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Abdominal wall reconstruction using biosynthetic absorbable mesh in high-risk complex ventral hernia

Finch David, Mehmood Sajid, Varghese Joseph

Department of General Surgery, Royal Bolton Hospital, Bolton, United Kingdom

Summary

BACKGROUND: Biosynthetic mesh may represent an improvement on biological and large pore synthetic meshes for high-risk complex ventral hernia repair. This study aimed to evaluate the performance of polyglycolic acid (PGA):trimethylene carbonate (TMC) biosynthetic mesh for reinforcement of the midline fascial closure in a single-stage repair of complex ventral hernias in high-risk patients.

METHODS: A retrospective review was undertaken for patients who underwent a planned open single-stage complex ventral hernia repair with a single unit of PGA:TMC biosynthetic mesh between May 2013 and August 2017. Data on outcome variables were recorded and quality of life assessed using the Short Form-12 (SF-12) instrument.

RESULTS: Overall, 56 patients underwent abdominal wall reconstruction for complex ventral hernias. All meshes were placed in the retrorectus position. Some 39% underwent component separation. The majority of patients (86%, n = 48) had high risk (grade 2 or 3) hernias according to the Ventral Hernia Working Group classification. Overall hernia recurrence rate was 3.6% (n = 2). Postoperative surgical site infection occurred in 26.8% (n = 15). Median follow-up by clinical examination was 6 months (range 4–17). Median telephone follow-up was 21 months (range 4–54). Pre- and post-treatment SF-12 quality of life assessments demonstrated significant improvements in both the physical and mental components.

CONCLUSION: This study reports a large series of abdominal wall reconstructions using biosynthetic mesh in complex ventral hernia. The findings indicate promising early outcome data associated with use of biosynthetic mesh. Larger well-controlled studies with longer follow-up are needed for confirmation of these findings.

Keywords: *biosynthetic mesh, ventral hernia, repair*

Correspondence:
Mr David Finch, Department of General Surgery, Royal Bolton Hospital, Minerva Road, Bolton, BL4 0JR, United Kingdom, Davidfinch[at]nhs.net

Introduction

Complex ventral hernias in patients at high risk of postoperative complications present a significant management challenge. Abdominal wall reconstruction with mesh reinforcement is commonly required to facilitate a tension-free hernia repair. Selection of an appropriate reinforcement material is considered fundamental to preventing recurrence and complications associated with complex hernia repairs.

The conventional options for complex hernia repair with mesh included either a permanent synthetic mesh or an absorbable biological mesh. The high risk of contamination of the surgical field in such cases certainly limits the use of synthetic non-absorbable meshes [1]. Whereas biological source-derived meshes incorporate into the native tissues and resist infections, they are degraded owing to accelerated enzymatic action in such situations [2]. Despite high mesh salvage rates in the event of infections occurring, biological meshes are indeed associated with high recurrence rates in such circumstances [2, 3]. Such clinical concerns, along with their associated high cost, have limited the routine use of biological meshes [4].

Biosynthetic materials have the potential to represent an improvement over biological prostheses. As with biological mesh, biosynthetic meshes are absorbable, and provide the necessary mechanical support and reinforcement until cellular infiltration of the matrix scaffold has resulted in sufficient tissue generation for native reinforcement. Their breakdown via hydrolysis may offer a unique advantage when challenged with bacterial colonisation, making them particularly attractive choice over biological meshes [5].

Biosynthetic meshes have the added advantage of uniformity and predictability, unlike biological meshes, which can be almost as diverse as the tissue from which they are harvested. Mechanical properties, including compliance, elasticity, and strength retention, as well as rate of absorption and degradation, can easily be tailored by simply altering the polymer-based composition of these meshes [6]. There are also comparatively fewer mandatory storage, transport, or pretreatment requirements to preserve the integrity and function of these products. One of the most significant advantages of these meshes may be a substantial reduction in cost [6].

There are currently four biosynthetic meshes available: Vicryl® Woven Mesh (PGA:PLA), Gore® Bio-A® Tissue Reinforcement, Phasix™ Mesh and TIGR® Resorbable

Matrix. Each is composed of varying degrees of biodegradable polymer with absorption times from as little as 2 months ranging up to 3 years.

The perceived benefits of biosynthetic meshes are yet to be supported by convincing clinical outcome data. There is significant paucity of evidence for the use of these meshes in complex ventral hernia repairs. Indeed, an expert consensus guided by systematic review on ventral hernia management was unable to provide any clear recommendations for the routine use or effectiveness of biosynthetic meshes [7]. This study was, therefore, undertaken to report our moderate-volume single centre experience to add to the evidence on this subject. We aimed to evaluate the outcomes of polyglycolic acid:trimethylene carbonate (PGA:TMC) biosynthetic mesh for the reinforcement of the fascial closure in a single-stage repair of complex ventral hernias in predominantly high-risk patients.

Methods

Patients and setting

A retrospective, single centre review of patients undergoing abdominal wall reconstruction between May 2013 and August 2017 was undertaken. Only the patients who underwent a planned single-stage abdominal wall reconstruction for complex ventral incisional hernias with biosynthetic mesh insertion were eligible for inclusion in this study. Patients were excluded if they had a primary ventral hernia, a non-absorbable or biological mesh was inserted, or the hernia did not meet definition of a complex hernia. Complex hernias were defined as per the consensus classification described by Slater et al. [8]. This classification system categorised complex hernias into minor, moderate and major complex hernias using patient and hernia characteristics across four domains including defect size and location, patient history and risk factors, contamination and soft tissue condition, and clinical scenario [8]. Eligible patients were identified from the hospital operating records management information database.

Assessment and planning

A computed tomography (CT) scan was obtained as standard for all cases provisionally considered suitable for abdominal wall reconstruction. All patients underwent comprehensive multidisciplinary team evaluation to assess the size of the hernia and extent of loss of domain, and to identify occult hernia defects. The defects were measured on CT scan and documented as maximum vertical (cm) and horizontal (cm) dimensions in accordance with the European Hernia Society (EHS) guidelines [9]. All measurements were taken by a specialist gastrointestinal consultant radiologist who was a core member of the multidisciplinary team. Patients routinely received bowel preparation preoperatively for decompression of the bowel to facilitate manipulation and closure.

Surgical technique

All abdominal wall reconstructions employed retro rectus mesh implantation using the Rives-Stoppa repair technique. In brief, the Rives-Stoppa repair involved incision in the posterior rectus sheath with extension of dissection to the linea semilunaris and re-approximation of the posterior rectus sheath to allow mesh placement in the retrorectus space [10]. Dissection of the fascial defect included a laparotomy with additional procedures undertaken where indicated. Myo-fascial release was performed as deemed necessary to permit tension-free fascial closure. A component separation was defined as incision in one of the lateral abdominal wall muscles (transversus abdominis or external oblique muscle). An anterior component separation was performed when external oblique muscle was released. A posterior component separation was defined as incisions in both the posterior rectus sheath and the transversus abdominis muscle. In all cases, PGA:TMC Gore® Bio-A® Tissue Reinforcement mesh (W. L. Gore & Associates, Inc., Arizona, USA) was placed in the retrorectus position without suture fixation. Posterior and anterior sheaths were closed with a continuous 2.0 PDS (Ethicon, New Jersey) suture. Two drains were usually placed in the subcutaneous fat layer anterior to the anterior sheath and removed postoperatively when drainage reached a threshold of ≤30 ml/day.

Follow-up

Patients remained in hospital until they were ambulatory and their diet intake and bowel functions were satisfactory. Patients were followed up in the clinic for the first 3–6 months and thereafter only if there were any clinical concerns. A subsequent telephone follow-up was conducted for patient-reported outcome in the medium term.

Outcomes

Data on baseline and outcome variables were collected, including patient demographics, comorbidities, hernia characteristics, postoperative complications and quality of life (QoL).

The primary outcome was the rate of hernia recurrence, determined by physical examination at the last clinical follow up, and from patient-reported outcome by telephone follow-up to record any late recurrences. A reported lump, pain, tenderness or reappearance of a hernia were all investigated with an abdominal CT scan to establish the presence or absence of recurrence. The secondary outcomes included incidence of wound events. Wound events were classified as surgical site infection (SSI) based on Centers for Disease Control (CDC) criteria into superficial, deep, or organ space infection [11]. Surgical site occurrences (SSO) were defined in accordance with the Ventral Hernia Working Group (VHWG) definitions [12, 13].

The quality of life was assessed retrospectively using the Short Form-12 (SF-12) instrument. Mean differences in the reported scores were compared.

Statistical analysis

Statistical analysis was undertaken using SPSS version 17.0 for Windows (Chicago, Illinois, USA). Descriptive statistics were used to summarise all variables and presented as median (range) for continuous variables and frequency (percent) for categorical variables. Pre- and postoperative SF-12 component summary scores were compared using a paired sample t-test. The significance level was set at $p < 0.05$.

Results

A total of 56 eligible patients, with the median age 63 years (range 25–84), underwent abdominal wall reconstruction using biosynthetic mesh over the study period. Of those, 55% (n = 31) were females. The median body mass index was 29 kg/m^2 (range19–37). A quarter (n = 14) of the patients had a recurrent ventral hernia. Some 30% had previous abdominal wall infections and another 24% were diabetic. The patient demographics and baseline characteristics are presented in table 1.

The majority of patients (n = 48, 85.7%) were classified as high-risk for postoperative complications as per the modified VHWG classification system (VHWG grade 2 and 3). Moreover, approximately a quarter (n = 13, 23.2%) had clean-contaminated or contaminated wounds (CDC class II and III). The median size and width of hernia defects were 83 cm^2 (range 22–442) and 8cm (range 4–32), respectively. The wound and hernia characteristics are outlined in table 2.

All repairs were performed in a Rives-Stoppa fashion with retrorectus mesh placement. Twenty-two (39%) patients required an element of component separation to achieve tension-free myo-fascial closure (table 3).

Hernia recurrence

Overall hernia recurrence found by clinical examination was 3.6% (n = 2) at median follow-up of 6 months (range 4–17). No additional hernia recurrence was identified following a median telephone follow-up of 21 months (range 4–54) in 34 patients. No further presentations with hernia repair-related complications were identified following review of medical records in the remaining patients not available for telephone follow up (n = 22). Of the two hernia recurrences, times to recurrence were 6 and 11 months, respectively.

The first of these recurrences occurred in a 54-year-old male, VHWG grade 1, CDC class I wound, who had a previous laparoscopy converted to open right hemicolectomy for caecal carcinoma. At the time of abdominal wall reconstruction the patient underwent bilateral anterior release to achieve closure and, other than developing a seroma postoperatively, this patient had initially made an uncomplicated recovery.

The second hernia recurrence was in a 66-year-old male with multiple co-morbidities. He had three parastomal procedures previously and a staphylococcal-infected parastomal mesh in situ. His primary surgery was pan-proctocolectomy for Crohn's disease. With a VHWG grade 3, CDC class III wound, this patient underwent abdominal wall reconstruction, excision of infected mesh, re-siting of the stoma and apronectomy. He had bilateral posterior component separation and postoperatively developed a deep wound infection, which drained spontaneously through a superficial wound dehiscence. This patient developed a recurrent hernia at the site of the previous stoma.

Secondary outcomes

The postoperative wound events are presented in table 4. The incidence of SSI was 26.8% (n = 15), of which six

Table 1: Patient characteristics (n = 56).

Characteristic	n (%)
Age (years)*	63 (25–84)
Gender	
– Female	31 (55.4)
– Male	25 (44.6)
ASA grade	
– I	3 (5.4)
– II	36 (64.3)
– III	16 (28.6)
– IV	1 (1.8)
Body mass index (kg/m^2)*	29 (19–37)
Obesity (body mass index ≥30 kg/m^2)	22 (39.3)
Recurrent hernia	14 (25)
Previous abdominal wall infection	17 (30.4)
Inflammatory bowel disease	6 (10.7)
Active smoking	13 (23.2)
Diabetes mellitus	14 (25)
Chronic obstructive pulmonary disease	10 (17.9)

ASA = American Society of Anaesthesiologists * Median (range)

Table 2: Wound and hernia characteristics (n = 56).

Characteristic	n (%)
VHWG grade	
Grade 1	8 (14.3)
Grade 2	28 (50)
Grade 3	20 (35.7)
CDC wound classification	
Clean (class I)	43 (76.8)
Clean-contaminated (class II)	12 (21.4)
Contaminated (class III)	1 (1.8)
Reasons for contamination	
Presence of stoma	9 (16.1)
Bowel resection	0 (0)
Infected mesh removal	2 (3.6)
Repair of gastrointestinal fistula	2 (3.6)
Non-healing abdominal wound	0 (0)
Stoma reversal	3 (5.4)
Parastomal hernia repair	4 (7.1)
Urology or gynaecology procedure	1 (1.8)
Cholecystectomy	2 (3.6)
Other	3 (5.4)
Hernia defect characteristics	
Defect size (cm^2)*	83 (22–442)
Defect width (cm)*	8 (4–32)
Defect length (cm)*	10 (–23)
Hernia complexity criteria	
Minor	14 (25)
Moderate	30 (54)
Major	12 (21)

CDC = Centers for Disease Control; VHWG = Ventral Hernia Working Group * Median (range)

Table 3: Operative characteristics (n = 56).

Characteristic	n (%)
Component separation	
Posterior and anterior	3 (5.4)
Posterior	15 (26.7)
Anterior	4 (7.2)
No component separation	34 (60.7)
Placement of mesh	
Retrorectus location	56 (100)
Days to drain removal*	14 (2–78)

* Median (range)

were superficial and nine were deep infections. No organ space infections were reported. There were no mesh infections requiring mesh removal in this series. The most common SSO postoperatively was seroma formation, occurring in 32.1% (n = 18) of cases. Median time to removal of the last drain was 14 days (range 2–78). All patients with SSI had underlying risk factors, which are shown in table 5. All the patients developing an SSI (n = 15, 26.8%) were in either grade 2 or grade 3 VHWG category. No surgical site infections were recorded in grade 1 VHWG patients. Superficial wound dehiscence was observed in seven patients, all with multiple underlying high risk features to include VHWG grade 2 or 3 (n = 7), chronic obstructive pulmonary disease (COPD) (n = 5), abdominal wall infection (n = 3), obesity (n = 2), and diabetes. All of these patients were treated conservatively, with one patient requiring vacuum-assisted closure.

Median hospital stay was 7 days (range 3–63). Hospital stay was greater than 30 days in three patients. Most SSO were managed with conservative measures. Three patients required interventions, which included percutaneous drainage of large superficial seroma, evacuation of a large superficial haematoma and vacuum-assisted closure therapy for methicillin-resistant *Staphylococcus aureus* (MRSA) wound infection and superficial dehiscence, respectively.

Table 4: Postoperative wound events (n = 56).

Event	n (%)
Surgical site occurrence	
Surgical site infection	15 (26.8)
Seroma	18 (32.1)
Fistula	0 (0)
Bowel obstruction	0 (0)
Wound dehiscence	7 (12.5)
Haematoma	5 (8.9)
Surgical site infection	
Superficial incisional infections	6 (10.7)
Deep incisional infections	9 (16.1)
Organ space infections	0 (0)
Hernia recurrence	2 (3.6)

Table 5: Risk factors associated with surgical site infections (n = 15).

	n (%)
VHWG grade	
Grade 1	0 (0)
Grade 2	6 (40)
Grade 3	9 (60)
Risk factors	
Abdominal wall infection	5 (33.3)
Diabetes	6 (40)
Smoking	1 (6.6)
Obesity	7 (46.7)
Chronic obstructive pulmonary disease	6 (40)
Inflammatory bowel disease	3 (20)
Other concurrent procedures (CDC class II or III)	6 (40)

CDC = Centers for Disease Control; VHWG = Ventral Hernia Working Group

Quality of life

Significant improvements were observed in both the physical and mental component summary scores of the SF-12 quality of life instrument in the 34 patients who participated in the assessment from the baseline score of 36.1 to 42.3 in physical score and 40.8 to 49.4 in mental score (table 6).

Discussion

The biosynthetic meshes have been deemed a potential cost-effective alternative to conventional approaches for complex ventral hernia repair. Traditionally, the hernia repair in contaminated fields using biological mesh was considered the automatic choice to avoid the use of a permanent synthetic material. However, there are continuing concerns over the outcomes and complications related to the use of biological meshes [14, 15]. Systematic reviews and expert consensus have not found clear benefit to recommend routine use of the biological and biosynthetic meshes [16]. Biosynthetic meshes are in their relative infancy and not much is known about their efficacy and efficiency. Earliest small series have reported wide-ranging clinical outcomes, with incidences of hernia recurrence and SSO ranging from 0 to 15% and 0 to 28%, respectively [17–19]. Such variability is the direct result of early experience and inconsistent mesh implantation approaches in low power, small studies. This retrospective study adds to the body of evidence from larger studies that has started to accumulate more recently [20, 21].

The observed incidence of clinical and patient reported hernia recurrence in this study compares favourably with the two recent large studies that report outcomes related to the use of biosynthetic mesh in abdominal wall reconstruction. The Complex Open Bioabsorbable Reconstruction of the Abdominal Wall (COBRA) study was a prospective, multicentre study that evaluated the use of PGA:TMC biosynthetic mesh for reinforcement of midline fascial closure in complex ventral hernias within contaminated or clean-contaminated surgical fields [20]. At 2-year follow up, recurrence rates of 17%, reduced to 13% with mesh in the retrorectus position, were reported [20]. The observed difference in recurrence in our study, compared with COBRA study, is explained by shorter follow-up and the smaller proportion of CDC class II and III patients. More recently, a multicentre study of 169 patients reported a recurrence rate of 3.2% with the use of a biosynthetic mesh in combination with a synthetic mesh in a retromuscular position [21]. Although the study found comparable recurrence rates, there were fewer high-risk patients and a combination mesh approach was adopted. However, it is also worth noting from these studies that retrorectus mesh placement appears to provide the best outcome, and such an approach was followed as standard in the current study.

Table 6: Mean Short Form-12 quality of life outcomes (n = 34).

.	Baseline	Postoperative	p-value
SF-12 Physical	36.1	42.3	<0.001
SF-12 Mental	40.8	49.4	<0.001

The incidence of surgical site infection in the current study (26.3%) was higher than the best available data from COBRA study (18%) and the study by García-Ureña and colleagues (12%) [20, 21]. These differences, however, may be attributable to the higher number of recurrent and high-risk repairs undertaken in the current study. All patients had complex ventral incisional hernias. In addition, the included patients represented a predominantly high-risk group for development of SSI (86% VHWG grade 2 or 3). Therefore the SSI rate in this study of 25.8% is a realistic and expected clinical outcome. Insertion of biosynthetic mesh ensured that none of these patients required mesh explantation, which carries serious morbidity. Therefore the biosynthetic mesh offered a safe strategy for abdominal wall reconstruction in this group of patients. Moreover, additional procedures performed at the time of abdominal wall reconstruction or pre-existing high-risk conditions for contamination (table 2) meant that the higher incidence of SSI was an expected observation. All patients with SSI were treated conservatively. However, one patient with SSI developed hernia recurrence; in this case abdominal wall reconstruction was undertaken in CDC class III contaminated field and high-risk grade 3 VHWG class for recurrence.

The current study highlights the predicted accuracy of surgical site infection as predicted by the VHWG classification. The majority of patients in this cohort (n = 48, 85.7%) were classified as high risk for postoperative complications (VHWG grade 2 and 3). Grade 2 patients included those with comorbidities and previous wound infections, whereas grade 3 patients were stratified based on CDC definitions of wound contamination. As depicted in our results, all the patients developing an SSI (n = 15, 26.8%) were either grade 2 or grade 3. Therefore the modified VHWG grading system was very accurately associated with development of SSI. However, it is reassuring to note that none of the grade 1 patients developed an SSI and only 15 out of 48 patients (31.2%) who were predicted to be high risk for SSI developed an SSI.

Of the other surgical site occurrences, wound dehiscence and seroma formation were the most notable outcomes. All seven patients with wound dehiscence had underlying multiple high risk factors, of which obesity and COPD were clearly standout co-morbidities. The role of these conditions has been well established and these, alongside other risk factors (table 1), should be subjected to rigorous preoperative optimisation to reduce the risk of SSO [12]. Historically, seroma formation remains one of the commonest surgical site occurrences following ventral hernia repair involving meshes [22, 23]. Arguably, biological meshes are reported to carry a higher incidence of this event [15, 24, 25]. Development of a clinically significant seroma often prolongs hospital stay, leads to readmission and, in some cases, needs intervention to drain the seroma. In the current study, seroma occurred in a significantly high proportion (32.1%) of patients; however, only one patient required intervention with percutaneous drainage. These data remain similar to those associated with biological meshes [15, 24]. These observations are important to note since our data indicate a similar incidence of seroma formation compared with biological meshes and may not offer any advantage over a biological prosthesis in this respect. Future studies should endeavour to investigate this further.

We used the SF-12 instrument to investigate patients' quality of life following the abdominal wall reconstruction. The quality of life analyses suggest that the patients experienced better health and wellbeing. A significant improvement in both the mental and physical component summaries was reported. Plymale et al. observed improved quality of life based on the SF-12 survey in their study of 31 patients with complex ventral hernia repair [19]. The observed changes in quality of life were commensurate with hernia repair outcomes, as noted previously [26, 27]. However, it is also important to note that the observed difference in quality of life in our study may be the outcome of the surgical technique of Rives-Stoppa repair with a contribution from biosynthetic mesh insertion.

There are certain limitations that should be considered whilst interpreting the results of this study. It was a retrospective review and, whereas efforts were made to extract data to ensure entirety and accuracy, limitations in the use of standard definitions and their applicability should be appreciated. In particular, the clinical follow up was relatively short compared with previous published studies. This limitation was partially offset by both the telephone follow up and review of medical records for any delayed outcome. Any patients with concerning symptoms at telephone follow up were invited for clinical examination and CT scan assessment. We suggest that readers appreciate these limitations whilst interpreting the results, although, reassuringly, no further recurrences were diagnosed after telephone follow up was completed. It is also clinically relevant to note that the absorption of Gore Bio-A mesh is complete by 6 months after its implantation and as such the repair has no reliance on mesh beyond this stage. The authors would suggest due consideration is paid to these limitations; nevertheless, these data add value to the small body of evidence in use of biosynthetic meshes whilst we await larger prospective studies with longer follow up.

Conclusion

This retrospective study reports one of the larger single centre series of biosynthetic mesh use in complex ventral hernia repair. A consistent approach of stratification of complex ventral hernia characteristics for contamination, surgical site infection and complexity of defects, along with the consistent mesh implantation technique, add much needed value to this dataset [16]. The observed clinical and patient-reported outcomes suggest biosynthetic absorbable mesh may provide a clinically effective solution in these patients albeit with similar complications profile to that of biological mesh. Nevertheless, controlled data from larger randomised studies are needed to confirm these findings in order to benchmark best practice in this group of patients.

Disclosure statement

No financial support and no potential conflict of interest relevant to this article were reported.

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