



Outcomes of biosynthetic absorbable mesh use in high risk CDC Class I ventral hernia repair: a single surgeon series

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Abstract

Purpose Biosynthetic absorbable meshes have emerged as suitable alternatives to permanent synthetic and biologic meshes in complex ventral hernia repair in contaminated wounds. Evidence regarding the use of these products in clean wounds is currently scant. This paper presents a large single surgeon series using GORE[®]BIO-A[®] (W.L. Gore & Associates, Newark, DE) (Bio-A) tissue reinforcement in high risk patients with predominantly CDC Class I wounds.

Methods Retrospective review of a prospectively maintained database of consecutive patients who underwent open ventral hernia repair with biosynthetic absorbable mesh was conducted. Ventral Hernia Working Group (VHWG) classification based on patient demographics and Centers for Disease Control (CDC) wound type were collected prospectively. All patients were followed up for a minimum of 12 months post-operatively.

Results 155 patients were included with a mean post-operative follow up of 29 months (range 12–62 months). Mean age was 61.8 years with an average BMI of 33.5 kg/m². 147 patients (94.9%) were classified as VHWG 2 or 3 based on comorbidities or surgical field contamination. 69% ($n = 107$) of wounds were designated CDC Class I. Mean hernia size was 119.7cm² with recurrent defects comprising 32.3% ($n = 50$). Retrorectus mesh repair was achieved in 84.5% of patients ($n = 131$). Post-operative wound events occurred in 19.3%. No mesh was explanted. Hernia recurrence rate was 9.0% with a mean time to recurrence of 14 months. There was no significant difference in recurrence rates between clean and contaminated wounds.

Conclusion This study supports the use of Bio-A in high risk ventral hernias, demonstrating a safe and durable repair across all wound classes. Ongoing follow-up continues to monitor for late complications and recurrence.

Keywords BioA · Biosynthetic mesh · Ventral hernia · Hernia repair · Recurrence

Introduction

The use of prosthetic material in the repair of ventral hernias (VHR) was first proposed by Theodor Billroth in 1878 [1]. Its role is to reinforce weakened tissue and provide tension-free repair that facilitates the incorporation of host fibrocollagenous tissue [2]. Mesh is now widely accepted as the gold standard for ventral and incisional hernia repair with significantly reduced recurrence rates observed when compared with primary suture repairs [3, 4].

Ventral hernia repair remains an active topic of research and discussion despite considerable technological

advancements over the last century. It is increasingly difficult for clinicians to make an objective choice on either the repair method or type of reinforcement used due to the quality of existing evidence and the sheer number of mesh products available for use.

International guidelines are largely based on expert consensus [5] due to a paucity of controlled data in defined patient populations and the heterogeneity of surgical techniques used in hernia repair. It is well established that patients with significant comorbidities including obesity, diabetes, chronic obstructive pulmonary disease (COPD), immunosuppression, smoking and advanced age, experience more frequent post-operative complications in addition to higher rates of hernia recurrence [6, 7].

Resorbable synthetic biomaterials have evolved in response to a growing need for safe and cost-effective alternatives to permanent synthetic meshes which have been plagued by complications of infection, erosion and fistula

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formation [8, 9]. Unlike permanent synthetic meshes, bioabsorbables provide a short-term mechanical model for future scar prior to polymer resorption, whereby the strength of the repair becomes dependent on the patient's own tissue integrity, rather than the device itself.

As humans cannot regenerate native soft tissues, an even layer of thicker scar tissue may be best biologically available alternative to a native aponeurosis without the risks and adverse effects of a foreign object that may also be a stimulus for constant inflammation and foreign body giant cell reaction [10, 11]. Biosynthetics may also alleviate the religious and cultural concerns associated with implantation of human or animal-derived material [12]. While their relative cost and uncertain clinical benefit initially hampered their widespread routine use [13], there is now some evidence promoting the cost-effective application of resorbable biosynthetic materials in ventral hernia repair [14–16].

Currently available devices in this category comprise a variety of synthetic polymers including polyglycolide, polylactide, trimethylene carbonate and poly-4-hydroxybutyrate [17]. At the time of publication, there are no prospective comparative studies to advise the optimum clinical scenario for their respective use. Clinical applications are extrapolated from pre-clinical data [18] and case series [5, 17] with most recent data reported in clean-contaminated and contaminated wounds [19–24] where their use was first popularized due to their relative resistance to infection even in the presence of bacterial contamination.

Bio-A (W.L. Gore & Associates, Newark, DE) is a proprietary biosynthetic web scaffold comprised of 67% polyglycolic acid (PGA) + 33% trimethylene carbonate (TMC) specifically designed for soft tissue reinforcement. This material undergoes hydrolysis and is replaced with dense vascularized scar tissue after approximately 6–7 months [25]. Like other resorbable meshes, Bio-A serves as a biological scaffold for repopulation and revascularization of host cells without generating a significant host inflammatory response [26, 27]. It appeals as an “ideal” tissue reinforcement in complex abdominal wall reconstruction, providing the durability and flexibility to maintain the dynamic structure of the abdominal wall without the associated complications of a permanent, fixed synthetic material [28].

Rosen et al.'s landmark COBRA study [29] was the first to prospectively evaluate the role of Bio-A to reinforce primary midline fascial closure in single-staged repairs of primarily clean-contaminated and contaminated ventral hernias. It remains the largest observational study on the use of Bio-A published to date.

This paper presents a single-surgeon series using Bio-A in open ventral hernia repair in predominantly Class I (clean) wounds. At the time of publication, it is only the third longitudinal study (with the largest cohort to date) to evaluate this product in open ventral hernia repair and the only study

to compare its use across all wound types in a high-risk patient population. Our aim was to complement the findings of COBRA by supporting the demonstrated safety and efficacy of Bio-A and determine its application in the elective (clean) setting in patients at high risk for post-operative complications.

Methods

All patients who underwent open complex ventral hernia repair by the author (KS) using bioabsorbable mesh (GORE®BIO-A®) between November 2015 and December 2020 were identified via retrospective review of a prospectively maintained database. Consent and ethical approval for collection and use of patient data were obtained from the appropriate local institutional ethics committees. Written informed consent was obtained from each patient prior to undergoing their surgical procedure.

Data collection

Prospectively collected information included baseline patient demographic data, comorbidities, body mass index (BMI), number of previous hernia repairs and hernia defect size on pre-operative imaging (length × width). Operative details included operating time, type of repair (mesh placement), concomitant intra-abdominal procedures and use of component separation or pre-operative Botox to the abdominal wall to facilitate midline closure.

Wound status was classified in accordance with Centre for Disease Control (CDC) criteria [30]. Patients were also stratified by the modified Ventral Hernia Working Group (VHWG) grading for assessment of risk of surgical site occurrences [31].

Inclusion and exclusion criteria

Data were collected for all patients who underwent open ventral hernia repair with bioabsorbable mesh by the author. There were no specific exclusion criteria. Only patients with a minimum of 12 months follow-up were included in the data analysis. Smoking rates in Australia are low (11.4%) [32]. Smoking cessation was mandated at least 4 weeks prior to elective surgery. This was not an exclusion criterion, rather a requisite condition instructed by the operating surgeon to reduce the risk of post-operative infection and recurrence. Patients were provided with relevant resources and support to achieve this. Hence, there were no current smokers in this group.

Surgical technique: retrorectus repair

Rives–Stoppa repair with retromuscular placement of Bio-A has been our preferred approach to large ventral hernias since 2015. With the exception of inguinal hernias, we rarely use permanent synthetic mesh in abdominal wall reconstruction and avoid placement of any prosthetic device within the abdominal cavity.

The retrorectus space was dissected and the hernia sac contents returned to the abdomen. The posterior rectus sheath was closed with 2/0 PDS (Ethicon; Cincinnati, OH) suture and/or linear stapler. Biosynthetic mesh (Bio-A) was trimmed to fit and placed in the retrorectus space. No fixation of the mesh was used. Where the retrorectus plane was obliterated or inaccessible, mesh was placed pre-peritoneally. In cases with greater than 50% loss of domain or in defects where the rectus muscles could not be brought to the midline, pre-operative Botox injections to the lateral abdominal wall and/or component separation was performed to gain a tension-free fascial closure. There was no mesh bridging using Bio-A as the product is not designed or indicated for this.

A 10-French suction drain was routinely placed in the retrorectus space and the anterior sheath was closed over the mesh using 2/0 PDS, small bite technique. Subcutaneous talc was used to reduce post-operative seroma, as were subcutaneous drains. The wound was closed with a continuous subcuticular suture and routinely covered with a foam-based negative pressure dressing for 5 days. Oral nutrition was typically recommenced 6 h post-operatively. Indwelling bladder catheter (if present) was removed on post-operative day 1–3 when the patient was able to mobilize. Surgical drains were removed when output was less than 100 ml per day and no patients left the hospital with drains in situ.

Panniculectomy was performed in patients with excessive or redundant abdominal wall skin or pannus. In these cases, a transverse skin incision (or transverse and vertical midline incisions (Fleur-de-lis) was used depending on the location of the redundant skin.

Follow-up protocol

Face-to-face post-operative follow-up was conducted by the operating surgeon (KS) at 2 and 6 weeks and then yearly intervals thereafter. Computed tomography (CT) scan of the abdomen was obtained routinely at the 6-week visit. As Bio-A is a relatively new product to the market, we developed this strict post-operative protocol to identify any early complications or issues relating to patient safety with this device. Large seromas were drained immediately (even if subclinical) to remove any fluid which may prevent anterior and posterior tissue integration of the Bio-A or act as a nidus for bacterial proliferation.

Study endpoints

The primary study endpoint was hernia recurrence. This was determined clinically and confirmed with cross-sectional imaging. Hernia recurrence was defined as per the COBRA study [29] as a new hernia occurring within 7 cm of the repair area.

Secondary endpoints included wound events and other post-operative (non-hernia related) complications. Post-operative wound events were classified as per standardized definitions by Haskins et al. [33] as surgical site infection (SSI), surgical site occurrence (SSO), or surgical site occurrence requiring procedural intervention (SSOPI). Other post-operative complications included any deviation from the expected care pathway and included cardiac or respiratory complications, venous thromboembolism and delayed return of gut function beyond 48 hours (ileus).

Statistical analysis

Categorical data were expressed as n (%). Mean and standard deviation were used for normally distributed variables. Bivariate analyses were performed to evaluate the influence of CDC wound classification, VHWG grade, previous hernia repair, concomitant abdominal procedures and panniculectomy on patient outcomes. Differences between categorical variables were evaluated using Pearson Chi-square and Fisher's exact test. Unpaired *t* test was used to calculate the difference between two means. Two-tailed *p* values < 0.05 were considered statistically significant. Recurrence-free probability was estimated with a standard Kaplan–Meier method. Calculations were performed using GraphPad Prism 6.01 (GraphPad Software Inc, La Jolla, CA).

Results

From our prospective database of 197 patients, a total of 155 patients met the inclusion criteria of a minimum of 12 months post-operative follow-up (mean 29 months, range 12–62 months). 67% of patients were followed up for 24 months or more. No patients were lost to follow-up.

One hundred and forty-seven patients (94.9%) were classified as VHWG 2 or 3 based on comorbidities or surgical field contamination as per modified VHWG criteria. Patients were designated Grade 2 if they had one or more of the following comorbidities: obesity, diabetes mellitus, chronic obstructive airways disease or prior history of wound infection (risk of SSO = 27%). Patients were designated Grade 3 if they had a contaminated or dirty surgical field (risk of

SSO = 46%) [31]. As above, there were no smokers in our patient cohort.

The vast majority ($n = 107$, 69%) of wounds were CDC Class I (clean) wounds. Baseline demographics are summarized in Table 1. Wounds were designated Class II or III in the event of a small bowel resection following adhesiolysis or where any concomitant intra-abdominal procedure was performed involving intestinal tract entry. Of the 8 patients deemed to have Class 4 wounds, these comprised enterocutaneous fistulae (2), removal of pre-existing infected mesh

(3), repositioning of an existing colostomy (1) and reversal of Hartmann's procedure to restore intestinal tract continuity (2). In no circumstances was Bio-A placed in a visibly contaminated field.

Fifty patients (32.3%) had recurrent incisional hernias with 54% of those ($n = 21$; 13.5% of total) having undergone more than one previous hernia repair. The mean hernia defect area was 119 cm² (range 9–625 cm²) with 36 patients (23.2%) requiring an adjunctive muscular component separation to achieve midline fascial closure. Complete midline

Table 1 Baseline patient demographics

	ALL ($n = 155$) CDC Class 1–4	Clean ($n = 107$) CDC Class 1	Contaminated ($n = 48$) CDC Class 2–4	<i>p</i>
Age (years) (\pm SD)	61.8 (\pm 12.8)	60.5 (\pm 13.3)	64.8 (\pm 11.2)	0.049
BMI (kg/m ² \pm SD)	33.5 (\pm 8.1)	32.9 (\pm 6.9)	35 (\pm 10.2)	0.132
Gender (n , %)				
Male	60 (38.7%)	38 (35.5%)	22 (45.8%)	0.285
Female	95 (62.3%)	69 (64.5%)	26 (54.5%)	
VHWG classification (n , %)				
Grade 1	8 (5.1%)	8 (7.4%)	0 (0%)	N/A
Grade 2	99 (63.9%)	99 (92.6%)	0 (0%)	
Grade 3	48 (31%)	0 (0%)	48 (100%)	
CDC classification (n , %)				
Class 1	107 (69%)	107 (100%)	0 (0%)	N/A
Class 2	26 (16.8%)	0 (0%)	26 (54.2%)	
Class 3	14 (9%)	0 (0%)	14 (29.2%)	
Class 4	8 (5.2%)	0 (0%)	8 (16.6%)	
Recurrent hernia (prev repair) (n , %)	50 (32.3%)	31 (29%)	19 (37.5%)	0.199
> 1 defect (n , %)	24 (15.4%)	17 (15.9%)	7 (14.6%)	1.00
Mean hernia defect area (cm ² \pm SD)	119.7 (\pm 97)	106.5 (\pm 86.5)	149.6 (\pm 112.3)	0.010
Previous bariatric surgery (n , %)	32 (20.6%)	24 (22.4%)	8 (16.7%)	0.521
Average pre-op weight loss (kg \pm SD)	15.3 (\pm 24)	16.3 (\pm 23.2) kg	14.6 (\pm 25.9)	0.685

Bold type indicates statistically significant *p* values ($p < 0.05$)

Table 2 Operative details

	ALL ($n = 155$)	Clean ($n = 107$)	Cont ($n = 48$)	<i>p</i>
Operative time (mins \pm SD)	139 (\pm 55)	127 (\pm 48)	168 (\pm 59)	< 0.001
Mesh placement (n , %)				
Retrorectus	131 (84.5%)	89 (83.2%)	42 (87.5%)	0.137
Preperitoneal	22 (14.2%)	18 (16.8%)	4 (8.3%)	
Intraperitoneal	2 (1.3%)	0 (0%)	2 (4.2%)	
Concomitant intra-abdominal procedure	38 (24.5%)	8 (7.5%)	30 (62.5%)	< 0.001
Adhesiolysis > 60 min (n , %)	29 (19.7%)	12 (11.2%)	17 (35.4%)	< 0.001
Panniculectomy (n , %)	82 (52.9%)	60 (56%)	22 (45.8%)	0.297
Pre-operative botox (n , %)	16 (10.3%)	10 (9.35%)	6 (12.5%)	0.575
Myofascial release (n , %)	36 (23.2%)	20 (18.7%)	16 (33.3%)	0.063
Transversus abdominus	33 (21.3%)	18 (16.8%)	15 (31.2%)	
External oblique	3 (1.9%)	2 (1.9%)	1 (2.1%)	
Mean hospital stay (days \pm SD)	7.8 (\pm 6.6)	6.2 (\pm 2.5)	11.3 (\pm 10.4)	< 0.001

Bold type indicates statistically significant *p* values ($p < 0.05$)

Table 3 List of concomitant intra-abdominal procedures

Procedure	<i>n</i>
Small bowel resection	11
Cholecystectomy	7
Hysterectomy	4
Reposition ileal conduit	2
Colostomy closure post-Hartmann's procedure	2
Ileostomy closure	1
Appendectomy	1
Reposition ileostomy	1
Hiatus hernia repair	1
Liver transplant	1
Revision of gastroenterostomy	1
Construction of new ileal conduit	1
Construction of new colostomy	1
Drainage of pancreatic pseudocyst	1
Distal pancreatectomy	1
Splenectomy	1
Adrenalectomy	1
Total	38

fascial closure was attained in all 155 patients. Further operative details are listed in Table 2.

Concomitant procedures were performed during abdominal wall reconstruction in 38 patients (24.5%) as detailed in Table 3 reflecting the hepatobiliary practice of the surgeon. Mean length of inpatient stay was 7.8 (± 6.6) days and was predictably longer in patients with wound contamination or following a concurrent intrabdominal procedure ($p = < 0.001$). Mean operating time was 139 (± 55 min) with longer operating times observed in patients with Class II–IV wounds, or where a concomitant intra-abdominal procedure or extensive adhesiolysis (> 60 min) was performed ($p = < 0.001$).

Operative complications are detailed in Table 4. Wound events occurred in a total of 30 patients (19.6%) with no significant difference in SSI, SSO or SSOPI between clean (CDC Class I) and contaminated (CDC Class II–IV) wounds ($p = 0.831$) or VHWG grade 2–3 patients ($p = 0.0652$). The 8 patients (5.1%) designated VHWG 1 also had CDC Class 1 (clean) wounds. Only one of these patients had a documented SSO (hematoma). This was not statistically significant ($p = 1.00$).

There was no statistically significant increase in surgical site occurrences in patients who underwent concomitant intra-abdominal procedures ($p = 0.481$). Increased wound event rates were noted in patients who had a panniculectomy, irrespective of wound class ($p = 0.015$ and $p = 0.010$). No bioabsorbable mesh was explanted. Non device-related

Table 4 Complications

	ALL (<i>n</i> = 155)	Clean (<i>n</i> = 107)	Contaminated (<i>n</i> = 48)	<i>p</i>
Total wound events	30 (19.3%)	21 (19.6%)	9 (18.8%)	1.000
Surgical site infection (SSI) (<i>n</i> , %)	3 (1.9%)	2 (1.9%)	1 (2.1%)	1.000
Surgical site occurrence (SSO) (<i>n</i> , %)	10 (6.5%)	7 (6.5%)	3 (6.3%)	1.000
Wound hematoma	3	3	0	
Superficial wound dehiscence	3	3	1	
Skin edge necrosis	3	1	2	
Intra-abdominal collection (spontaneously drained)	1	0	1	
Surgical site occurrence requiring procedural intervention (SSOPI) (<i>n</i> , %)	17 (11%)	12 (11.2%)	5 (10.4%)	1.000
Evacuation of wound hematoma	3	3	0	
Drainage of subcutaneous seroma	5	3	2	
Drainage of retrorectus seroma	7	5	2	
Delayed primary closure of wound	2	1	1	
Other post-operative complications (<i>n</i> , %)	10 (6.5%)	5 (4.7%)	5 (10.4%)	0.286
Respiratory failure	1	1	0	
Acute pulmonary oedema	1	1	2	
Prolonged ileus	3	1	0	
Peripheral venous thromboembolism	1	1	1	
Pulmonary embolus	2	1	1	
Re-laparotomy for intestinal obstruction	1	0	1	
Hernia recurrence	14 (9.0%)	9 (8.4%)	5 (10.4%)	0.763
Mean time to recurrence (months)	13.8	12	14.2	0.638

Table 5 Factors associated with post-operative wound events (SSI/SSO/SSOPI)

All patients	Wound event (<i>n</i> = 30)	No wound event (<i>n</i> = 125)	<i>p</i>
BMI mean, kg/m ²)	34.3 (± 6.9)	33.4 (± 8.4)	0.565
Hernia defect size (mean, cm ²)	124.7 (± 77.4)	118.9 (± 101.3)	0.754
Concomitant procedure (<i>n</i> , %)	9 (30%)	29 (23.2%)	0.481
Panniculectomy (<i>n</i> , %)	22 (73.3%)	60 (48.0%)	0.015
Contaminated field (CDC 2–4)	9 (30%)	41 (32.8%)	0.831
VHWG 2–3	28 (93.3%)	119 (95.2%)	0.652
Clean wounds (CDC Class I) only	Wound event (<i>n</i> = 21)	No wound event (<i>n</i> = 86)	<i>P</i>
BMI (mean, kg/m ²)	33.5 (± 6.3)	32.7 (± 7.1)	0.631
Hernia defect size (mean, cm ²)	116.7 (± 80.1)	103.7 (± 88.2)	0.540
Concomitant procedure (<i>n</i> , %)	1 (3.3%)	7 (5.6%)	1.00
Panniculectomy (<i>n</i> , %)	17 (80.9%)	43 (50%)	0.010

Bold type indicates statistically significant *p* values (*p* < 0.05)

post-operative complications occurred in 10 patients (6.5%) with a non-significant increase observed in patients with wound contamination (*p* = 0.286) (Table 5).

There were 14 hernia recurrences (9.0%) with a mean time to recurrence of 14 months (range 3–24 months). Recurrences were evaluated clinically and confirmed radiologically by CT scan. There was a marginally lower but non-significant rate of hernia recurrence in Class I wounds (8.4% vs 10.4%, *p* = 0.763).

Eight (57.1%) of the 14 patients who developed recurrent hernias were morbidly obese with a BMI greater than 35 kg/m² at the time of recurrence. Nine (64.3%) had undergone prior repair of their incisional hernia with four of these patients having three or more previous procedures for the same hernia. 64.3% (*n* = 9) of recurrences occurred in Class I wounds. This was not statistically significant.

Post-operative wound complications did not appear to influence overall risk of hernia recurrence (*p* = 0.737). Of those patients with recurrence (*n* = 14), one had experienced an earlier wound complication (superficial skin necrosis) and one required percutaneous drainage of a superficial wound

seroma. None of the patients with hernia recurrence had intra-abdominal or mesh-related complications. There were no wound complications noted beyond the 6-week post-operative period.

Previous hernia repair was associated with an increased risk of earlier recurrence (*p* = 0.014) (Fig. 1) and was identified as an independent risk factor for recurrence overall (*p* = 0.019) (Fig. 2). No other specific operative or demographic features were significant in the incidence of hernia recurrence (Table 6).

Discussion

This retrospective study evaluated the use of synthetic bio-absorbable mesh (Bio-A) in 155 of the typically high-risk patients who present with incisional hernias. We report a hernia recurrence rate of 9.0% across all wound classes after a mean follow-up of 29 months. For each of the recurrences,

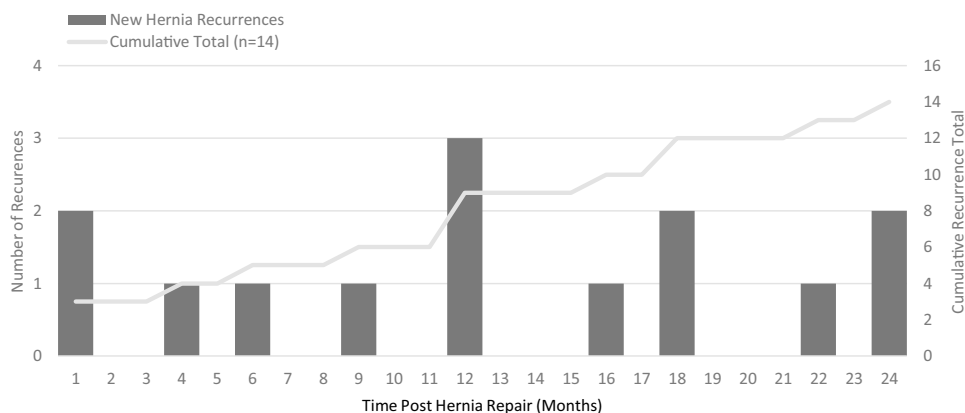
Fig. 1 Timing of hernia recurrences

Fig. 2 Effect of previous repair on hernia recurrence rate

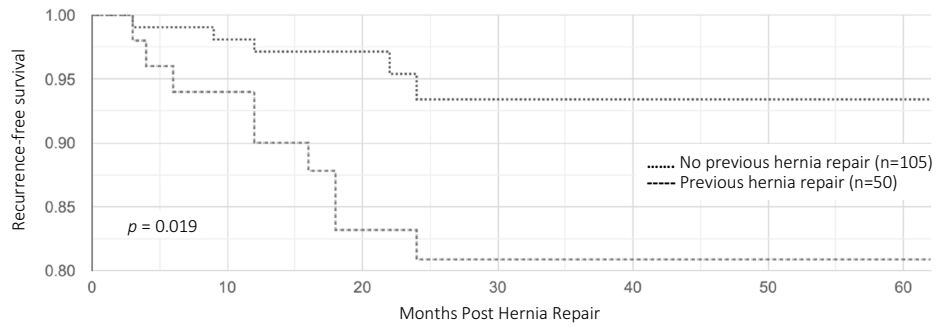


Table 6 Factors associated with hernia recurrence

All patients	Recurrence (n = 14)	No recurrence (n = 141)	p
BMI (mean, kg/m ²)	35.1 (± 9.6)	33.4 (± 8.0)	0.458
Hernia defect size (cm ²)	98.6 (± 66)	121.78 (± 99.4)	0.396
SSI/SSO/SSOPI (n, %)	2 (14.3%)	29 (20.55%)	0.737
Previous hernia repair (n, %)	9 (64.3%)	41 (29.1%)	0.014
Panniculectomy (n, %)	6 (42.8%)	76 (53.9%)	0.576
Contaminated field (CDC 2–4)	5 (35.7%)	43 (30.4%)	0.764
VHWG 2–3	14 (100%)	133 (94.3%)	N/S
Clean wounds (CDC Class I) only	Recurrence (n = 9)	No recurrence (n = 98)	p
BMI (mean, kg/m ²)	37.0 (± 8.2)	32.5 (± 6.7)	0.062
Hernia defect size (cm ²)	80.8 (± 34.8)	108.8 (± 89.1)	0.358
SSI/SSO/SSOPI (n, %)	1 (11.1%)	20 (20.4%)	0.501
Previous hernia repair (n, %)	6 (66.7%)	25 (25.5%)	0.017
Panniculectomy (n, %)	3 (33.3%)	57 (58.1%)	0.151

Bold type indicates statistically significant p values (p < 0.05)

it is this author’s opinion that specific technical factors (most commonly insufficient mesh overlap of the defect or failure to address rectus divarication) were identified as contributors. There were no midline recurrences or evidence of central mesh failure in this group. This supports the notion that repair technique is just as important, if not more than, the longevity of the prosthetic device used in ventral hernia repair.

Patients with CDC Class I wounds were younger on average (60.5 vs 64.8 years; p = 0.049) with smaller mean hernia defects (106.9 vs 149.6 cm²; p = 0.010). This did not translate to any observed reduction in the rate of complications or recurrences in this subgroup. In addition, the incidence of a wound event (SSI/SSO/SSOPI) did not correlate with an increased risk of hernia recurrence in clean or contaminated wounds.

The total recorded SSO rate of 19.3% seems comparatively high but must be viewed in the context of a significant proportion of patients undergoing concurrent panniculectomy and our protocol for routine drainage of all seromas (as detailed above).

While no statistically significant increase in total surgical site occurrences (SSO) could be demonstrated between wound classes, there was a significant increase in the observed wound event rate in patients who underwent concurrent panniculectomy which is well documented as having an increased risk of wound infection and seroma [34, 35]. In practice, it seems feasible that these complications would relate to perfusion of and tension on the skin flaps rather than a consequence of the mesh used in the abdominal wall repair. There was no increase in hernia recurrence observed in patients who underwent panniculectomy. These findings will be further evaluated in a future post hoc analysis. Panniculectomy is frequently requested in this group of patients and continues to be a standard part of our practice despite the risk of these additional wound issues.

Five of the seven patients requiring post-operative drainage of a retrorectus seroma did not have suction drains placed at the time of their index procedure. These repairs were performed early in the series (2015–2016) and our practice was subsequently updated to include routine drainage of the retrorectus space. While such wound events are

unfortunate complications, we found that seroma development was not a risk factor for subsequent hernia recurrence.

We attribute our comparatively low incidence of surgical site infection and wound dehiscence to the routine use of a closed-incision foam-based negative pressure wound device which was left in place for 5 days post-operatively. The use of these devices in the prevention of SSI in ventral hernia repair has been validated by recent meta-analyses [36, 37]. More importantly, in the event of a wound complication, there was no demonstrable increase in hernia recurrence. This is presumably because infection does not lead to central mesh failure in bioabsorbable devices, unlike permanent synthetic meshes [38, 39].

Our mean length of hospital stay (7.8 days) is longer than several American and European centers [21, 24, 29, 40, 41]. The state of Queensland is 2.5 times the size of Texas and we are one of very few centers to offer complex hernia surgery. Patients have vast distances to travel home and commercial airlines do not permit air travel for 10 days following major surgery. This accounts for our relatively increased length of stay.

Comparison with previously reported data is limited by availability of published studies in similar patient populations. This is further confounded by an absence of a universally accepted standardized hernia classification system [18]. We have reviewed the available literature and drawn comparisons from subgroups in comparable studies of patients with VHWG 2 or 3 hernias where appropriate (Table 7).

Rosen et al.'s COBRA study demonstrated efficacy regarding hernia recurrence, wound complications and quality of life for patients undergoing contaminated ventral hernia repair with Bio-A [29]. This longitudinal study observed patients over 24 months after repair of complex ventral hernias considered contaminated or clean-contaminated

(CDC Class II and III). 84% of patients completed the requisite 24 month follow-up. Results were reported as a single cohort and there was no subgroup comparison between wound classes. VHWG data were not reported, hence risk assessment is made based on wound contamination rather than patient comorbidities. As in our current study, primary fascial closure was achieved in all patients. Our recurrence rate of compares favorably with this study (9.0% vs 17%), with a lower SSI/SSO/SSOPI rate (19.3 vs 28%) as would be expected in predominantly Class I wounds.

Cho et al. [40] subsequently reported positive outcomes using retrorectus Bio-A in 74 patients across all wound classes (66.2% CDC Class 1). Patients were comparable in terms of baseline demographics and CDC/VHWG grading but with a larger mean hernia size of 163.1 cm² (vs 119.7 cm²). Recurrence rate in the retrorectus group was reported as 8.1% for CDC Class 1 wounds. With an average of 22 months follow-up, they report only six patients (7.4%) with wound complications at 30 days and no re-operation or mesh explantation required during the target 18 month study period. While the primary aim of this study was to compare retrorectus and intraperitoneal mesh placement, relevant similarities to our own patient cohort warrants the selected comparisons.

Roth et al. [41] recently published clinical data for Phasix™ (C.R Bard/Davol, Warwick, RI), a poly-4-hydroxybutyrate (P4HB) mesh with a resorption time of 12–18 months. This is an update of their 2018 study of the same cohort [42]. They analyzed 121 patients with CDC Class I incisional hernias > 10 cm² in size with no more than 3 previous repairs and at least 1 “high risk” medical comorbidity. Mesh was placed in the retrorectus (73%) or onlay (27%) position in these patients. Fascial closure was achieved in 94% of cases with component separation performed in 44%. They report a total wound event rate of

Table 7 Comparison with other longitudinal studies of high-risk patients (minimum 12 month follow-up)

Author	Year	n	CDC class	Mean age (Y)	BMI kg/m ²	Size cm ²	Mesh used	SSI/SSO/SSOPI	Recurrence rate	Mean follow-up (months)
Slater	2020	107	I	60.5	32.9	106.5	RR Bio-A	19.6%	8.4%	29
		48	II–IV	64.8	35.0	149.6	RR Bio-A	18.8%	10.4%	
Rosen [29]	2017	104	I–IV	58.0	28.0	137	RR Bio-A	28%	17%	24 ^a
Cho [40]	2019	49	I	56.1	34.4	163.1	RR Bio-A	10.9% ^b	8.2%	22
		74	I–IV	56.2	34.7	156.2	RR Bio-A	16.2%	8.1%	
Roth [41]	2021	121	I	54.7	32.2	115.7	RR P4HB	31.4%	17.9%	36 ^c
Messa [44]	2019	70	I–IV	58.6	33.0	323	RR P4HB	30.0%	5.7%	24
Rognoni [45]	2020	75	N/R	59.0	30.0	431	RR P4HB	17.3%	8%	26

RR retrorectus mesh, N/R data not reported

^a84% of patients completed 24 month follow-up (mean not stated)

^bData reported at 30 days post-operatively

^c69% of patients completed 36 month follow-up (mean not stated)

15.9% (9.3% SSI + 6.6% SSOPI) but an additional device-related complication rate of 15.7%. Recurrence is reported as 17.9% with only 69% of patients completing the requisite 36 month follow-up.

Patients in this study are demographically similar to those in our study with a mean age of 54.7 years, mean BMI of 32.2 kg/m² and mean hernia area of 115 cm². There are no data available to compare safety and efficacy in clean-contaminated or contaminated wounds as the study was limited to Class I wounds only in line with current FDA regulations [43]. It should also be noted that Bio-A and Phasix™ differ in their composition (PGA + TMC vs P4HB) and resorption time (6 months vs 18 months) making direct comparison fundamentally biased [16].

One of the most important studies on the use of P4HB in ventral hernia repair is the paper by Messa et al. [44]. This is a single-surgeon series of 70 patients, again with similar demographics (age, BMI, CDC, VHWG) albeit with a substantially larger mean hernia size of 323 cm². With an average post-operative follow-up of 24 months (range 12.2–41 months), they report a hernia recurrence rate of only 5.7%. Of significance, there were no recorded mesh infections or mesh explantation despite a 30% SSO rate, again tipping the scales in favor of bioabsorbable over permanent synthetic meshes in this setting. Consistent with the findings of our study, they did not identify a difference in hernia recurrence, SSI or SSOPI between clean and contaminated wounds.

More recently, Rognoni et al. published the current outcomes of P4HB use in the Italian Hernia Registry with a mean follow-up of 26 months [45]. Like Roth's study, their analysis was limited to VHWG 2 and 3 patient but with no details regarding CDC wound classification reported. In addition, 19% of patients had intraperitoneal placement of mesh, accounting for 50% of their reported recurrences. In the absence of specific subgroup evaluation, meaningful comparison with our evaluated patient cohort is limited.

We have thus demonstrated the safe and efficacious use of biosynthetic resorbable mesh (Bio-A) in open ventral hernia repair with wound event and hernia recurrence rates comparable to similar published series with equivalent or longer follow-up. Our study comprised predominantly Class 1 (clean) wounds in patients at higher risk of recurrence by modified VHWG criteria. This expands the findings of COBRA, identifying potential universal application of Bio-A in complex ventral hernia repair across all wound classes.

The Rives–Stoppa technique is generally considered the gold-standard approach to complex ventral hernia repair [46, 47]. Our results support Cho [40] and Rosen's [29] previously reported benefits of retrorectus placement of bioabsorbable mesh and highlight the importance of technique over device choice. Operative technique appears to have the

most significant influence on recurrence in our study, with specific technical factors identified in each of the 14 documented hernia recurrences in this series.

These learning points have led to some notable changes in our practice. Specifically, we now routinely address any evident rectus diastasis (especially in higher BMI patients) by complete dissection of the retrorectus plane and filling this space entirely with an appropriately sized mesh in an effort to reduce lateral recurrences. Primary fascial closure to restore the linea alba remains the fundamental goal of our repair, with pre-operative Botox injection and/or component separation used to achieve this. In view of our retrorectus seroma rate of 4.5% ($n=7$), we continue to assess and review our drainage protocols.

The issue of “what happens to the mesh” is further demonstrated by our experience with Bio-A. On at least two occasions, we have re-operated on patients with hernia recurrences and two other patients who required laparotomy for other reasons (with incidental previous Bio-A repairs). At the time of re-operation, it was observed that the tissue that had been reinforced with Bio-A was robust and elastic and was a useful adjunct for further repair (or primary closure of the re-opened abdomen). This was especially so in the earlier part of the series, where our Bio-A coverage of the entire retrorectus space was lacking and the hernia had recurred at the edge of the mesh. Samples of the tissue that had replaced the Bio-A were sent for histological evaluation, confirming mature scar tissue with fibroblasts, vascular network and dense collagen deposition.

Strengths and limitations

Subjects evaluated in this study represent a population of consecutive patients undergoing complex ventral hernia repair in our care. A single-surgeon series offers insight into the effects of a relatively consistent technique of repair and aids reliable and robust patient follow-up (no patients were lost to follow-up in this series). Complicated and comorbid patients were not excluded and thus considered reflective of a genuine patient population encountered in everyday practice. All patients were followed for a minimum of 12 months (mean 29 months), allowing for assessment of early recurrence after expected Bio-A reabsorption at 6 months. It is well established that long-term follow-up is critical to the detection of hernia recurrences. This patient cohort will continue routine annual follow-up with more patients to be added to the series as they reach the 24 month analysis threshold. In addition, 3 and 5 year analyses are planned to assess long-term recurrence rate.

The lack of a control group limits the applicability of our results. Evaluating the use of long-acting resorbable mesh ultimately necessitates direct comparison with a permanent synthetic reinforcement. Further studies in the form of

comparative trials are needed to clarify their context for use, particularly in relation to CDC wound class and VHWG risk stratification. Our own recent study [20] comparing Bio-A to a permanent synthetic mesh was a retrospective observational design which carries the implicit biases in mesh and patient selection that a randomized controlled trial would mitigate. Long-term follow-up data and cost–benefit analyses would provide additional support to simplify individualized mesh choice in ventral hernia repair, particularly in specific populations at high risk of complications and/or recurrence [16].

In this study, no statistically significant distinction could be made between any other relevant patient or procedural factors that predispose SSO. This was likely an effect of sample size (Type II error) and larger studies or meta-analyses with larger cohorts would be better placed to evaluate the effect of these factors on SSO rates. Ultimately, in the absence of any such studies, we rely on extrapolation from observational data. However, variability in operative technique and hernia characteristics (as well as the lack of universal outcome criteria) limits any meaningful comparison between series [18]. We support the use of standardized wound classifications (CDC) and hernia risk stratification as per the Ventral Hernia Working Group [31] to enable comparative analysis of observational data.

Conclusion

The role of long-acting resorbable meshes in abdominal wall reconstruction is evolving. This prospective, single-surgeon series is the first to evaluate the use of Bio-A synthetic bio-absorbable mesh in incisional ventral hernias in clean (Class 1) wounds in patients at high risk for complications and builds on the existing observational data supporting its use in clean-contaminated and contaminated settings.

Bio-A showed favorable outcomes across all wound types with perioperative wound complication and recurrence rates similar to those published in other series. The absence of observed long-term complications supports its use as our preferred tissue reinforcement option for ventral hernia repair in patients at high risk of wound or mesh-related complications, irrespective of wound class.

Individualized mesh choice in ventral hernia repair relies on long-term complication surveillance data. Comparative trials are needed to further elucidate the potential context for use of Bio-A and determine its safety and efficacy in specific clinical settings. Universal outcome reporting of complex abdominal wall reconstruction would facilitate the development of a clinical registry that would help surgeons (and patients) assess the real-world clinical performance of these devices.

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Availability of data and material De-identified data and statistical methods calculations available for review on request. Maintained in secure database to protect patient privacy.

Declarations

Conflict of interest Assoc Prof Kellee Slater has received personal honoraria from WL Gore for speaking at educational events. Dr Alison Smith has no conflicts of interest or financial disclosures.

Human and animal rights All procedures performed on human participants in this study were carried out in compliance with local ethical standards and the 1964 Helsinki Declaration and its later amendments.

Ethical approval Approved by Ramsay Healthcare Queensland Human Research Ethics Committee (Protocol 19/35) and Metro South Human Research Ethics Committee (EC00167).

Consent to participate Formal written consent was sought from patients prior to surgery to be included in a secure database for research and publication purposes. Copy of written consent form available on request.

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