



Recurrent intestinal fistulation after porcine acellular dermal matrix reinforcement in enteric fistula takedown and simultaneous abdominal wall reconstruction

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Abstract

Purpose Porcine acellular dermal matrix (PADM) has been promoted as a suitable material for the reinforcement of the abdominal wall in Ventral Hernia Working Group (VHWG) Grade 3/4 wounds by Ventral Hernia Working Group et al. (Surgery 148(3):544–548). We describe our experience of, and assess the mechanisms for the failure of PADM (Permacol™) in intestinal and abdominal wall reconstruction (AWR) for enterocutaneous fistulation (ECF).

Methods All patients referred to our unit who had PADM used for AWR and ECF were studied from a prospectively maintained database. Follow-up data until 31/12/2018 were analysed. PADM was explanted at further surgery and examined histologically.

Results 13 patients, (median age-58.5 years) underwent AWR with PADM reinforcement. Twelve of these (92%) patients had developed abdominal wall defects (AWD) and ECF following complications of previous surgery. Six patients underwent fistula takedown and AWR with PADM, of which 5(83%) refistulated. Seven patients referred to us had already undergone similar procedures in their referring hospitals and had also refistulated. Median (range) time to fistulation after AWR with PADM was 17 (7–240) days. In all cases, PADM had been used to bridge the defect and placed in direct contact with bowel. At reconstructive surgery for refistulation, PADM was inseparable from multiple segments of small intestine, necessitating extensive bowel resection. Histological examination confirmed that the PADM almost completely integrated with the seromuscular layer of the small intestine.

Conclusion PADM may become inseparable from serosa of the human small intestinal serosa when it is left in the abdomen during reconstructive surgery. This technique is associated with recurrent intestinal fistulation and intestinal failure and should be avoided if at all possible.

Keywords Porcine acellular dermis · Permacol™ · Enterocutaneous fistulation · Open abdomen

Introduction

Definitive surgical repair of large abdominal wall defects presents a significant challenge when combined with enterocutaneous fistula takedown [1]. The presence of a contaminated or dirty wound is associated with a 20–70% risk of surgical site infection (SSI) [2–4] following abdominal wall repair, and increases the risk of hernia recurrence by

up to 25% [5]. The combination of contamination or frank infection and an abdominal wall defect continues to present a significant surgical dilemma. Suture repair alone leads to an unacceptably high risk of hernia recurrence, which can be more than halved by the use of a reinforcing mesh [6–8]. In larger and more complex defects, separation of muscular components without mesh reinforcement is associated with a risk of hernia recurrence approaching 40% [9]. The poor results of abdominal wall reconstruction (AWR) in the absence of reinforcement by a suitable mesh has led to the adoption, for routine use, of a variety of synthetic non-absorbable implants in this setting. These materials are widely available, relatively inexpensive, and have been associated with good results [10]. When the wound is contaminated or frankly dirty however, synthetic non-absorbable

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mesh is usually considered inappropriate because subsequent mesh infection may occur, and if so is usually solved only by mesh removal, with ultimate failure of the repair in up to 75% of cases [10].

The need to reinforce repairs in contaminated or dirty abdominal wall defects has led to the development of a variety of “biologic” implants derived from animal dermis, pericardium or small intestinal submucosa, and these materials have been said to withstand infection [11]. Although randomised controlled trial evidence to support the use of any of these materials is currently lacking, professional guidance favours the use of biologic implant material for ventral hernia repair in dirty or contaminated wounds [2].

While the use of biologic implants has at least provided an alternative to suture repair in dirty or contaminated wounds, the use of such materials in the largest defects has been associated with poor results, especially when it is not possible to approximate native tissues, resulting in “bridging”. The use of a collagen implant to bridge an abdominal wall defect has been associated with a risk of hernia recurrence of between 44 and 88% [11, 12] and appears to be associated with a doubling in complication rates, including increased wound dehiscence and implant exposure, with the hernia recurring considerably sooner than in non-bridged repairs [13, 14].

The use of a collagen implant as a bridge in abdominal wall reconstruction also potentially brings the biological material into direct contact with intestinal serosa. While little is known about this interaction it remains unclear whether these devices can, in all circumstances, be safely left in contact with the bowel. The use of Permacol™ (Medtronic, Minneapolis, MA, USA), a porcine acellular dermal matrix (PADM) implant which has been processed to increase the amount of collagen cross-linking, [15, 16] has been specifically advocated for abdominal wall reconstruction because of durability, biological compatibility and safety. While this material had specifically been said by its manufacturers to be safe for placement within the peritoneal compartment, our previously published experience of the use of this material in this setting, for bridging dirty abdominal wounds after resection of enteroatmospheric fistulas produced extremely poor results, notably doubling the incidence of refistulation when compared with that when absorbable synthetic materials were used [17].

The reasons for the apparent increase in the rate of fistulation when PADM is used in the peritoneal compartment is unclear and, although the interaction between the implanted material and the gut serosa seems likely to be important there have been no human studies which have specifically addressed the relevant pathophysiological mechanisms. To identify clinical and pathological factors common to the development of intestinal fistulas in this setting, we present an analysis of patients referred to our specialised centre who

have developed intestinal fistulas following the use of PADM in this setting including a histological examination of PADM explanted at subsequent reconstructive surgery.

Methods

A retrospective analysis of a prospectively maintained database of patients consecutively referred to our unit between 1st January 2006 and 31st December 2017 was undertaken. Demographics, comorbidity, operative details, and post-operative management and outcome were collected for all patients who had undergone AWR with intestinal reconstruction for enteroatmospheric fistulation (EAF) with intraperitoneal placement of PADM as a reinforcing prosthetic in the abdominal wall repair. Whether the patient had had a fistula prior to the initial surgery, the preoperative underlying diagnosis and the total number of preceding operations were noted.

Operative details including urgency of surgery (elective vs emergency), time of surgery, seniority of the operating surgeon, presence of skin cover at the conclusion of surgery and presence of a stoma were recorded. Postoperative complications including superficial- and deep-wound dehiscence, infection, implant extrusion or disintegration, recurrent incisional hernia, and refistulation were identified for all patients.

Patient follow-up recorded until 31st December 2018 including clinic visits, further surgical procedures for fistulas, nutritional outcome, nutritional autonomy (i.e., continued requirement for home parenteral nutrition (HPN) and mortality were analysed. Data are presented as median (range).

In two cases, the explanted PADM at subsequent surgery was removed with associated fistulating bowel and subjected to histological analysis. Tissues were formalin fixed and paraffin embedded, followed by examination of hematoxylin and eosin-stained tissue sections. Van Gieson’s stain (a mixture of picric acid and acid fuchsin) was used for differential staining of collagen and connective tissue. All histological examination was conducted by an expert histopathologist (SH).

Results

We treated 13 patients (10 male), median (range) age 58.5 (38–86) years who developed enterocutaneous fistulation after abdominal wall reinforcement using PADM. Seven of these 13 patients were referred to us from other hospitals. Table 1 summarises patient demographics, operative and outcome details.

Table 1 Patient details

Age /sex	Primary diagnosis	No. of previous laparotomies	Indication for Permacol™	CDC ³ /VHWG ¹ classification	Post-permacol™ complication
42/m*	Pancreatitis leading to colonic fistula	4	Fistula take down + AWR reinforcement	III/3	Recurrent skin breakdown, recovered
64/f*	Incisional hernia	3	Fistula take down + AWR reinforcement	III/3	Refistulated in 8 months
66/m*	Adenocarcinoma rectum	4	Fistula take down + AWR reinforcement	III/3	Refistulated in 1 month
38/f*	Crohn's disease	2	Crohn's fistula/ urological sepsis + AWR reinforcement	IV/4	Fistulated and extruded
68/f*	Ulcerative colitis	3	Fistula take down + AWR reinforcement	III/3	Refistulated 17 days later
86/m*	Diverticular disease	3	Fistula take down + AWR reinforcement	III/3	Refistulated post-op
77/m	Pseudo-obstruction	2	Dehiscence and Fistula after limited right hemicolectomy	III/3	Fistulated in 3 months
52/m	Ulcerative colitis/ Malignancy	3	Fistula take down + AWR reinforcement	III/3	Refistulated—unknown duration
70/m	Transitional cell cancer bladder—cystoprostatectomy	6	Fistula take down + AWR reinforcement	IV/4	Refistulated 2 weeks
50/m	Adenocarcinoma colon	14	Fistula take down + AWR reinforcement	III/3	Refistulated in 7 days
48/f	Incisional hernia	5	Fistula take down + AWR reinforcement	III/3	Refistulated
53/m	Incisional hernia	7	Infected mesh removal, Fistula take down + AWR reinforcement	IV/4	Refistulated
74/m	Necrotising fasciitis	2	Fistula take down + AWR reinforcement	III/3	Extruded

*Permacol™ used by us

Twelve of the 13 patients (92%) developed recurrent fistulation after intestinal reconstructive surgery for an intestinal fistula in which PADM was left within the peritoneal cavity. The thirteenth patient developed a de novo fistula following treatment of full thickness abdominal wound dehiscence, in which PADM was placed within the peritoneal cavity.

Patients underwent a median (range) of 3 (2–14) laparotomies prior to undergoing AWR with intraperitoneal PADM. One or more consultant surgeons with experience in intestinal fistula surgery performed all operations during daytime hours. During AWR with PADM, four patients sustained serosal tears or enterotomies, which were suture repaired during adhesiolysis. Nine patients had an intestinal anastomosis at the time of AWR. The median width of the fascial defect between opposing rectus abdominis muscles was 172 (108–234) mm when measured by preoperative Computerised Tomography (CT). All surgeons used transfascial non-absorbable sutures to fix the PADM to the abdominal wall defect. It was possible to interpose the omentum between the implant and the viscera in only 3 (23%) patients and in the remainder the bridging material was left in direct contact

with the viscera. Full skin cover over the implanted PADM was possible in 11 (84.6%) patients.

Outcome of initial surgery (n = 13)

Eleven patients (84.6%) developed enteroatmospheric fistulas following intraperitoneal PADM placement. Median time to fistulation in nine of these patients was 15 (7–240) days. It was not possible to determine the time to fistulation in the remaining patients, as these details were not recorded at the referring hospitals. Two of these patients (2/11) had extruded the implant through the wound 5 days and 3 months later, respectively, due to lack of skin coverage. One patient had recurrent skin breakdown secondary to pseudomonas infection, which eventually healed in 6 months. One patient died postoperatively due to severe intra-abdominal sepsis by which time the PADM had been extruded.

Six patients who developed PADM-associated fistulation underwent further AWR and fistula takedown under our care. During reconstructive surgery, implanted PADM material was found adherent both to the abdominal wall

and also the small bowel. It was notable, during dissection, however, that the implant was much more easily separated from the abdominal wall than the bowel, and, when an attempt was made to separate the implant from the bowel, the plane of dissection lay within the wall of the bowel, rather than between the implant and the serosa (Fig. 1). Examination of the PADM/bowel explanted in these procedures (Figs. 2, 3) clearly demonstrated that the PADM had become inseparable from the muscularis propria (MP) of the small bowel, with no plane of dissection even apparent histologically.

Outcome of patients with fistulation after AWR with PADM ($n = 11$)

After a median follow-up of 45 (7–154) months, four patients underwent successful intestinal reconstruction and AWR with Vicryl™ mesh (woven Polyglactin 910) and remain fistula-free. All of these patients required parenteral nutrition (PN) preoperatively, but managed to achieve nutritional autonomy following reconstruction. One patient underwent AWR with a pedicled sub-total lateral thigh flap and has been fistula-free, but left with short bowel syndrome (50 cm of small bowel anastomosed to colon) and dependent on PN. One patient had reconstruction with Vicryl™ mesh but refistulated again 3 months later and has remained on PN. Four patients with fistulas were managed conservatively (low output fistulas and the patients declined further surgery ($n = 2$), unfit to undergo further major reconstructive surgery ($n = 2$)) and one of these patients required PN. One patient (who was on PN) died postoperatively from multiple organ failure.

Under our care, seven patients achieved nutritional autonomy and four patients remain on PN. Of the patients who underwent reconstructive surgery, 5 (71.4%) remain fistula-free and without hernia recurrence.

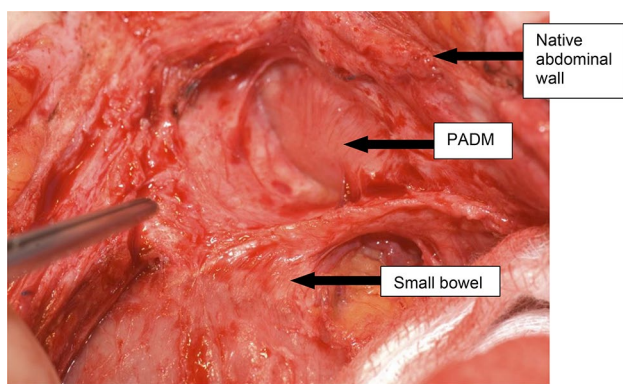


Fig. 1 Intraoperative photo demonstrating adhesions to Permacol™

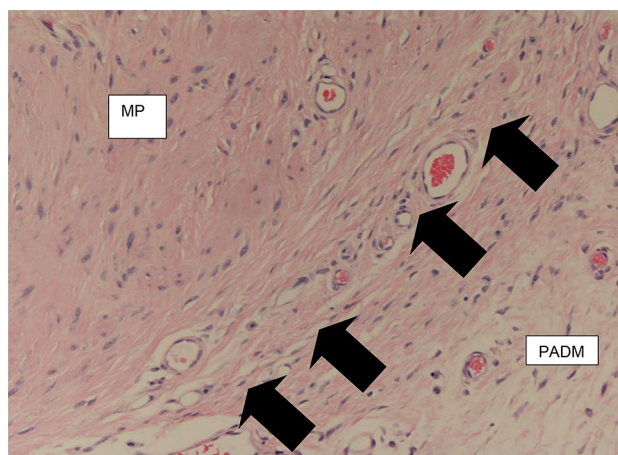


Fig. 2 Permacol™ bound to muscularis propria (MP)/Serosa of small intestine

Discussion

The current study examines outcomes of treatment in patients who underwent combined intestinal reconstruction and AWR using bridging PADM over a 5-year period. These data relate to our experience of the adverse outcomes of this treatment used at our own specialist centre, as well as the management of patients referred from other centres for management of complications of the same technique. The use of PADM in this setting resulted in intestinal fistulation in all 13 patients treated, and did so in the absence of a primary fistulating disease. The only factor common to all cases is that PADM had been used as a bridge and left in direct contact with the viscera.

It is widely accepted that, compared to techniques in which implanted materials are interposed between native

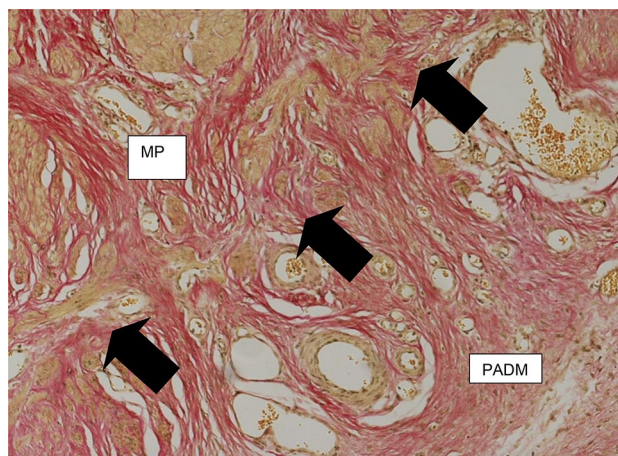


Fig. 3 Permacol™ bound to muscularis propria (MP)/serosa of small intestine

host tissues, simply bridging an abdominal wall defect is associated with a significantly higher risk of complications, and, in particular, hernia recurrence and wound failure [11, 13, 18]. The majority of reported outcomes of using PADM in AWR have tended to focus predominantly on its use in clean or clean-contaminated wounds, in which the results appear broadly comparable with those of synthetic mesh. However, a recent large multicentre audit, in which PADM was used in a single-stage AWR in more heavily contaminated or dirty wounds demonstrated a very high complication and hernia recurrence rate [19, 20]. While the long term efficacy of collagen implants for AWR in patients with VHWG Class 3 or 4 wounds has been questioned [12], it is important that, even if these materials might only serve to act as a temporary measure until contamination has resolved and a definitive repair in a non-contaminated environment can subsequently be undertaken, the use of such materials must at least be safe, and their use should not result in a higher incidence of recurrent or de novo fistulation than suture closure alone or the use of other materials, such as Polyglactin 910.

Acute severe intestinal failure, resulting in an open abdomen with fistulation (enteroatmospheric fistulation) is relatively uncommon, and it is unlikely that even a busy gastrointestinal surgical unit would see more than one or two such cases each year. There are few reliable epidemiological data and it is not possible to know in how frequently PADM might have been used without incident to bridge an open abdominal wound. It is also not possible to know how many cases were complicated, as in the series reported above by complex enteroatmospheric fistulation and intestinal failure but which were not referred to our specialist centre, either because the patient died or because they were treated successfully in their local hospitals. These issues are likely only to be addressed in future by the creation of national or international databases for implantation of prosthetic materials.

The outcome of the use of PADM in our centre, and at least in those patients referred from other centres suggest that it should be used with great caution if at all in this setting and it supports and extends the concerns we have raised previously—of the six patients who underwent elective enteroatmospheric fistula resection and AWR with bridging PADM under our care, 5 (83%) refistulated, with a median (range) time to fistulation of 17 (7–240) days, figures which are considerably worse than the 5.3% rate of recurrent fistulation we have reported previously, when bridging PADM was not employed [17].

The present study provides examples of adverse outcomes of the use of cross-linked biologic implants as a bridge, in contact with the viscera. We found that, despite the assurances from the manufacturer, the material appeared to behave more like a synthetic non-absorbable mesh with encapsulation, rather than complete wound remodelling

[21]. It is unclear whether all biological materials, notably those with lower levels of cross-linking may be safer in this setting. While some studies have suggested that more heavily cross-linked implants are associated with a greater incidence of complications, when compared with less cross-linked implants [22] others have shown unacceptably high complication rates when collagen implants are used to bridge fascial defects, irrespective of the degree of cross-linking [23]. Evidence from animal studies suggests that biological implants induce less inflammation and fewer dense adhesions than synthetic non-absorbable implants [24] and non-cross-linked biological implants are superior to cross-linked implants in this respect [24]. Cross-linking collagen fibres appears to induce an M1 rather than M2 macrophage response [25] and to slow the rate of implant degradation, without increasing adhesion formation [26]. Human data is however, limited, and mainly confined to in vitro studies, none of which reproduces the complex interaction between implant and human peritoneum [27, 28].

It should be noted that re-operation in these cases has been almost uniquely challenging, even by the technical standards of intestinal reconstructive surgery in the open abdomen. In particular, the need to protect bowel from further injury and salvage all available healthy intestine to avoid permanent intestinal failure was made especially difficult, not by the usual hostile adhesions, but by the presence of encapsulated PADM within the abdomen, which was not only densely adherent to the abdominal wall, but which had become virtually inseparable from multiple loops of otherwise healthy small intestine, necessitating additional bowel resection to remove the implanted foreign material. Histological examination of these specimens provided an explanation for this finding. Despite assurances that PADM can be safely left within the peritoneal cavity, examination of the interface between implant and bowel demonstrated complete integration of the seromuscular layer of the small intestine with the surface of the implant, a process which appeared to be associated with neovascularisation of the implant from the underlying intestinal wall. In addition, the remaining implant material was found encapsulated at the edges of the wound, suggesting that its behaviour in the human peritoneal cavity is more akin to a non-absorbable synthetic mesh, with failure of remodelling when PADM is used in this manner. The precise cellular and molecular mechanisms behind what is presumably inflammatory cross-talk between the intestinal serosa and PADM are unclear but the dense adherence we observed seem likely to represent an exaggerated version of the intraperitoneal inflammatory response which characterises adhesion formation and remodelling. Furthermore, these findings may provide a potential explanation for the “spontaneous” refistulation noted in these patients, weeks after PADM has been left in contact with the viscera and used as a bridge to close the abdomen. We postulate that the dense

adherence to the underlying viscera may result in the development of shearing forces between the fixed implant and the adherent bowel, leading to serosal injury and subsequent fistulation, as has been noted in the open abdomen [29].

The findings of the current study suggest that bridging abdominal wall defects during reconstructive surgery in the open abdomen should be avoided if at all possible and raise particularly serious concerns about the safety of the intraperitoneal use of PADM in this setting. The use of PADM has, therefore, been discontinued in our unit.

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Compliance with ethical standards

Conflict of interest The authors declare no conflict of interest.

Ethical approval For this study, ethical approval is not required.

Human and animal rights This paper does not involve any study on human or animal participants.

Informed consent For this type of study informed consent was not required.

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