patients with CDC class 1 wounds with known risk factors for wound infection. Other authors have attempted to create classification schemes for patients felt to be at increased risk for wound complications in an attempt to justify the use of biologic materials [14]. The rationale for utilizing a biologic material in this group of patients is related to the potential for postoperative wound complications which may potentially result in mesh infections. In a study of 995 patients, incisional hernia patients with a prior history of wound infections were found to have a threefold increase in wound complications compared to patients without prior wound infections [29]. While not all wound infections will result in prosthetic infections, a small percentage of wound complications can be expected to result in mesh infections which are more likely to require further surgery.

Although biologic graft repairs are generally more expensive than synthetic mesh repairs [30], in the event of a postoperative infection, synthetic meshes are more likely

to require mesh removal [23]. In 2003, the cost of a hospital-acquired infection (pulmonary, bloodstream, urinary, central nervous system, gastrointestinal, and soft tissue) in a medical patient was in excess of $15,000 [31]. Although peer-reviewed data describing the costs of a prosthetic mesh infection have not been reported in the literature, presumably the costs associated with mesh explantation would exceed the cost of treating hospital-acquired infections in medical patients. Accordingly, decisions for the utilization of a biologic graft material in patients with risk factors for wound complications must be individualized based on local factors and outcomes. In a study of 88 patients with Ventral Hernia Working Group Grade 2 hernias (CDC Grade 1 hernia with risk factors for wound infection) that underwent repair with synthetic mesh, the incidence of surgical site infection was 16 % of which only three patients required mesh excision [32]. Notwithstanding the cost of mesh infections, recurrent hernias add significant costs to the healthcare system and significantly increased recurrence rates are more likely to add to the cost of healthcare than rare mesh infections.

In the current study, the retrospective design makes it difficult to discern the rational for the decision to utilize a TS-HADM over a synthetic mesh. However, the recurrence rate in our study is substantially lower than the 61 % recurrence rate reported by Ko et al. [24] in the repair of non-contaminated hernias with a non-irradiated ADM. The improved outcomes may be related to patient factors, technique or alternatively the characteristics of the TS-HADM. Although the recurrence rate of 30 % in this patient group is not insignificant, it is not dissimilar to the recurrence rate reported with other ADMs in complex hernia repair [33]. In light of the economic health care climate, both the short-term and long-term costs associated with hernia care must be carefully considered. Future prospective trials comparing synthetic and biologic mesh materials in the high-risk non-contaminated hernia population are required to fully understand whether the additional cost of a biologic mesh compared to synthetic meshes is warranted.

In this study, the graft utilized to reinforce the hernia repair is processed with low-dose gamma irradiation to terminally sterilize the graft. In vitro studies have demonstrated an increase in the tensile strength of HADMs with low-dose gamma irradiation and significantly reduced elasticity without impacting proliferation of fibroblast cells [34]. Accordingly, the graft processing may impact its remodeling characteristics and potentially affect hernia repair outcomes. However, there are no human studies comparing gamma irradiated and non-gamma irradiated HADMs in hernia repair.

Abdominal wall reconstruction with a TS-HADM was associated with a significant hernia recurrence rate in patients at risk for developing postoperative wound complications. The best outcomes were seen when the TS-HADM was utilized as a reinforcement to the hernia repair at the time of a component separation procedure. Although wound complications occur frequently in this complex patient population, the need for graft removal is unlikely. Further prospective studies evaluating TS-HADMs in hernia repair are needed to define the optimal patient population for this tissue form.

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Conflict of interest JR declares a conflict of interest directly related to the submitted work; he is a consultant for CR Bard, Inc. and is on their speaker bureau. JR also declares a conflict of interest not related to the submitted work; he is a board member of the Musculoskeletal Transplant Foundation, has grant funding from Ethicon EndoSurgery and Covidien, and is on an Ethicon speaker bureau. KH declares a conflict of interest not directly related to the submitted work; he is on an industry speaker bureau. CB, KF, and JK declare no conflicts of interest.

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