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ORIGINAL ARTICLE

Incisional hernia repair with a slowly absorbable P4HB mesh: what happens after the mesh disappears? A retrospective longitudinal clinical study

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Abstract

Purpose To analyze the incisional hernia recurrence rate at a long-term follow-up using a biosynthetic long-term absorbable mesh in patients with a higher risk of surgical infection in a contaminated surgical field.

Methods This was a retrospective multicentric study. All patients undergoing incisional hernia repair between 2016 and 2018 at 6 participating university centers were included. Patients were classified according to the Ventral Hernia Working Group (VHWG). All consecutive patients who underwent abdominal wall repair using biosynthetic long-term absorbable mesh (Phasix®) in contaminated fields (grade 3 and 4 of the VHWG classification) were included. Patients were followed-up until September 2021. Preoperative, operative, and postoperative data were collected. All patients' surgical site infections (SSIs) and surgical site occurrences (SSOs) were recorded. The primary outcome of interest was the clinical incisional hernia recurrence rate.

Results One hundred and eight patients were included: 77 with VHWG grade 3 (71.3%) and 31 with VHWG grade 4 (28.7%). Median time follow-up was 41 months [24; 63]. Twenty-four patients had clinical recurrence during the follow-up (22.2%). The SSI and SSO rates were 24.1% and 36.1%, respectively. On multivariate analysis, risk factors for incisional hernia recurrence were previous recurrence, mesh location, and postoperative enterocutaneous fistula.

Conclusions At the 3 year follow-up, the recurrence rate with a biosynthetic absorbable mesh (Phasix®) for incisional hernia repair in high-risk patients (VHWG grade 3 and 4) seemed to be suitable (22.2%). Most complications occurred in the first year, and SSI and SSO rates were low despite high-risk VHWG grading.

Keywords Biosynthetic mesh · Contaminated surgery · Incisional hernia repair · Recurrence

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Introduction

The incidence of incisional hernia after laparotomy occurs in up to 20% according to the current literature [1]. The use of a mesh during incisional hernia repair (IHR) is a standard of care worldwide [2, 3]. However, Koktovic et al. showed that the benefits attributable to synthetic mesh might be impaired in part by mesh-related complications [4]. Furthermore, in a contaminated surgical field, the use of a synthetic mesh is a matter of debate. This has led to the development of biologic and biosynthetic meshes. Biologic matrices are collagen-based scaffolds of porcine or bovine origin. The benefits of biologic meshes in contaminated fields have been hampered due to high complication (34–62%) and recurrence rates (24–30%), as well as their elevated cost [5, 6].

Among biosynthetic meshes, poly-4-hydroxybutyrate (P4HB) is an absorbable synthetic polymer scaffold derived from a transgenic form of *Escherichia coli* [7, 8]. These meshes are called "biosynthetic" long-term absorbable meshes (Phasix®, Beckton-Dickinson, US) because of their breakdown by hydrolysis. This method of resorption offers major advantages when challenged with bacterial colonization during complex abdominal wall repair. Previous studies have demonstrated the safety and short-term efficacy of Phasix® mesh in both clean and contaminated surgical fields [9, 10].

The absorption process of Phasix® takes 12–18 months [11], and recurrence after this period is a major concern. This study presents an update of our previous work with a longer follow-up beyond the resorption time of the biosynthetic mesh [10]. The aim of this study was to evaluate the recurrence rate and its risk factors after IHR with Phasix® in a contaminated surgical field (VHWG grade 3 and 4). The secondary objective was to evaluate the morbidity rate of incisional hernia after 24 months of FU.

Methods

Study design

Six French university hospitals (i.e., the Strasbourg, Dijon, Bordeaux, Besançon, Lyon and Reims hospitals) included all their consecutive patients who underwent IHR with the use of a P4HB mesh between May 2016 and September 2018. The follow-up was performed in September 2021. Each patient had either a Phasix® (onlay, retromuscular location) or a Phasix ST® (intraperitoneal location) mesh.

Regarding the degree of contamination of the surgical field, patients were categorized using the Ventral Hernia Working Group classification (VHWG) [12]. Ventral Hernia Working Group grade 1 refers to the "low-risk" group of complications and no history of wound infection; VHWG grade 2 refers to the "comorbid" group (those with obesity, diabetes, history of smoking, chronic obstructive pulmonary disease (COPD); VHWG grade 3 refers to a potentially contaminated" group with previous wound infection, a stoma, or a concomitant gastrointestinal (GI) procedure. VHWG grade 4 represents dirty fields. Patients who underwent a clean IHR or had a prophylactic mesh in the absence of hernia were excluded.

Patients with a follow-up of less than 24 months were excluded from the study. Clinical recurrence was the main endpoint of the study. Postoperative complications were collected as secondary outcomes: general complications and specific complications at the operative site: surgical site infection (SSI) and occurrence (SSO).

Pre- and intraoperative patient data were collected using medical chart review. After surgery, patients who consented to participate in a prospective follow-up protocol were included. The study was conducted under Institutional Board Ethics Committee approval and registered on ClinicalTrial ID: NCT04132986. All patient gave informed consent to participate in this study.

Data collected

Demographic, preoperative, and operative characteristics were recorded based on clinical files. They included age, sex, body mass index, previous comorbidities, and risk factors (smoking, obesity, diabetes, COPD, history of wound infection, and hernia repair at the same site, immunosuppression due to cancer or treatments, and obstructive sleep apnea syndrome), VHWG scores, mesh size, number of previous attempted repairs, location of the mesh, fixation of the mesh and drainage. Indications for the use of biosynthetic absorbable mesh were described.

The size of the abdominal wall defect could not be obtained from the records for all patients. The size of the mesh was recorded instead. Patients were divided into 3 groups according to the size of the mesh used: medium meshes 10 × 15 cm, 15 × 20 cm, and 8 × 8 cm; large meshes 20 × 25 cm and 25 × 30 cm; and very large meshes 20 × 40 cm, 30 × 35 cm, 30 × 45 cm, 40 × 30 cm, and 50 × 50 cm. The precise method of repair, mesh fixation, and drainage were left to the choice of the surgeon.

Recurrence was diagnosed on physical examination by an experienced surgeon. SSI was defined by superficial and deep infections [13]. SSO was defined by cellulitis, SSI, seroma, hematoma, enteral fistula, infected mesh, and wound disunion. Complications were graded according to the Dindo-Clavien classification [14]. A

complication ≥ grade III was considered major, and ≤ grade II was considered minor. Only the most serious complications will be considered.

Statistical analysis

Qualitative variables were described as percentages and compared with a chi-2 test or Fisher's exact test as appropriate. Quantitative variables were described with their mean and standard deviation and/or as a median and interquartile range. Student's *t* test was used to compare means of continuous variables if they were normal, and the Mann–Whitney–Wilcoxon test was used if they were not. The threshold of significance was set at $p < 0.05$. A Kaplan–Meier survival analysis was performed to study recurrence.

Variables having a $p < 0.20$ in the univariate analysis were retained for the multivariate analysis. A center effect was assessed by comparing two models: one with the center as an explanatory variable and the other without the center (positive if $p < 0.05$).

Results

Population characteristics

One hundred and eight patients were included. The median total follow-up was 41 months (IQR: 24–63), and the mean total follow-up was 41 ± 9.2 months. Patient characteristics, comorbidities, and patterns of surgical contamination are presented in Table 1. The mean age was 61.4 (± 13.1 years), with a male majority (55.6%). The average BMI was 29.2 kg/m^2 ± 6.9 SD, and 43.5% of the patients had previously undergone hernia repair.

Incisional hernia characteristics and treatment

A medium mesh (10 × 15 cm, 15 × 20 cm, 8 × 8 cm) was used in 40 patients (37%), a large mesh was used in 44 patients (40.7%), and a very large mesh was used in 23 patients (21.3%) (1 with data not known) (Table 1).

Seventy-seven patients (71.3%) had a grade 3 VHWG, and 31 patients (28.7%) had a grade 4 VHWG. A stoma was present in 35.1% of cases, and a concomitant GI procedure was present in 50.1%.

Meshes were implanted in a retromuscular position in 56 patients (51.9%), in an intraperitoneal position in 49 patients (45.4%) and in an onlay position in 3 patients (2.8%). The fascia was closed in 94.4% of all patients. Most surgical procedures were performed by laparotomy (99.1%).

Long-term recurrence

The total clinical recurrence rate was 22.2% ($n = 24$), with a mean total follow-up of 41 ± 9.2 months. The mean time to recurrence was 18 ± 13 months (Fig. 1). Among the 24 recurrences, there were 8 recurrences (33%) during the period between 12 and 18 months postoperatively and 9 recurrences (37.5%) after 18 months. The majority of recurrences before 12 months concern intraperitoneal meshes (85.7%). After 12 months postoperatively, among the 17 recurrences, there were 10 intraperitoneal meshes and 7 in retromuscular position. Univariate analysis showed that preoperative mesh location ($p = 0.03$) and postoperative enterocutaneous fistula ($p = 0.004$) were significant risk factors for recurrence (Table 2). Recurrence rates were 32.7% for intraperitoneal location ($n = 16$), 12.5% in retromuscular position ($n = 7$) and 33% in onlay location ($n = 1$). Multivariate analysis showed that mesh location (retromuscular vs. intraperitoneal), re-recurrent incisional hernia and postoperative enterocutaneous fistula were significant independent risk factors for recurrence (Table 3).

Long-term postoperative wound events

Most complications occurred in the first year (Fig. 2). The total SSO rate was 36.1% ($n = 39$). According to the Dindo–Clavien classification, 20 patients (18.5%) had at least one minor complication, and 31 patients (28.7%) had at least one major complication. The SSI rate was 24.1%.

Discussion

This study provides important insight regarding the long-term performance of P4HB mesh at a time point at which the mesh has resorbed. Animal studies have assessed mechanical testing and found similar strengths between P4HB mesh-repaired sites and native porcine abdominal walls at 18 months [15]. However, clinical results are necessary to confirm this aspect. Long-term repair strength seems dependent upon the strength of the native abdominal wall in combination with the host tissue regenerated at the repair site. Given their biodegradable characteristics, biosynthetic meshes are often used in patients at high risk of complications, particularly in contaminated fields. This large multicenter cohort included only grade 3 and 4 VHWG patients undergoing IHR with a biosynthetic long-term absorbable

Table 1 Population characteristics

	N (%)	Median (min–max)	Mean ± SD
Gender			
Female	60 (55.6%)		
Male			
Age	108	62 (27–94)	61.4 ± 13.1
Total follow-up (months)		41.0 (23–63)	41 ± 9.2
Recurrence			
Yes	24 (22.2%)		
No	84 (77.8%)		
Surgical modality			
Elective case	85 (78.7%)		
Emergency case	23 (21.3%)		
Surgical approach			
Open surgery	107 (99.1%)		
Laparoscopic surgery	1 (0.9%)		
BMI (kg/m2)		27.8 (17.7–52.9)	29.2 ± 6.93
Tobacco history			
Yes	32 (29.4%)		
No	76 (70.4%)		
Diabetes mellitus			
Yes	18 (16.7%)		
No	90 (83.3%)		
COPD			
Yes	13 (12.0%)		
No	95 (88.0%)		
Sleep apnea			
Yes	15 (13.9%)		
No	93 (86.1%)		
Re-recurrent incisional hernia			
Yes	45 (41.7%)		
No	63 (58.3%)		
Ventral working group classification			
Grade 3	77 (71.3%)		
Grade 4	31 (28.7%)		
Mesh dimensions			
Medium	40 (37.0%)		
Large	44 (40.7%)		
Very large	23 (21.3%)		
Mesh location			
Intraperitoneal	49 (45.4%)		
Retromuscular	56 (51.9%)		
Onlay	3 (2.8%)		
Length of hospital (days)		9 (0–53)	11.8 ± 9.9
SSO			
Yes	39 (36.1%)		
No	68 (63.9%)		
SSI			
Yes	26 (24.1%)		
No	82 (75.9%)		
Postoperative enterocutaneous fistula			
Yes	9 (8.3%)		
No	99 591.7%)		

Table 1 (continued)

	N (%)	Median (min–max)	Mean ± SD
Clavien–Dindo classification			
No complication	57 (52.8%)		
Minor (I–II)	20 (18.5%)		
Major (III–V)	31 (28.7%)		

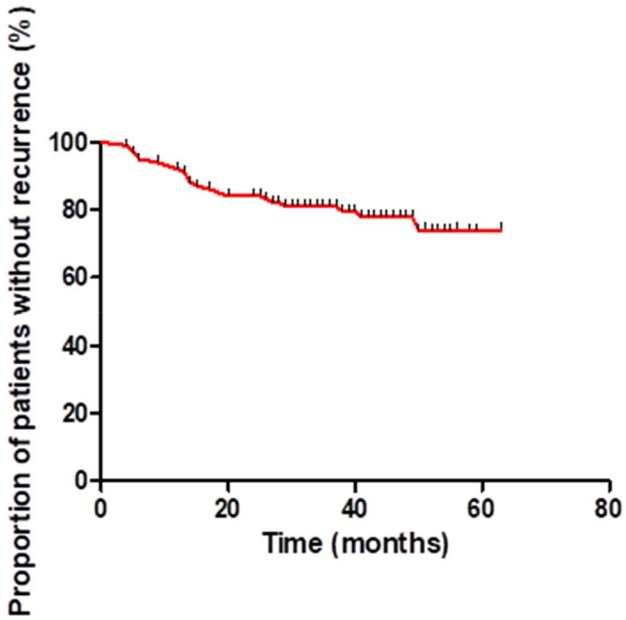

Fig. 1 Hernia recurrences over time (solid line) with 95% confidence intervals (dotted lines) (Kaplan–Meier analysis)

P4HB mesh and showed a 22.2% recurrence rate with a median FU of 41 months. Significant recurrence risk factors were mesh location, re-recurrent incisional hernia, and postoperative enterocutaneous fistula. Our series included a long-term SSO rate of 36.1% and an SSI rate of 24.1%.

Clinical data regarding long-term outcomes for ventral hernia repair utilizing biosynthetic mesh in contaminated or infected wounds are scarce. For several years, biologic meshes have been used in contaminated and infected wounds, but the evaluation of postoperative results was disappointing [5]. The RICH trial reported 66% surgical site occurrence and 28% hernia recurrence after 2 years of follow-up with a biologic noncross-linked mesh [6]. Similar results were found with a cross-link mesh [5]. Biosynthetic mesh showed better results than biologic mesh in terms of SSO and SSI rates [16–18]. In the study of Charleux-Muller et al. including a large majority of mVHWG grade 3 IH (79%) with biosynthetic meshes, the SSO rate was 39.5%, and the SSI rate was 22.3% at 1 year [10]. In the current study, long-term SSO and SSI did not differ from SSO and SSI rates at 1 year. The majority of SSOs and SSIs at the 3 year FU appeared during the first year of the follow-up.

Table 2 Univariate analysis: risk factors for recurrence at 2 year FU

	Odds ratio	95% confidence Interval	*p* value
Gender Female Male	0.604	0.243–1.51	**0.35**
Surgical modality Elective Emergency	0.684	0.208–2.25	**0.78**
Tobacco history	0.744	0.265–2.09	**0.62**
Diabetes mellitus	0.657	0.173–2.49	**0.76**
COPD	0.261	0.03–2.12	**0.29**
Sleep apnea	0.497	0.104–2.37	**0.51**
Re-recurrent incisional hernia	2.39	0.949–6.03	**0.1**
Fascia closure Bridge Fascia closure	1.46	0.162–13.1	**1.0**
Ventral hernia Working group Classification (Grade 3 or 4)	1.33	0.500–3.52	**0.63**
Mesh location Onlay Retro muscular Intraperitoneal	–	–	**0.03**
Mesh dimensions Medium Large Very large	–	–	**0.96**
Clavien–Dindo classification	–	–	0.82
Surgical site occurrence (SSO)	2.11	0.840–5.31	**0.15**
Surgical site infection (SSI)	0.789	0.262–2.38	**0.79**
Postoperative enterocutaneous fistula	9.00	2.05–39.4	**0.004**

Bold values are significant variables

Concerning the long-term recurrence rate, the COBRA study with biosynthetic Bio-A® midline reinforcement showed 18% recurrence at the 2 year follow-up [19]. In a prospective multicenter study with Phasix® meshes, Roth JS et al. showed a recurrence rate of 18% at the 3 year follow-up, but only 68% of patients had completed the total follow-up [20]. Van Rooijen et al. showed an 11% recurrence rate among 84 patients with a median follow-up

Table 3 Multivariate analysis: risk factors for recurrence at 2 year FU

Variables	Estimate	*p* value	Odds ratio	95% confidence interval	
				Lower	Upper
Re-recurrent incisional hernia					
Yes vs. no Ref No	1.234	**0.025**	3.434	1.1679	10.096
Mesh location					
Retromuscular vs. intraperitoneal	− 1.370	**0.014**	0.254	0.0853	0.757
Onlay vs. intraperitoneal *Ref* intraperitoneal	− 0.384	0.783	0.681	0.0444	10.447
SSO					
Yes vs. No Ref No	0.394	0.502	1.483	0.4688	4.693
Postoperative enterocutaneous fistula					
Yes vs. No Ref No	2.052	**0.025**	7.783	1.2973	46.699

Bold values are significant variables

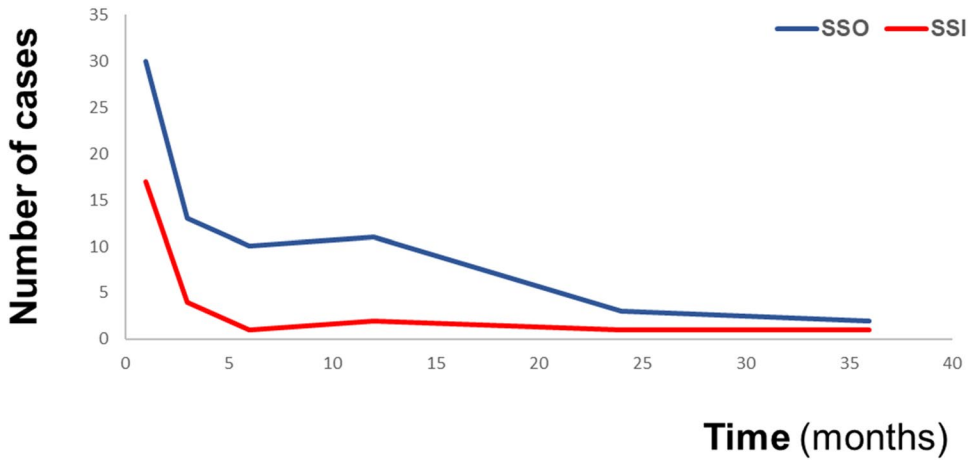

Fig. 2 Evolution during the follow-up of surgical site occurrences (SSOs) and surgical site infections (SSIs)

of 24 months [21]. Recently, Claessne JJM et al. showed a 10% recurrence rate for 71 patients treated with biosynthetic meshes (41 Phasix® and 30 BioA®) with a follow-up of 20 months [22]. The recurrence rate in the current study was slightly higher. However, the longer follow-up with a median FU of 41 months, more high-risk patients (VHWG grade 3 and 4) and the variety of mesh locations (retromuscular and intraperitoneal locations) could explain this rate compared with other studies in the literature.

The analysis of recurrence rate over time gives also interesting information, notably recurrences during and after resorption. The majority of recurrences (> 70%) occurred after 12 months from the mesh implantation which is probably corresponds to the period of mesh resorption. The majority of recurrences before 12 months concern intraperitoneal meshes, while after 12 months postoperatively, the recurrence rate was similar between intraperitoneal and retromusuclar approaches. Early recurrences before 12 months could probably be related to a technical problem with more frequent recurrences with intraperitoneal approach. Later recurrences (> 12 months) could be related to resorption of the mesh. However, the data collected cannot permit to detail the location of the recurrence and specify its mechanisms.

Mesh location was a significant risk factor for recurrence in the present study. There was 12.5% recurrence when the mesh was placed in the retromuscular position, whereas the recurrence rate was increased by threefold when the mesh was in the onlay or intraperitoneal position. Several studies have demonstrated ratios of two to three times greater onlay recurrence rates compared to retromuscular recurrence rates, comparable to the present study [23, 24]. In the COBRA and Van Roijen et al. studies, 90% and 100% of meshes were located in the retromuscular position, respectively [19, 21]. This factor could explain the higher rate of recurrence in the present study, with

45.4% of patients receiving intraperitoneal mesh. The use of the retromuscular location in this study was probably limited given the fear of a greater recurrence rate in case of the use of slowly absorbable meshes no longer allowing the use of this location again in case of recurrence. In the present study, 43.5% of patients had undergone a previous incisional hernia repair. Postoperative complications and previous recurrences are frequently considered risk factors for recurrence [25]. Furthermore, patients with multiple IH recurrences have a higher risk of contaminated or dirty fields (VHWG grade 3 and 4), which is an unfavorable risk profile of iterative recurrence.

Long-term follow-up is crucial to estimate the real recurrence rate in a cohort. The German HERNIAMED registry showed that in one year, only 35% of the recurrences occurred and that patients should be followed for 10 years to be able to identify 92% of total recurrences [26]. For biologic meshes in contaminated environments, recurrence rates ranged from 17 to 19% at 1 year and from 21 to 28% at 2 years [5]. Regarding synthetic meshes in the French registry of unselected noncomplex incisional hernia repairs [27], recurrence rates of 18% at 1 year and 28% at 2 years were higher, as supposed. These results were similar to the Spanish registry EVEREG [28], which had a recurrence rate of 20.7% per year. These high rates may also reflect a systematic search for recurrence on a prospective basis, which is not necessarily the case in retrospective studies. The recurrence rate in the present study in high-risk patients was roughly the same as that found with synthetic mesh.

The main limitation of this study is its retrospective design. However, the good adherence of these complex patients to the follow-up minimizes the risk of bias. There is no study available with more than 100 patients and a long follow-up regarding biosynthetic long-term resorbable meshes in contaminated fields. The second limitation is that the clinical diagnosis underestimated the recurrence rate compared to routine imaging [29, 30]. However, in complex abdominal wall repair (including patients with contaminated and infected fields), the goal is to avoid a new operation. In fact, clinically undetected recurrences often do not require an operation.

In conclusion, the recurrence rate achieved with a slowly absorbable P4HB mesh in high-risk patients (VHWG grades 3 and 4) is lower than that obtained with biologic meshes in the same population and similar to that of currently available synthetic meshes in the general population.

Author contributions All authors have approved the manuscript and meet the requirements for authorship.

Declarations

Conflict of interest The authors declare no conflict of interest. P Ortega Deballon received grants from Covidien/Medtronic, LifeCell/Acelity and Bard/Beckton-Dickinson within the past 5 years. V Dubuisson received grants from Bard/Beckton-Dickinson and LifeCell/Acelity within the past 5 years. Y Renard received grants from BD(r), LifeCell/Acelity and Hartmann within the past 5 years.

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