

Indications and Outcomes of a Cross-Linked Porcine Dermal Collagen Mesh (Permacol) for Complex Abdominal Wall Reconstruction: A Multicenter Audit

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Abstract

Introduction To reduce the occurrence of complications in the setting of high-risk patients with contaminated operative field, a wide range of biologic meshes has been developed. Yet, few series have reported outcomes after abdominal wall repair (AWR) using such meshes. Permacol is an acellular porcine dermal collagen matrix with a cross-linked pattern. This study reports short- and long-term outcomes after AWR for incisional hernia using Permacol.

Materials and methods All consecutive patients undergoing single-stage open AWR using Permacol mesh at eight university hospitals were included. Mortality, complication and hernia recurrence rates were assessed. Independent risk factors for complications and hernia recurrence were identified with logistic regression and Fine and Gray analysis, respectively.

Results Overall, 250 patients underwent single-stage AWR with Permacol. Nearly 80% had a VHWG grade 3 or 4 defect. In-hospital mortality and complication rates were 4.8% ($n = 12$) and 61.6% ($n = 154$), respectively. Reintervention for complications was required for 74 patients (29.6%). Mesh explantation rate was 4% ($n = 10$). Independent risk factors for complications were smoking, defect size and VHWG grade. After a mean follow-up time of 16.8 months (± 18.1 months), 63 (25.2%) experienced hernia recurrence. One-, 2- and 3-year RFS were 90%, 74% and 57%, respectively. Previous AWR, mesh location and the need for reintervention were independent predictors of hernia recurrence.

Discussion Single-stage AWR is feasible using Permacol. Mortality and complication rates are high due to patients' comorbidities and the degree of contamination of the operative field. Given the observed recurrence rate, the benefit of biologics remains to be ascertained.

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Introduction

The use of a mesh is recommended in order to avoid recurrence after abdominal wall reconstruction (AWR) for incisional hernia [1, 2]. Yet, surgical site occurrence (SSO)

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and especially surgical site infection (SSI) stand as the most dreadful complications increasing the risk of hernia recurrence [3, 4]. To reduce the occurrence of complications in the setting of high-risk patients or contaminated surgical site, a wide range of biologic meshes has been developed. Further, to improve patient selection toward reduced SSO and hernia recurrence, the Ventral Hernia Working Group (VHWG) proposed a four-level grading system recommending the use of biologic mesh in the case of grade 3–4 and discussing it for grade 2 [5–7]. Although the short-term safety of biologics has been established, outcomes provided by each type of biologic mesh and comparisons with synthetic meshes in similar indications are scarce in the literature, owing to the lack of evidence [8]. Biologic matrices are collagen based and derived primarily from porcine or bovine origin. Tissue type varies from dermis to intestinal submucosa and pericardium. Additionally, matrix patterns range from non-cross-linked to cross-linked or layered products. These different patterns and characteristics are supposed to provide resistance to bacterial collagenase while avoiding mesh encapsulation [9, 10]. While a few large series and a systematic review have evaluated some different types of biologic meshes, few series have reported mid- or long-term outcomes after AWR with any of them [8, 11–17].

The aim of this retrospective study was to describe the current use and outcomes in AWR using Permacol observed from a large multicenter experience.

Methods

Study population

Permacol is an acellular porcine dermal collagen matrix with a cross-linked pattern (Medtronic, Minneapolis, MN, USA). Data on all consecutive patients aged 18 years or older undergoing single-stage open AWR using Permacol mesh from January 2010 to January 2016 were retrospectively collected at eight university hospitals.

Data collection

Data were collected by a retrospective review of medical records obtained at each center. Patient demographics

including age, sex, comorbidities, body mass index (BMI), history of previous abdominal surgeries and hernia defect characteristics were documented. Smoking was defined as active smoking within 3 months of surgery. Permacol use was indicated in patients deemed at high risk of SSO due to comorbidities or due to an actual operative field contamination. Causes of operative field contamination were determined as follows: (1) presence or creation of a stoma; (2) concomitant digestive resection/anastomosis; (3) presence of infected mesh/chronic wound infection; (4) inadvertent enterotomy with surgical site contamination during ventral or incisional hernia repair; (5) presence of chronic enteral fistula; and (6) emergent laparotomy with or without peritoneal sepsis. Additionally, each operation was graded according to the VHWG grading system [5].

Operative details such as mesh position, mesh fixation, midline closure status, need for component separation techniques and drain placement and position were also collected. These technical aspects were at the discretion of the attending surgeon and may have varied across the study centers and over the study period according to local practices.

Concerning short-term outcomes, any postoperative event including SSO and SSI occurring within 30 days and deemed as leading to deviation from the normal postoperative course was considered a complication and graded according to the Dindo–Clavien classification [18]. In patients with multiple complications, the highest grade was retained. Readmission rate within 30 days after discharge was also evaluated.

After the 6 weeks postoperative visit, follow-up was not standardized among all participating centers. Some centers had a policy of yearly visit with or without routine CT scan. Hernia recurrence was defined by CT scan or physical examination and was documented from operative clinics' follow-up, physician examinations and postoperative radiology reports and imaging.

Statistical analysis

Categorical variables were presented as frequency (percentage), and continuous variables as mean (\pm standard deviation SD). For descriptive analysis, these variables were compared with Pearson χ^2 test (or Fisher exact test) and *t*-test, respectively. For exploratory analysis, Wald χ^2 test was used to test the influence of parameters on the variable of interest.

All perioperative variables associated with complications in univariate analysis ($p < 0.20$) were included in a multiple logistic regression model in order to identify independent risk factors for postoperative complications.

Recurrence-free survival (RFS) was defined as the interval between date of primary repair and date of last

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follow-up, date of death or date of recurrence and estimated with the Kaplan–Meier method. All perioperative variables associated with hernia recurrence in univariate analysis ($p < 0.20$) were included in a Fine and Gray proportional hazard model. This competing risk regression analysis was used to identify independent predictors of recurrence, with death without recurrence as a competing risk. A subdistribution hazard ratio (SHR) was defined to describe the relative effect of covariates on the event of interest. For each multivariate model, a backward selection was used, with a threshold of 0.100 for keeping into the model.

All p values were based on two-tailed statistical tests, and $p < 0.05$ was considered to indicate statistical significance. Analyses were performed with SAS[®] software, version 9.4 (SAS Institute, Inc.).

Results

Patient characteristics

Over the study period, 250 patients underwent AWR using a Permacol mesh. Mean age of all patients was 61.7 years (± 13.5 years), and mean BMI was 31.2 kg/m^2 ($\pm 7.9 \text{ kg/m}^2$). Ninety-one patients (36.4%) had undergone previous AWR. Overall, 202 patients (80.8%) had a unique defect and 44 had multiple defects (17.6%); in 175 patients (70%) the defect involved the midline. Additional patient demographics are described in Table 1.

Indications for biologic mesh

The majority of patients were within grade 3 or 4 of the VHWG classification ($n = 199$, 79.6%). Causes of operative field contamination (VHWG grade 3 and 4) warranting Permacol use included: (1) presence or creation of a stoma, $n = 56$ (28.1%); (2) concomitant digestive resection/anastomosis, $n = 52$ (26.1%); (3) presence of infected mesh/chronic wound infection, $n = 40$ (20.1%); (4) inadvertent enterotomy with surgical site contamination during ventral or incisional hernia repair, $n = 25$ (12.6%); (5) presence of chronic enteral fistula, $n = 16$ (8.0%); and (6) emergent laparotomy with or without peritoneal sepsis, $n = 10$ (5%).

Operative details

Overall, the biomesh was placed mostly in the intraperitoneal position (underlay) ($n = 172$, 68.8%). Retromuscular mesh position (sublay) use increased over time, from 7.3% ($n = 9$) before 2013 to 33.1% ($n = 42$) since 2013 ($p < 0.001$). Conversely, the use of the so-called bridge position (inlay) decreased from 17.9% ($n = 22$) before

2013 to 0.8% ($n = 1$) since 2013 ($p < 0.001$). The use of onlay mesh position ($n = 4$) did not change over time. Anterior aponeurotic closure was achieved in 190 patients (76%). To aid in achieving aponeurotic closure of the defect over the biomesh, components separation technique was performed in five patients (2.6%). Drains were placed in 178 patients (71.2%), with a mean number of 2.6 per patient (± 1.2).

Short-term outcomes

Overall in-hospital mortality was 4.8% ($n = 12$). Causes for postoperative deaths were septic shock ($n = 7$) from abdominal ($n = 5$) and pulmonary origin ($n = 2$), or multiorgan failure ($n = 5$). In-hospital complication rate was 61.6% ($n = 154$).

One hundred and twenty-two patients (48.8%) experienced SSO consisting mainly of abscess ($n = 81$, 66.4%). Reintervention was required for 74 patients (29.6%) mostly due to intraperitoneal complications ($n = 23$, 31.1%), wound abscess ($n = 27$, 36.5%) and other SSOs such as seroma ($n = 8$, 10.8%), hematoma ($n = 9$, 12.2%) and wound dehiscence ($n = 7$, 9.5%). Ten of them (13.5%) underwent mesh explantation because of mesh disruption or migration. All explantations occurred in the setting of SSI (deep SSI = 5, wound abscess = 5). Risk factors for complications identified in univariate analysis are presented in Table 2. Smoking ($p = 0.002$), VHWG grade ($p = 0.015$) and defect size ($p = 0.004$) were independently associated with the occurrence of complications (Table 2). Median hospital stay was 20 (± 24) days. Thirty-day readmission rate was 14.8% ($n = 37$).

Long-term outcomes

During the study period, 10 patients (4%) died after hospital discharge owing to cancer-related causes ($n = 7$) or terminal organ failure ($n = 3$). After a mean follow-up time of 16.8 months (± 18.1 months), 22 patients (8.8%) had chronic wound infection and 63 (25.2%) experienced hernia recurrence (mean 21.7 months). One-, 2- and 3-year RFS were 90, 74 and 57%, respectively. Among patients followed up longer than 3 years ($n = 43$), 11 patients (25.6%) presented hernia recurrence. Predictors of hernia recurrence in univariate analysis are given in Table 3. A previous AWR ($p < 0.001$), mesh location ($p = 0.023$) and the need for reintervention ($p = 0.015$) were independent predictors of hernia recurrence (Table 3). Among those patients who developed a hernia recurrence, 25 (39.7%) had redo AWR. Among them, data on mesh status at reintervention were available in 21 patients. Partial mesh resorbing was evidenced in 12 patients (57.1%), while 9 patients had an intact but nonintegrated mesh (42.9%).

Table 1 Cohort description ($n = 250$)

	Full cohort ($n = 250$)	No morbidity ($n = 96$)	Morbidity ($n = 154$)	p^*
Baseline characteristics				
Gender				
Male	121 (48.4%)	44 (45.8%)	77 (50%)	0.521
Female	129 (51.6%)	52 (54.2%)	77 (50%)	
Age, years	61.7 (\pm 13.5)	61.9 (\pm 14.1)	61.6 (\pm 13.1)	0.863
Body mass index, kg/m ²	31.2 (\pm 7.9)	31.0 (\pm 7.9)	31.3 (\pm 7.9)	0.820
HBP	128 (51.2%)	44 (45.8%)	84 (55.6%)	0.180
COPD	32 (12.8%)	6 (6.3%)	26 (16.9%)	0.014
Diabetes	47 (18.8%)	13 (13.5%)	34 (22.1%)	0.093
Liver cirrhosis	6 (2.4%)	3 (3.1%)	3 (2%)	0.554
Immunodeficiency	33 (13.2%)	14 (14.6%)	19 (12.3%)	0.610
Smoking	60 (24%)	12 (12.5%)	48 (31.2%)	0.001
Previous AWR	91 (36.4%)	35 (36.5%)	56 (36.4%)	0.988
Hernia characteristics				
Defect size, cm				
≤ 5	24 (9.6%)	16 (16.7%)	8 (5.2%)	0.004
[6–10]	65 (26%)	23 (24%)	42 (27.3%)	
> 10	66 (26.4%)	17 (17.7%)	49 (31.8%)	
Missing value	95 (38%)	40 (41.7%)	55 (35.7%)	
VHWG grade				
2	51 (20.4%)	29 (30.2%)	22 (14.3%)	0.010
3	145 (58%)	48 (50%)	97 (63%)	
4	54 (21.6%)	19 (19.8%)	35 (22.7%)	
Operative characteristics				
Mesh location				
Retromuscular	51 (20.4%)	22 (22.9%)	29 (18.8%)	0.669
Intraperitoneal	172 (68.8%)	65 (67.7%)	107 (69.5%)	
Onlay/inlay	27 (10.8%)	9 (9.4%)	18 (11.7%)	
Anterior aponeurotic closure	190 (76%)	71 (74%)	119 (77.3%)	0.551
Drain	178 (71.2%)	66 (68.8%)	112 (72.3%)	0.499

Numbers are expressed as mean (standard deviation), unless otherwise specified

AWR abdominal wall repair, COPD chronic obstructive pulmonary disease, HBP high blood pressure, VHWG Ventral Hernia Working Group
*Pearson χ^2 test (or Fisher exact test) and t -test as appropriate

Discussion

In the setting of contaminated or infected surgical field, AWR has evolved from a two-stage to a single-stage surgery. However, complex AWR remains associated with high mortality, complication and reintervention rates (4.8%, 61.6% and 29.6% in our series, respectively). These findings are consistent with other series reporting complex AWR outcomes and are certainly related to patients' characteristics [13, 14, 17, 19]. Indeed, patients undergoing AWR with biologic meshes cumulate risk factors such as obesity, iterative AWR, concomitant digestive surgery, smoking or ongoing infection.

To the best of our knowledge, the current series is one of the largest series evaluating outcomes after AWR using a

cross-linked porcine dermal collagen mesh. The majority of patients (80%) had a VHWG grade 3 or 4 defect. This point contrasted with the largest series to date that included around 40% of grade 1–2 patients [17]. This may account for a higher rate of SSO observed in the current study. Of note, the VHWG grade was an independent risk factor for complication and should be considered for patient information and perioperative management. However, the ability of risk stratification of the VHWG classification remains debated, especially between grade 3–4 patients [20]. Additionally, defect size was independently associated with the occurrence of complications. Rosen et al. [14] have reported the clinical relevance of the defect size in terms of complications and recurrence. Large defect size is often associated with challenging anterior aponeurosis

Table 2 Risk factors for complications within 30 days in univariate and multivariate analysis ($n = 250$)

	Effect	Unadjusted OR (CI 95%)	p^*	Adjusted OR (CI 95%)	p^*
Gender	(Female vs male)	0.846 (0.508–1.410)	0.522		
Age, years		0.998 (0.979–1.018)	0.863		
BMI, kg/m ²		1.004 (0.969–1.040)	0.819		
HBP	(Yes vs no)	1.418 (0.850–2.366)	0.181		
COPD	(Yes vs no)	3.047 (1.205–7.705)	0.019	–	
Diabetes	(Yes vs no)	1.808 (0.900–3.633)	0.096	2.115 (0.999–4.481)	0.050
Liver cirrhosis	(Yes vs no)	0.616 (0.122–3.115)	0.558		
Immunodeficiency	(Yes vs no)	0.824 (0.392–1.733)	0.610		
Smoking	(Yes vs no)	3.170 (1.583–6.347)	0.001	3.215 (1.557–6.640)	0.002
Previous AWR	(Yes vs no)	0.996 (0.586–1.691)	0.988		
Defect size, cm			0.006		0.004
	≤ 5	Ref.		Ref.	
	[6–10]	3.652 (1.358–9.822)	0.010	3.814 (1.330–10.935)	0.013
	>10	5.765 (2.095–15.863)	0.001	6.696 (2.274–19.717)	0.001
	Missing value	2.750 (1.073–7.050)	0.035	2.764 (1.013–7.542)	0.047
VHWG grade			0.011		0.015
	2	Ref.		Ref.	
	3	2.664 (1.386–5.119)	0.003	2.705 (1.341–5.456)	0.006
	4	2.428 (1.106–5.333)	0.027	2.758 (1.186–6.412)	0.018
Mesh location			0.670		
	Retromuscular	Ref.			
	Intraperitoneal	1.249 (0.662–2.354)	0.492		
	Onlay/inlay	1.517 (0.573–4.016)	0.401		
Anterior aponeurotic closure	(Yes vs no)	1.197 (0.663–2.163)	0.551		
Drain	(Yes vs no)	1.212 (0.693–2.119)	0.500		

AWR abdominal wall repair, BMI body mass index, COPD chronic obstructive pulmonary disease, HBP high blood pressure, OR odds ratio, VHWG Ventral Hernia Working Group

*Wald χ^2 test

closure resulting in increased recurrence rates [13]. While these data were unfortunately lacking in nearly 40% of the operative reports in our cohort, surgeons should systematically consider defect size for decision-making and patient information.

The use of a cross-linked porcine mesh has allowed a single-stage AWR with a 1-, 2- and 3-year recurrence rate of 10, 26 and 43%, respectively. This finding is similar to other series reporting long-term recurrence rates ranging from 28% at 2 years to 66% at 5 years, after AWR in contaminated fields using porcine dermal collagen matrices [13, 15–17, 19, 21]. However, the ability to compare the outcomes of different biologics in the literature is very limited due to the great heterogeneity in patients' selection, surgical scenarios, technique and matrices. For instance, the RICH study evaluated a non-cross-linked porcine dermal collagen mesh in 80 patients in scenarios close to those of our series and reported a 2-year hernia recurrence rate of 28% [13]. Additionally, in the current study, among patients followed up longer than 3 years, 11 patients

(25.6%) experienced hernia recurrence diagnosed after 3 years. This observation underlines that long-term follow-up is thus warranted in all future prospective studies about AWR. Additionally, technical details may have influenced hernia recurrence in the current study, as anterior closure was not achieved in all patients and component separation techniques were poorly used.

Yet, should we be satisfied with such recurrence rates after AWR using biologics? Before the biologics era, the policy for AWR in contaminated fields in Europe was a two-stage procedure. The first stage consisted in placing a quickly resorbable mesh leading in most patients to a recurrence. Then, a synthetic mesh was placed for the definitive repair. Thus, almost 100% of patients were undergoing a second operation (supposed to be the "definitive" repair). From this point of view, avoiding a second operation for more than half of the patients may be considered as an improved outcome.

Regarding technical considerations, mesh placement has evolved over time toward more retromuscular mesh

Table 3 Associations between covariates and time to recurrence in univariate and multivariate analysis ($n = 250$)

		Unadjusted SHR (CI 95%)	p^\dagger	Unadjusted SHR (CI 95%)	p^\dagger
Baseline characteristics					
Gender	(Female vs male)	1.207 (0.740–1.967)	0.451		
Age, years		0.985 (0.969–1.001)	0.066		
Body mass index, kg/m ²		0.998 (0.967–1.030)	0.912		
HBP	(Yes vs no)	1.029 (0.633–1.671)	0.909		
COPD	(Yes vs no)	0.839 (0.421–1.671)	0.617		
Diabetes	(Yes vs no)	0.912 (0.526–1.583)	0.744		
Liver cirrhosis	(Yes vs no)	0.562 (0.105–2.995)	0.500		
Immunodeficiency	(Yes vs no)	1.068 (0.564–2.023)	0.840		
Smoking	(Yes vs no)	1.502 (0.880–2.563)	0.136		
Previous AWR	(Yes vs no)	2.388 (1.468–3.885)	0.001	2.601 (1.598–4.233)	<0.001
Hernia characteristics					
Defect size, cm			0.692		
	≤ 5	Ref.			
	[6–10]	0.781 (0.241–2.532)	0.681		
	> 10	1.056 (0.326–3.423)	0.928		
	Missing value	1.105 (0.350–3.488)	0.865		
VHWG grade			0.545		
	2	Ref.			
	3	1.198 (0.583–2.462)	0.622		
	4	1.522 (0.685–3.384)	0.303		
Operative characteristics					
Mesh location			0.097		
	Retromuscular	Ref.		Ref.	
	Intraperitoneal	0.548 (0.290–1.036)	0.064	0.432 (0.231–0.810)	0.009
	Onlay/inlay	0.904 (0.384–2.129)	0.817	0.723 (0.305–1.713)	0.461
Fascial closure	(Yes vs no)	0.718 (0.429–1.204)	0.209		
Reintervention	(Yes vs no)	1.458 (0.899–2.366)	0.127	1.831 (1.123–2.987)	0.015

AWR abdominal wall repair, COPD chronic obstructive pulmonary disease, HBP high blood pressure, SHR subdistribution hazard ratio, VHWG

Ventral Hernia Working Group

[†]Wald χ^2 test

placement while bridging has been gradually abandoned. This evolution is likely due to recent recommendations and series reporting higher recurrence rates associated with the bridging and intraperitoneal techniques [14, 21, 22]. However, in contrast to Rosen et al. [14], retromuscular mesh placement was not associated with lower hernia recurrence as compared to intraperitoneal mesh placement in the current series. The small number of patients who underwent a retromuscular mesh placement and its growing use in the later part of the study period may account for this finding. Other recurrence risk factors were identified in the current study. Notably, previous AWR was recently reported as a risk factor for recurrence [14]. The need for reintervention was also identified as independently associated with a higher risk of recurrence. Rosen et al. [14] identified the occurrence of SSO as a risk factor for recurrence. In the current study, more than half of the

patients experiencing SSO required reintervention. Consequently, patients experiencing SSO, especially those requiring reintervention, should be considered at higher risk of recurrence. The preoperative wound contamination grade was also previously reported as associated with hernia recurrence [15]. Given that the majority of the cohort (80%) had a VHWG class III–IV wound, wound contamination was not associated with hernia recurrence.

Our current results are limited for several reasons related to their retrospective design. First, indication for biologic mesh and operative techniques was not standardized across the study centers. Still, the majority of the cohort study was grade 3–4 patients and mesh placement was mostly intraperitoneal. Second, all institutions participating in this study are referral centers for complex large hernias repair. Consequently, our results might not be extrapolated to AWR for smaller contaminated hernias. Third, although

outcomes are similar to other studies evaluating the use of biologics for AWR, the current findings cannot be extended or compared to the use of other meshes. One of our aims was to avoid considering all biologics as equivalent before comparing them. Finally, although the mean follow-up was close to 17 months, follow-up was not standardized and not longitudinal. Consequently, time between hernia repair and recurrence cannot be accurately established, and recurrence frequency might have been underestimated. Future studies with a prospective, longitudinal, clinical and radiological follow-up are needed.

Conclusion

According to this large multicenter experience, single-stage complex AWR is feasible using a cross-linked porcine biologic matrix. Mortality and complication rates associated with the repair are high due to the patients' comorbidities and the degree of contamination of the operative field. While the utility of biologic meshes for AWR remains disputed, further prospective studies are required to appraise the role of biologics in similar settings [23].

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Compliance with ethical standards

Conflict of interest P. Ortega-Deballon has received grants from Covidien/Medtronic, Bard and LifeCell/Acelity. The other authors have no disclosures.

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