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ORIGINAL ARTICLE

The use of an acellular porcine dermal collagen implant in the repair of complex abdominal wall defects: a European multicentre retrospective study

P. Giordano[1] · R. D. Pullan[2] · B. Ystgaard[3] · F. Gossetti[4] · M. Bradburn[5] · A. J. McKinley[6] · N. J. Smart[7] · I. R. Daniels[7]

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Abstract
Background The use of biological materials for the repair of complex abdominal wall defects has increased over the years; however, the role of these materials in routine practice remains unclear. The aim of the study was to evaluate clinical outcomes following the use of Permacol™ porcine collagen surgical implant in complex abdominal wall repair.
Methods This subset analysis of seven European sites from a multicentre retrospective study included patients undergoing open or laparoscopic surgery and treated with Permacol™ surgical implant. Inguinal, parastomal, diaphragmatic, perineal, and hiatal repairs were excluded. Only patients with at least 12 months of follow-up after surgery were included.
Results A total of 109 patients (56 males and 53 females) were included. Patients had a median of two comorbidities (range 0–6). Thirty-three per cent of patients were treated for recurrent hernia. All but one case used an open approach. Sixty-six per cent were Center for Disease Control wound class II–IV at the time of surgery. Fascial closure was achieved in 69%. Median follow-up length was 720 days (range 368–2857). Recurrence rates at 1 and 2 years were 9.2 and 18.3 %, respectively, and were higher in cases without fascial closure. One-year recurrence was higher following use of an onlay technique ($P = 0.025$). In a multivariate analysis, among 16 comorbidities examined only fascial closure significantly impacted 1-year recurrence ($P = 0.049$).
Conclusions Data from this large retrospective multicentre European study strongly suggest the use of Permacol™ porcine collagen surgical implant to be safe and effective for complex abdominal wall repair. The recurrence rate was impacted by fascial closure.

Keywords Ventral hernia · Recurrence · Surgical mesh · Abdominal wall · Biocompatible materials · Porcine collagen · Incisional

Clinical Trial Registration Number: NCT01214252 (http://www.clinicaltrials.gov).

✉ P. Giordano
p.giordano@londoncolorectal.org

[1] Barts Health, Whipps Cross University Hospital, Whipps Cross Rd., Leytonstone, London E11 1NR, UK

[2] Torbay Hospital, Torquay, Devon, UK

[3] St. Olavs Hospital, Trondheim, Norway

[4] Umberto I Policlinic, Rome, Italy

[5] Wansbeck Hospital, Ashington, Northumberland, UK

[6] Aberdeen Royal Infirmary, Aberdeen, UK

[7] Royal Devon & Exeter NHS Foundation Trust, Exeter, Devon, UK

Introduction

The term "complex abdominal wall hernia/defect" (CAWD) has been widely used but without a universally accepted definition. Similarly, classification systems for CAWD have been proposed but have not been used extensively [1]. Criteria for defining CAWD have recently been proposed based on size and location of the hernia, contamination and the presence of certain soft tissue conditions, patient history and risk factors/comorbidities, and specific clinical situations [2]. Several factors have been reported to indicate the necessity of special closure techniques, including large defect size, lack of stable skin coverage, recurrence of defect after previous repairs,

infected or exposed mesh, patient who is systemically compromised, compromised local abdominal tissues, and concomitant visceral complications [3]. Consequently, the reconstruction of CAWD, termed a complex abdominal wall repair (CAWR), often poses considerable technical challenges. A wide array of techniques has been described in order to achieve repair, including different forms of abdominal wall component separation (with and without prosthetic support), progressive preoperative pneumoperitoneum, and reductive bowel resection [4–10].

The resulting heterogeneity in CAWD definition, surgical approaches, and prostheses used within the surgical literature has limited meaningful comparisons between techniques and materials used for reconstruction. The use of biological materials for CAWR, either on their own or in combination with other techniques, has progressively increased over the years [11, 12]. Biological materials may have the potential advantage of facilitating the repair while reducing morbidity. The wide range of biological materials used for this purpose and the scarcity of available clinical data, often reported with variable and conflicting outcomes, have not helped to clarify a definitive role for these materials [11, 12]. In view of the uncertain clinical outcomes and expense of the material compared to standard synthetic prostheses, recent editorials have suggested a moratorium on the use of biological materials in CAWR until further evidence is available [13, 14].

The aim of this study was to evaluate clinical outcomes associated with the use of acellular porcine dermal collagen (Permacol™ surgical implant; Covidien, Mansfield, MA, USA) in CAWR for at least 12 months [15–17].

Materials and methods

This was the European subset analysis from a multicentre retrospective study of patients treated with Permacol™ surgical implant in CAWR [18]. Seven European centres with established practices in CAWR and use of biological mesh participated. Each centre received local ethics committee approval for the study. Written informed consent was obtained for patients receiving study-specific follow-up visits. Clinical notes of all patients operated on for ventral or incisional abdominal wall repair were reviewed, and data of all patients meeting the inclusion criteria were retrieved and entered in a specifically designed online database. Quality of data entered was externally monitored. Inclusion and exclusion criteria are listed (Table 1). Patients meeting the eligibility criteria, preoperative data, and procedural data were retrieved. Postoperative data, including complications and evidence of hernia recurrence, were collected. Data quality was externally monitored.

For the purposes of this study, a CAWD was defined as infected, contaminated, clean contaminated, or clean with a history of infected or contaminated field, atypical hernia location, loss of domain, fascial dehiscence, and/or requiring abdominal wall mobilization for wound closure.

Data collection

Preoperative data collection included demographic information, associated risk factors, prior abdominal wall surgery history, previous medical history, history of prior mesh infections, or other superficial or deep surgical site infections. Procedural data collection included the indication for surgery, surgical approach (open or laparoscopic), duration of operation, American Society of Anaesthesiologists (ASA) classification, size of defect and mesh, implantation method with surgical technique, fixation method, wound classification, and intraoperative complications. Postoperative data included any type of documented complication or adverse event, management of complications, and evidence of hernia recurrence.

Outcome measures

The primary outcome measure was hernia recurrence, as defined by clinical assessment. A review of medical records with documentation of abdominal examination fulfilled the criteria of either "no hernia" or "hernia recurrence". For patients without a confirmed diagnosis based on a review of the medical records or if the medical records were not dated 12 months after surgery, further clinical assessment was arranged. If no recurrence was demonstrated on clinical examination, the patient was deemed to meet the criteria of "no hernia".

Statistical analysis

Statistical analysis was performed using SAS version 9.2. Qualitative variables are described by the absolute and relative (%) frequency of each class or value and by 95 % confidence interval (CI). Quantitative variables are described by their mean and standard deviation. *P* values from the Chi-square test (or Fisher's exact test) are presented for categorical variables; *P* values from the *t* test (or Mann–Whitney test) are presented for continuous variables. In addition, a time-to-event analysis (using Kaplan–Meier estimates and Cox regressions) was performed to summarize the hernia recurrence data through 12 and 24 months, including both confirmed and unconfirmed recurrences. The date of event was the date of the visit during which the hernia recurrence was diagnosed. Subjects who did not have hernia recurrence within 12 or 24 months were censored at either 365 or 730 days

Table 1 Inclusion and exclusion criteria

Inclusion criteria	Exclusion criteria
Use of Permacol™ surgical implant for repair or reconstruction of abdominal wall defects, ventral hernias or incisional hernias	Repair without Permacol™ surgical implant
Minimum of 12-month follow-up	Repair of inguinal, parastomal, diaphragmatic, perineal or hiatal-type hernias
Emergency or elective surgery	Permacol™ surgical implant used as temporary means to manage laparotomy wounds
Open or laparoscopic approach	Concomitant malignancy
18 years or older	Any prior use of Permacol™ surgical implant in abdominal wall repair

postsurgery if they had a length of follow-up greater than 365 or 730 days; otherwise, censoring occurred at the time of latest information.

Results

A total of 109 patients from the seven European centres met the inclusion criteria and were entered in the database. Median age was 64 years (34–91) with 56 male patients (51.4 %). Patients had a median of 2 (0–6) comorbidities (Table 2) and a median body mass index (BMI) of 29.6 (17.6–55.2) with 41 (37.6 %) patients of BMI $\geq$ 30. Thirty-six (33.0 %) patients had undergone at least one previous abdominal wall hernia repair (range 1–5) and ten (9.2 %) had at the time of surgery an infected mesh from previous repair. Ninety-eight (89.9 %) cases were elective, of which 32 (32.7 %) were operated on for a recurrence.

Table 2 Comorbidities, patient history, and risk factors

Comorbidities/risk factors	$N = 109$
Diabetes	18 (16.5 %)
Obesity (BMI $\geq$ 30 kg/m^2)	41 (37.6 %)
Steroids use	10 (9.2 %)
Smoking	23 (21.1 %)
COPD	17 (15.6 %)
Previous malignancy	35 (32.1 %)
History of IBD	12 (11.0 %)
ASA grade	
1	9 (8.3 %)
2	62 (56.9 %)
3	36 (33 %)
4	2 (1.8 %)
CDC wound classification	
Class I	37 (33.9 %)
Class II	43 (39.4 %)
Class III	21 (19.3 %)
Class IV	8 (7.3 %)

BMI body mass index, *COPD* chronic obstructive pulmonary disease, *IBD* inflammatory bowel disease, *ASA* American Society of Anaesthesiologists, CDC Center for Disease Control

All except one of the procedures were carried out as an open approach. In the one case, the procedure consisted of a laparoscopic repair converted to an open operation as the patient had two previously failed mesh repairs, and the operation was converted to allow the excision of a synthetic mesh and the resection of a segment of small bowel fused with the mesh. One hundred patients were ASA class 2–4 (91.7 %; Table 2). A total of 72 (66.1 %) patients were Center for Disease Control (CDC) wound classification II–IV at the time of surgery, with 8 (7.3 %) patients having an infected mesh from previous repair in place (Table 2). It was not possible to assess accurately the median defect size retrospectively, which was not always reported in the operation notes. The median implant size used was 300 cm^2 (range 25–3168 cm^2). The most common method of implantation was underlay (sub-fascial, intraperitoneal) with 43 patients (39.4 %), followed by onlay (supra-fascial) with 30 patients (27.5 %), and sublay (retromuscular, extra-peritoneal) with 24 patients (22.0 %). An inlay technique (no overlap) was used only in 12 (11.0 %) patients. In 26 patients, the repair was associated with component separation of the external oblique aponeurosis as described by Ramirez [19]. Fascial closure was achieved in 74 (69.2 %) cases.

Sixty-six postoperative events were reported with wound infection and seroma formation being the two most common events (Table 3). Median follow-up length was 720 days (range 368–2857).

At 1 year, 10 recurrences were identified for an overall recurrence rate of 9.2 %. At 2 years, 20 recurrences were identified (18.3 %) (Table 4). The recurrence rate was affected by fascial closure. In the 10 patients with hernia recurrence in the first year, fascial closure was achieved in four cases; thus, the recurrence rate was 5.4 % (4/74) in

Table 3 Postoperative morbidity

Postoperative morbidity	$N = 109$ patients
Wound infection	15 (13.8 %)
Seroma formation	18 (16.5 %)
Haematoma	7 (6.4 %)
Chest complications	5 (4.6 %)
Fistula	3 (2.8 %)
Abdominal wall sinus	9 (8.3 %)
Mesh tearing	2 (1.8 %)
Poor cosmesis	2 (1.8 %)
Other	5 (4.6 %)
Total complications	66

patients with fascial closure and 18.2 % (6/33) in the group where fascial closure was not achieved $P = 0.066$ (2 patients with missing data). Similarly, of the 20 patients with hernia recurrence up to 2-year follow-up, recurrence rates were 17.6 % (13/74) with fascial closure and 21.2 % (7/33) without fascial closure ($P = 0.65$; Chi-square test). The type of wound and/or concomitant infection at the time of surgery did not impact the recurrence rate (Table 4). Postoperative morbidity did not influence recurrence rate: wound infection and seroma were associated with recurrence only in two patients, including one case with mild seroma and one case with moderate wound infection. The 12-month recurrence rate was higher (6/30) when an onlay technique was used compared to the other techniques $P = 0.025$ (Fisher's exact test) (Table 5).

A multivariate analysis was performed to identify those comorbidities that may have had a significant impact on the 12- and 24-month recurrence rates (Table 6). Only fascial closure significantly impacted the recurrence rate at 12 months ($P = 0.049$). At 24 months, there were no comorbidities significantly impacting the recurrence rate.

Discussion

The use of biological materials has been advocated for CAWR when conventional synthetic materials may be contraindicated or considered at high risk of complications [6, 7, 12, 20, 21]. These patients often present with extremely large and complex abdominal wall defects, normally as a consequence of a previous "abdominal catastrophe". In many cases, the abdominal contents protrude permanently through the defect and are contained within the hernia sac outside the abdominal cavity. Patients may also have an associated stoma and/or bowel fistula. Some patients may have previously been operated on with synthetic mesh and suffered from wound infections and/or mesh-related complications. Frequently, patients will present with associated comorbidity and will be at higher risk of postoperative infection. For these reasons, repairing such defects can be extremely challenging and hazardous, making conventional prosthetic materials unsuitable. The use of biological materials in these cases may overcome some problems related to the use of a synthetic mesh; however, the cost of these materials and the lack of convincing supportive clinical data have prevented their widespread use.

The objective of the current study was to evaluate clinical outcomes following use of an acellular porcine dermal collagen surgical implant (Permacol™ surgical implant) in CAWR. Despite the risk of infection and the complexity of the cases, postoperative morbidity was relatively low, with seroma formation (16.5 %) and wound infection (13.8 %) being the most common problems. Three patients (2.8 %) developed a small bowel fistula. The overall recurrence rate was 9.2 % at a median follow-up of 1 year and 18.3 % at 2-year median follow-up. While infection is a common and significant postoperative occurrence that increases the risk of hernia recurrence

Table 4 Recurrence rate according to CDC wound classification and comorbidities

Recurrences within 12 months				Recurrence according to patient comorbidities		
Wound classification	*N*	Overall recurrences	%	No comorbidity	1 comorbidity	≥2 comorbidities
Class I	37	7	18.9	0	1	6
Class II	43	2	4.7	0	1	1
Class III	21	1	4.8	1	0	0
Class IV	8	0	0	0	0	0
Recurrences within 24 months[a]						
Class I	37	10	27.0	0	1	9
Class II	43	8	18.6	1	2	5
Class III	21	2	9.5	1	0	1
Class IV	8	0	0	0	0	0

CDC Center for Disease Control

[a] Median follow-up length was 720 days (range 368–2857 days)

Table 5 Recurrence rate according to technique

Surgical technique	*N*	Recurrences within 12 months	Recurrences within 24 months[a]
Inlay	12	1 (8.3 %)	1 (8.3 %)
Onlay	30	6 (20.0 %)	10 (33.3 %)
Sublay	24	2 (8.3 %)	3 (12.5 %)
Intraperitoneal	43	1 (2.3 %)	6 (14.0 %)
Total	109	10 (9.2 %)	20 (18.3 %)
P value		0.025	0.013

[a] Median follow-up length was 720 days (range 368–2857 days)

Table 6 Multivariate Cox regression between hernia recurrences and comorbidities

Comorbidities	Recurrences within 12 months *P* values (10/109 subjects with recurrence)	Recurrences within 24 months[a] *P* values (20/109 subjects with recurrence)
Diabetes	0.547	0.785
Obesity (BMI $\geq$ 30 kg/m^2)	0.647	0.954
COPD	0.995	0.117
Corticosteroids	0.996	0.994
Smoking	0.783	0.897
Heart disease	0.998	0.997
Hypertension	0.998	0.997
Age $\geq$ 60 years	0.093	0.097
History of cancer	0.087	0.083
Recurrence	0.399	0.959
Fascia closure	0.049	0.725
Wound graduation		
Class II	0.069	0.348
Class III	0.180	0.121
Class IV	0.995	0.992
Postoperative seroma	0.605	0.492
Postoperative wound infection	0.794	0.642

BMI body mass index, *COPD* chronic obstructive pulmonary disease

[a] Median follow-up length was 720 days (range 368–2857 days)

following complex repairs, in our study neither morbidity nor recurrence rate was affected by the type of wound and/or the presence of concomitant infection.

This low rate is compared to other published results. For example, up to nearly one-quarter of ventral hernias repaired with synthetic mesh can recur within three years [22]. However, poor results have been reported in CAWR using Permacol™. Abdelfatah et al. [23] reported a retrospective analysis of 65 complex ventral abdominal wall repairs using Permacol, including 50 % class II–IV patients. In their study, infection requiring mesh removal was reported in 25 % of patients and hernia recurrence was reported in 66 % after a mean follow-up of over 5 years. Cheng et al. [24] examined Permacol™ surgical implant use in 195 patients (50 % reinforcement of a primary fascial repair and 50 % bridging) and reported a complication rate of 39.5 % with mean follow-up of 2.1 years, the most common complications being infection (13 %) and recurrence (12 %). Zerbib et al. [25] reported an analysis of a non-crosslinked, porcine extracellular dermal matrix (Strattice™, LifeCell Corporation) implanted in 14 CDC class IV patients with 13 months of follow-up; recurrence was observed in 43 % of patients, and two patients experienced wound infection. Therefore, outcomes following CAWR with biological mesh can vary widely and are influenced by patient, surgical technique, and material factors.

Patient factors, such as comorbidity, risk of infection, and prior repairs, have been shown to impact outcomes. In 2010, the Ventral Hernia Working Group (VHWG) reviewed the available evidence and produced recommendations on the use of biological materials [26]. The VHWG also proposed a surgical site occurrence (SSO) risk grading system as an instrument to help surgeons stratify patients' risk of developing postoperative complications. Their conclusions were that biological materials should be

considered every time there is a potential risk of SSO (grade 2–3) and should be the preferred option when the risk of SSO is significant (grade 4) [26]. In our study, while 98.2 % of the patients were of VHWG grade 2–4, postoperative complications did not influence the incidence of recurrence. This suggests that while a hostile environment like a contaminated or infected field increases the risk of SSO making the use of synthetic material contraindicated, it did not affect the performance of the Permacol™ surgical implant in this study. The number of comorbidities, while not a significant predictor of recurrence in the multivariate analysis, had a negative impact on outcomes, particularly in class I patients. Of the seven class I patients with recurrence to 1 year, six were patients with two or more comorbidities. As previously reported, we found a relationship between previous repair and increased chance of failure. In a comparable retrospective cohort study, the 5-year rate of reoperation was 24 % after the first reoperation, 35 % after the second, and 39 % after the third; the 7-year rate after three reoperations approached 50 % [27]. Forty-two per cent of the patients in our study had undergone at least one previous repair.

Surgical technique also varies across studies. The use of bridging strategies has been associated with increased recurrence rates. In the current study, fascial closure was achieved in 70 % of patients. Among 16 comorbidities examined in a multivariate analysis, only fascial closure was a significant predictor of the 1-year recurrence risk, and recurrence rates were higher when fascial closure was not achieved (5.4 % with fascial closure and 18.2 % without fascial closure at 1 year). Similarly to the Abdelfatah et al. [23] study, recurrence rates were 20 % and 53 %, respectively, when Permacol™ was used as a reinforcement of a primary fascial closure by onlay or intraperitoneal sublay techniques. However, when used to bridge a fascial defect, the hernia recurrence rates were greater than 80 %. Such results are not limited to Permacol™. In the RICH study assessing the outcome of infected or contaminated ventral hernia repair using Strattice™ porcine dermal matrix, the overall recurrence rate at 24 months was 28 % [21]. However, in patients who had a fascia-to-fascia closure with or without component separation, the recurrence rate was 23 %, while in patients in whom fascial closure was not obtained the recurrence rate was significantly higher (44 %) [21]. In another study with Strattice™ porcine dermal matrix used as a bridging mesh, recurrence was reported in 8/9 (88.9 %) patients [28]. In a study comparing fascial bridging versus fascial reinforcement repair using a human acellular dermal matrix in CAWR, the recurrence rate was 80 % when used as a bridge [29]. Therefore, approximation of the fascia over the implant is strongly recommended.

Conclusions

We acknowledge that the retrospective nature of this very large multicentre study may necessitate a number of potential limitations; however, our data strongly suggest that the use of Permacol™ for CAWR is safe and effective. Furthermore, fascial closure impacts the recurrence rate, reinforcing the importance of closure technique. A prospective observational study is currently underway to further investigate the clinical outcomes for the use of Permacol™ surgical implant in this selected group of highly challenging patients.

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Conflict of interest P.G. declares conflict of interest directly related to the submitted work (Consultancy fees; Covidien); R.D.P. declares conflict of interest directly related to the submitted work (board consultancy and administrative fees; Covidien; paid to R.D.P.'s institution) and conflict of interest not directly related to the submitted work (teaching/lecture honoraria and travel expenses; Covidien); B.Y. declares conflict of interest not directly related to the submitted work (lecture fees; Covidien); F.G. declares conflict of interest directly related to the submitted work (committee participation fees; Covidien; paid to F.G.'s institution); M.B. declares conflict of interest directly related to the submitted work (administrative and data entry fees; Covidien; paid to M.B.'s institution); A.M. declares conflict of interest directly related to the submitted work (administrative and data entry fees; Covidien; paid to A.M.'s institution) and conflict of interest not directly related to the submitted work (travel expenses; Covidien); N.J.S. declares conflict of interest not directly related to the submitted work (teaching/lecture honoraria and travel expenses; Covidien); I.D. declares conflict of interest directly related to the submitted work (board consultancy and administrative fees; Covidien; paid to I.D.'s institution) and conflict of interest not directly related to the submitted work (teaching/lecture honoraria and travel expenses; Covidien).

Ethical approval This study was conducted in accordance with the declaration of Helsinki and all national and local regulations were adhered to.

Informed consent Informed consent was obtained from all individual participants included in the study.

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