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Long-term outcome of absorbable synthetic mesh in clean ventral hernia repairs

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Abstract

Background There are many materials available for the reinforcement of complex abdominal wall reconstruction, including permanent synthetic, biologic, and absorbable synthetic meshes. The recurrence rate of complex hernia repairs beyond 5 years has not been reported. We hypothesized that the use of absorbable synthetic mesh in clean wounds would yield favorable long-term outcomes.

Study Design Patients who underwent open complex ventral hernia repair with clean wounds (CDC class 1) using absorbable synthetic mesh (Bio-A, Gore, Flagstaff, AZ) in the retrorectus position were retrospectively reviewed. Chart review and a validated telephone questionnaire to screen for recurrence were utilized to evaluate and document hernia recurrence.

Results A total of 49 patients were included in this study. Patients were followed for recurrences for up to 105 months, with a mean follow-up time of 62.4 months (5.2 years). The total number of midline hernia recurrence was 7 out of the original 49 patients (14%). The mean and median recurrence time are 37.4 and 38.8 months, respectively. Kaplan–Meier survival analysis estimated hernia recurrence rate as 2%, 4.6%, 7.1%, 12%, 15%, and 18% at 12, 24, 36, 48, 60, and 72 months, respectively.

Conclusion The use of absorbable synthetic mesh in clean wound ventral hernia repair resulted in favorable long-term recurrence rates. The recurrence rate of absorbable synthetic mesh is similar to that of permanent synthetic mesh, which gives a viable option for patients in whom permanent synthetic mesh is not an option.

Keywords Ventral hernia · Absorbable synthetic mesh · Abdominal wall reconstruction · Hernia recurrence

The use of tension-free prosthetic material greatly improves outcome of ventral hernia repair [1]. In the U.S., more than 80% of hernia repairs use hernia reinforcement mesh [2]. Currently, permanent synthetic mesh remains the most used material in ventral hernia repair. Permanent synthetic mesh provides long-term durability and strength to reinforce the weakened abdominal wall [3, 4]. However, permanent synthetic mesh is associated with post-operative foreign body reaction and infection due to its permanent nature. The use of permanent synthetic mesh is particularly unfavorable in contaminated fields due to high risk of post-operative infection. Moreover, as the rate of co-morbidities such as obesity and type 2 diabetes continue to rise, the risk of wound complications in hernia repair remains high, which can lead to mesh infections. Initially, biologic mesh was introduced to address the need for mesh material suitable for the increasing population that is high risk for wound complications. Compared to permanent synthetic mesh, biologic mesh was hypothesized to promote tissue ingrowth, to decrease foreign body reaction, and to be more resistant to infection. However, bridging biologic mesh eventually leads to eventration and hernia recurrence. Reinforcing biologic mesh has better long-term results, but seroma formation and cost limit its use [5, 6].

Absorbable synesthetic mesh for abdominal wall reconstruction was first introduced in 2003. It is designed to reinforce the closure of fascia and facilitates the ingrowth of native cells [2]. In addition, since it is synthetic, it is not limited to tissue availability and cost [7]. Moreover, studies have shown that the use of absorbable synthetic meshes resulted with minimal serious complications associated with the prosthetic during 2-year follow-up in treating abdominal wall defects [6]. Another recent study has also demonstrated positive outcomes and low recurrence rates of hernia reinforced with absorbable synthetic mesh at

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18 months in CDC class I, high-risk ventral, and incisional hernia repair [8]. However, no studies have reported the long-term outcome of absorbable synthetic mesh beyond 5 years in ventral hernia repair. We hypothesized that the use of absorbable synthetic mesh in clean wounds would yield favorable long-term recurrence outcomes.

Materials and methods

A retrospective review of prospectively maintained data was undertaken of patients who underwent open ventral hernia repair with absorbable synthetic mesh at the Medical College of Wisconsin between Sep 2011 and Jan 2015. IRB approval was obtained by the Medical College of Wisconsin and patient consent was not necessary due to the retrospective nature of this study. All procedures were performed by a single surgeon (MG). The outcomes of these patients have been reported previously with 22-month follow-up [9].

Open ventral hernia repair performed with absorbable synthetic mesh (Bio-A Tissue Reinforcement, WL Gore, Newark, DE) in clean wounds (CDC class 1) were included. Patient demographics including age, sex, body mass index, race, smoking status, diabetes status, number of recurrent hernia and previous repairs, and Ventral Hernia Working Group score were collected and evaluated. Perioperative and post-operative data, including hernia defect size, mesh size, American Society of Anesthesiologists score, operation time, and hospital length of stay, post-operative complication, and hernia recurrence were recorded. Hernia recurrence data were collected for up to 105 months. Hernia recurrence was determined based on either physical exam, imaging, or standardized telephone call interview [10].

Surgical procedure

The operative technique has been previously described [9]. Briefly, the patients underwent midline laparotomy. All cases were Centers of Disease Control and Prevention (CDC) class 1. The absorbable synthetic mesh (Bio-A, WL Gore, Flagstaff, AZ) was placed in the retrorectus position with at least 5 cm of overlap beyond the hernia defect in all directions. The mesh was secured with absorbable suture (PDS, Ethicon, Cincinnati, OH) and the midline fascia was closed with absorbable suture as well. Transversus abdominis release was performed when the surgeon felt that the midline closure would be under too much tension. Drains were typically placed in the retrorectus space anterior to the mesh and in the subcutaneous space.

Statistical analysis

Statistical analysis was performed using SPSS, version 21 (IBM Corp). Kaplan–Meier survival analysis was used to estimate hernia recurrence rate.

Results

Demographics

A total of 49 patients were included in this study. Chart review was performed for all 49 patients. Phone surveys were conducted for all except the 8 patients that were deceased. There were 13 male and 36 (73%) female patients. Racial composition included 45 (92%) white, 2 African American (4%), 1 Hispanic (2%), and 1 other (2%). Mean age was 56 ± 12. Mean body mass index was 34 ± 8.3 kg/m [2]. Three (6%) patients were diabetic. There were 16 (33%) former smokers and 6 (12%) active smokers. The mean American Society of Anesthesiologists score was 3 (Table 1). There were 17 (37%) recurrent hernias and the mean number of previous repairs was 0.7 ± 1.8. The VHWG classification consisted of 3 (6%) grade 1, 39 (80%) grade 2, and 7 (14%) grade 3 (previous infection) (Table 2).

Table 1 Patient demographics

Variable	*N* (%)
Subject	49
Female	36 (73.5%)
Age (years)	56.1 ± 12.3
Pre-op BMI (kg/m^2)	34.4 ± 8.3
Race	
African American	2 (4.1%)
Caucasian	45 (91.8%)
Hispanic	1 (2.0%)
Other	1 (2.0%)
Former smoker	16 (32.7%)
Current/recent smoker	6 (12.2%)
Diabetes mellitus	3 (6%)
American Society of Anesthesiologists (ASA) Classification*	
Class 1	0 (0%)
Class 2	15 (31.9%)
Class 3	32 (68.1%)
Class 4	0 (0%)

*ASA classification was missing in two patients

Table 2 Hernia and wound characteristics

Variable	*N* (%)
Recurrent Hernia	17 (43.6%)
Number of previous repairs	0.71 ± 1.8
Ventral Hernia Working Group grade	
Grade 1	3 (6.1%)
Grade 2	39 (79.6%)
Grade 3	7 (14.3%)
Grade 4	0 (0%)

Operative details

Mean hernia defect size was 163 ± 134 cm^2. Mean mesh size was 404 ± 207 cm^2. Mean operative time was 275 ± 87.1 min (Tables 2 and 3).

Post-operative details

Mean hospital length of stay was 6 ± 3 days. Five (10%) patients had perioperative complications, including hypotension, C. Diff, pre-renal AKI, respiratory distress, prolonged ileus, and erythema. There were 6 (12%) complications between discharge and 30-day post-operations which consisted of 2 superficial surgical site infections, including 2 with wound drainage, 1 with cellulitis, and 1 with erythema treated with antibiotics. There was 1 (2%) complication between 31 days and 12-month post-operation; this single complication was chronic skin and subcutaneous abdominal wall abscess. No post-operative complications were found between 12 and 24 months (Table 4). Patients were followed for recurrent events between 22 and 3192 days, with a mean follow-up time of 62.4 months (5.2 years). The total number of midline hernia recurrence was 7 out of the original 49 patients (14%). Five had a recurrent hernia and underwent subsequent hernia repair. Two were confirmed to have recurrent hernias by CT imaging but did not undergo hernia repair. The mean and median recurrence time are 37.4 and 38.8 months, respectively. Kaplan–Meier survival analysis estimated hernia recurrence rate as 2%, 4.6%, 7.1%, 12%, 15%, and 18% at 12, 24, 36, 48, 60, and 72 months, respectively (Fig. 1).

Table 3 Operative data

Variable	
Size of defect (cm^2)	163.1 ± 133.7
Size of mesh (cm^2)	404.5 ± 206.6
Operative time (min)	275.0 ± 87.1

Table 4 Surgical outcomes

Variable	*N* (%)
Length of stay	
Perioperative complications	5 (10.2)
Post-operative complications	7 (14.2)
DC to 30 days	6 (12.2)
31 days to 12 months	1 (2.0)
12–24 months	0 (0)
Overall complications	12 (24.5)
Recurrent midline hernia	7 (14.2)
DC to 1 year	2 (4)
1 to 2 years	1 (2)
2 to 3 years	0 (0)
3 to 4 years	1 (2)
4 to 5 years	2 (4)
5 to 6 years	1 (2)
> 6 years	0 (0)

Discussion

This study retrospectively evaluated the use of an absorbable synthetic mesh in 49 clean open complex ventral hernia repairs with an average of 62.4-month follow-up. The total number of midline hernia recurrence was 7 (14%) out of the 49 patients. The mean and median recurrence time are 37.4 and 38.8 months, respectively. Using the Kaplan–Meier survival analysis, the hernia recurrence rates were estimated as 2%, 4.6%, 7.1%, 12%, 15%, and 18% at 12, 24, 36, 48, 60, and 72 months, respectively. This study suggests that the use of absorbable synthetic mesh in clean wound ventral hernia results in favorable long-term recurrence rates. This study followed and expanded on a previous study conducted by our group which reported the outcome of absorbable synthetic mesh in complex ventral hernia repairs with an average of 22-month follow-up [9].

The prospective Complex Open Bioabsorbable Reconstruction of the Abdominal wall (COBRA) study reported a 17% Kaplan–Meier recurrence rate at 24 months and a 13% recurrence rate in those with mesh placement in the retrorectus position [6]. In comparison, our study reports a Kaplan–Meier recurrence rate at 4.6% at 24 months. A lower recurrence rate is expected in the current study compared to the COBRA study as this study only evaluated those with clean wounds (CDC class 1), whereas the COBRA study included clean-contained and contaminated wounds (CDC class 2&3). The presence of contamination has been shown to have an increase in matrix metalloproteinases and cell-mediated collagenase production which would lead to worse hernia outcomes [11, 12]. Therefore, it would be inappropriate to compare the long-term recurrence rate of contaminated hernias with the clean hernias in the current study.

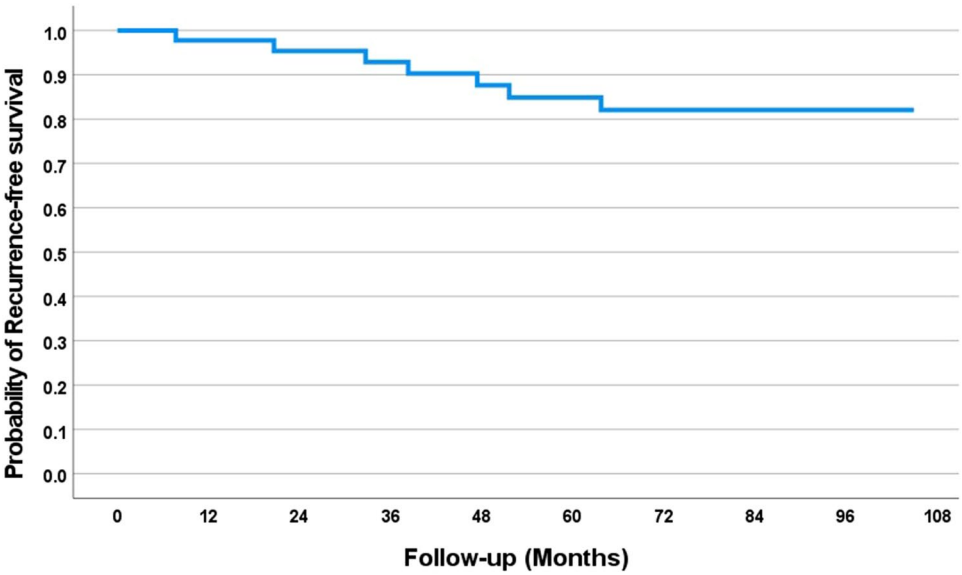

Fig. 1 Kaplan–Meier estimate of freedom from post-operative hernia recurrence: all participants

A prospective study by Roth et al. [8] on the use of a resorbable synthetic mesh, P4HB (Phasix), reported a 9% total recurrence rate at 18-month follow-up in those with clean wounds (CDC class 1) and increased risk of wound complications. Compared to our study, which used a different resorbable synthetic mesh material (Bio-A), we report a lower recurrence rate of 4% at a slightly longer follow-up period of 24 months. However, Roth et al. did not differentiate the recurrence rate based on surgical technique, with 73% retrorectus and 26% onlay placements. At 3-year follow-up, the same group of patients using PH4B had a 17.9% recurrence rate. There was a 10% recurrence rate in the retrorectus group and a 25% recurrence rate in the onlay group [13]. This adds additional evidence that the retrorectus space appears to have the best long-term results compared to onlay or intraperitoneal placement.

In the Repair of Infected or Contaminated Hernia (RICH) study, Itani et al. [5] reported the outcome of acellular porcine dermis mesh implanted in the retrorectus or intraperitoneal positions in clean-contaminated, contaminated, and dirty cases (CDC class 2, 3, & 4). The total recurrence rate was reported as 19% and 28% at 12 and 24 months, respectively. Like the COBRA study, the RICH study did not include those with clean wounds and thus a higher hernia recurrence rate is expected compared to our study. In addition, they showed improved outcomes with retrorectus placement of reinforcing material.

A recent study by Asaad et al. [14] reported the long-term outcome in abdominal wall reconstruction using acellular dermal matrix (bovine & porcine) with a median follow-up of 34 months (range, 6–139). Ninety-three (12.8%) of the 725 patients had a hernia recurrence. However, compared to the RICH study by Itani et al. [5], 41.7% of the defects in this cohort were clean. Moreover, this cohort represents a more diverse and complex demographic with only 70.2% of this abdominal wall reconstruction for initial and recurrent hernia. Moreover, 63% of patients had pre-op chemotherapy. Nonetheless, the Kaplan–Meier survival analysis estimated hernia recurrence rate as 4.9%, 13.5%, 14.27%, and 18.8% at 12, 36, 60, and 84 months.

Carbonell et al. [3] reported the surgical outcome of a permanent synthetic mesh (polypropylene) in clean-contaminated and contaminated wounds with a hernia recurrence rate of 7% given a mean follow-up of 10.8 ± 9.9 months. Although 94% of the hernia repairs were performed with mesh placed in the retrorectus positions, the recurrence rate specific to this surgical technique was not separately reported. One would expect a higher incidence of recurrence in a contaminated field as discussed earlier. The same group evaluated their outcomes in all patients who underwent retrorectus repair. With an average follow-up of 17 months, they found a 14.9% recurrence rate in their clean wound patients. However, they found a 22.9% recurrence rate with light-weight mesh and a 10.6% recurrence rate with medium-weight mesh [15].

One of the limitations of our study is the lack of surgical technique variations in which all the mesh placements were performed in the retrorectus fashion. Previous studies have shown differences in surgical outcome with different surgical techniques across all major mesh types, including the absorbable synthetic mesh [13]. Moreover, all hernia repair procedures were performed by a single surgeon. Also, this study included only clean wounds. Although a number of studies have used absorbable synthetic, biologic, and even permanent synthetic mesh in contaminated fields, all hernia materials are only indicated for use in clean wounds. There are data to suggest that biologic and absorbable meshes are the best options in contaminated fields, and many surgeons

utilize only permanent synthetic mesh in clean fields [5, 6]. Therefore, the use of absorbable synthetic mesh in clean wounds is mostly driven by patient's preference, concern for permanent product in body, and the risk of surgical site infection.

Current teaching suggests the use of permanent synthetic prosthetic reinforcement for long-term durable hernia repair. However, as the rate of obesity, type 2 diabetes, and other co-morbidities continue to rise, the risk of wound complications in hernia repair remains high. This rise in co-morbidities and their associated risk complications will likely manifest an increase in unfavorable clinical outcome. Our study adds to the growing body of literature supporting that absorbable synthetic mesh provides a safe and durable hernia repair with similar recurrence rates as permanent synthetic mesh.

Conclusion

This retrospective study showed that the use of absorbable synthetic mesh in clean wound ventral hernia repair resulted in favorable long-term recurrence rates. The recurrence rate of absorbable synthetic mesh is similar to that of permanent mesh. Absorbable synthetic mesh provides a viable option for patients in whom permanent synthetic mesh is not an option.

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Declarations

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