

Versatility of Poly-4-hydroxybutyrate (Phasix™) mesh in abdominal wall surgery

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ABSTRACT – Background – Poly-4-hydroxybutyrate (P4HB) is a naturally occurring polymer derived from transgenic *E. coli* bacteria with the longest degradation rate when compared to other available products. This polymer has been manufactured as a biosynthetic mesh to be used as reinforcement when repairing a variety of abdominal wall defects. **Objective** – We aim to describe our center initial experience with this mesh and discuss the possible indications that may benefit from the use of P4HB mesh. **Methods** – This is a descriptive retrospective study of patients who underwent abdominal wall repair with a P4HB mesh from October 2018 to December 2020 in a single, large volume, academic center. **Results** – A total of 51 patients (mean age 54.4 years, range 12–89) underwent abdominal wall reconstruction with a P4HB mesh between October 2018 and December 2020. The mean BMI was 30.5 (range 17.2–50.6). Twenty-three (45%) patients had a prior hernia repair at the site. We grouped patients into six different indications for the use of P4HB mesh in our cohort: clean-contaminated, contaminated or infected field (57%), patient refusal for permanent meshes (14%), those with high risk for post-operative infection (12%), visceral protection of second mesh (10%), recurrence with related chronic pain from mesh (6%), and children (2%). Median follow-up was 105 days (range 8–648). Two patients had hernia recurrence (4%) and 8 (16%) patients developed seroma. **Conclusion** – P4HB mesh is a safe and a viable alternative for complex hernias and high-risk patients with a low complication rate in the short-term. **Keywords** – Hernia; recurrence; infection; biosynthetic mesh; Poly-4-hydroxybutyrate.

INTRODUCTION

Patients requiring complex abdominal wall reconstruction bring a unique set of challenges to the surgeons caring for them⁽¹⁾. One of the tenants of abdominal wall repair is the use of reinforcing mesh, a concept that is well established in the literature and well accepted by most surgeons. Nonetheless, the use of mesh can result in morbid complications with significant impact in a patient's quality of life. As such, mesh technology has continued to evolve alongside surgical techniques and perioperative care to minimize complications. In recent years, the use of biologic mesh has gained popularity to minimize surgical site infections when working in contaminated and clean contaminated surgical fields⁽²⁻⁴⁾. Biologic meshes may have an advantage when working in contaminated wounds with respect to the clearance of bacteria, surgical site events, and overall morbidity. Often, biologic mesh can function as a bridge to additional therapy, allowing wound granulation and closure without the added morbidity of permanent mesh. Despite this, we have seen a rather slow adoption of these advanced meshes, which we theorize is at least in part due to its high cost and the lack of strong evidence for their use⁽¹⁾.

The synthetic absorbable meshes provide yet another option for these difficult case scenarios with some theoretical advantages over purely biologic mesh. Poly-4-hydroxybutyrate (P4HB) is a natural polymer derived from transgenic *Escherichia coli* and

boasts the longest degradation rate when compared to other available products^(5,6). This polymer has been designed and manufactured as a biosynthetic mesh that can be used for abdominal wall reconstruction. Theoretically, it allows for an initial and temporary transfer of weight-bearing tension from the native abdominal wall during the healing process. As the mesh is absorbed, the healing abdominal wall gradually starts to bear the load of the natural abdominal wall⁽¹⁾. With these properties, the P4HB mesh can have the best of both worlds: strength and flexibility associated with synthetic meshes, a completely yet slowly absorbable material, and overall better performance in infected fields^(7,8). In this study, we describe our center initial experience and propose safe indications for the use of P4HB mesh for abdominal wall reconstruction.

METHODS

Study design

This is a descriptive, retrospective study with patients who underwent abdominal wall repair with a P4HB mesh from October 2018 to December 2020 in an academic center. Patients submitted to open, laparoscopic, or robotic hernia repair were included in our cohort. This study was approved by the Institution Review Board number #2020-11160 and all HIPPA compliant mechanisms were followed.

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Data collection

Data were collected and divided in five sections: patient characteristics, indication for the P4HB mesh use, preoperative data, intraoperative data, and patient outcomes. Patient demographics and comorbidities were analyzed: age, sex, body mass index (BMI), diabetes mellitus (DM), hypertension, chronic obstructive pulmonary disease (COPD), smoking status, immunosuppression, steroid use, inflammatory bowel disease (IBD), hypoalbuminemia, number of prior abdominal surgeries, prior use of Botox™, and ASA class.

For preoperative data we collected information regarding history and chronicity of hernia, type of hernia (e.g., parastomal, incarcerated, etc.), and history and complexity of prior hernia repairs (e.g., takedown of enterocutaneous fistulae, panniculectomy, or open abdomen). We collected the Centers for Disease Control (CDC) wound classification for each case use. Intraoperative and postoperative data consisted of type of the approach, the use of drains, fixation of the mesh, duration of the surgery, length of stay, complications, readmissions, mesh removal, and death.

Statistical analysis

A descriptive analysis was performed. Continuous variables (age, BMI, length of stay, duration of surgery, number of prior abdominal wall surgeries) were reported as mean, standard deviation and range. Categorical variables were reported as frequencies and percentages. Data were analyzed using the SPSS v.26 Chicago: SPSS Inc.

RESULTS

A total of 51 patients underwent abdominal wall reconstruction between October 2018 and December 2020. All patients received P4HB mesh, Phasix (Bard) or Phasix ST (Bard), the coated version with Sepra® technology when contact with abdominal viscera was present. Patient sociodemographic characteristics and comorbidities are reported in TABLE 1. The main indication for P4HB mesh use was clean-contaminated, contaminated, and infected field in 29 (57%). This was followed by patient refusal to permanent mesh in 7 (14%), 6 (12%) high-risk patients, and visceral protection of a second mesh in five patients (10%), (TABLE 2). TABLE 3 shows operative data. Forty-seven patients presented with complex hernia history such as incarceration, enterocutaneous fistulas, open abdomen, or prior infected mesh. Forty one percent of the cases were performed on a clean surgical field. Six (12%) patients had botulinum toxin A (BTA) injection prior to surgery. Most hernias were ventral (86%), open surgery was performed in 53% of the cases, and a sublay was the most common mesh position (58%). Traumatic fixation with sutures and/or tacks was used in 49 (86%) cases. TABLE 4 shows postoperative results. Median length of stay (LOS) was 3 days (range 1–33). There were no early recurrences (<30 days) and two total recurrences (4%); one 11 months and the other at 18 months. One mesh (2%) was explanted during a reoperation due a non-mesh related complication. Two patients (4%) died due to non-mesh related reasons. The median follow up was 105 days (range 8–648).

DISCUSSION

In our study, we categorized each case use into six different indications for the use of P4HB mesh during abdominal wall reconstruction (TABLE 2). Our study demonstrates its use in select

TABLE 1. Patients characteristics.

Total: 51 patients	N (%)	Range
Mean age (years)	54.4	12–89
Female	31 (61)	
Male	20 (39)	
Mean BMI	30.5	17.2–50.6
Comorbidities		
HTN	24 (47)	
DM	12 (24)	
Smoking	9 (18)	
Hypoalbuminemia	8 (16)	
CAD	6 (12)	
Immunosuppression	4 (8)	
Steroid use	3 (6)	
IBD	2 (4)	
ASA		
1	2 (4)	
2	22 (43)	
3	24 (47)	
4	3 (6)	

BMI: body mass index (kg/m²); HTN: hypertension; DM: diabetes mellitus; CAD: coronary artery disease; IBD: inflammatory bowel disease; ASA: American Society of Anesthesiology score.

TABLE 2. Indications for the use of P4HB mesh.

	N (%)
Clean-contaminated / contaminated / infected field	29 (57)
Patient refusal to permanent mesh	7 (14)
High risk patient	6 (12)
Protection of second mesh	5 (10)
Chronic pain and recurrence	3 (10)
Childhood	1 (2)

patients may have favorable short-term results with low rates of surgical site occurrences (SSO). Many studies have shown the use of P4HB mesh in different abdominal wall locations and in different wound environments; these studies mainly center around the repair of complex ventral or incisional hernias^(1,7-15). Only one study, which exclusively looked at laparoscopic procedures, reported the use of PBH4 in the repair of inguinal hernias⁽¹²⁾. In our cohort, most repairs were indeed of ventral hernia defects (44 primary and 27 incisional), nonetheless we also included nine inguinal and two parastomal hernia repairs.

Hernia repairs in the setting of contaminated and clean contaminated surgical fields have long been a challenging problem for surgeons. For one, the use of permanent mesh has classically been associated with higher rates of infection when used in these

TABLE 3. Operative data.

	N (%)	Range
Preoperative findings		
Prior repair	23 (45)	
Incarceration	11 (22)	
Enterocutaneous fistula	10 (20)	
Open abdomen	2 (4)	
Prior infected mesh	1 (2)	
CDC wound classification		
Class 1	22 (41)	
Class 2	17 (35)	
Class 3	7 (12)	
Class 4	5 (10)	
Associated panniculectomy	19 (37)	
Surgical Approach		
Open	27 (53)	
Robotic	19 (37)	
Laparoscopic	5 (10)	
Hernia type		
Primary Ventral (umbilical, epigastric)	44 (54)	
Ventral Incisional	27 (33)	
Inguinal	9 (11)	
Parastomal	2 (2)	
Mesh position		
Onlay	16 (31)	
Sublay	16 (31)	
IPOM	14 (27)	
Inlay	5 (10)	
Phasix ST™ Mesh (coated)	21 (41)	
Mean defect area (cm ²)	81	2–600
Mean mesh area (cm ²)	270.4	9–875
Intraoperative complications	5 (10)	
Drain placement	21 (43)	
Types of mesh fixation		
Sutures	33 (65)	
Tackers + suture	12 (24)	
Tackers	4 (8)	
Glue	1 (2)	
No	1 (2)	

CDC: centers for disease control and prevention wound classification; IPOM: intraperitoneal onlay mesh.

TABLE 4. Postoperative results.

	N (%)	Range
Median LOS (days)	3	1–33
Complications within 30 days		
No	29 (56.8)	
Seroma	10 (19.6)	
Infection – SSI	7 (13.7)	
Hematoma	2 (4.1)	
Evisceration	1 (2)	
Enterocutaneous fistula	1 (2)	
Partial SBO	1 (2)	
Readmission in 30 days	9 (18.4)	
Hernia recurrence	2 (4.1)	
Mesh explantation	1 (2)	
Median Follow up (days)	105	8–648

LOS: length of stay; SSI: surgical site infection; SBO: small bowel obstruction.

bacteria-laden surgical fields^(16,17). The development of biologic mesh promised an improved performance in contaminated fields and a feasible alternative to the poorly performing synthetic mesh that was commercially available. However, early studies showed that while these meshes did perform better in infected fields, they also harbored a significantly higher rate of recurrence in the long run. In fact, the RICH study showed a recurrence rate of 28% after 2 years of follow-up using a biologic porcine graft when used in contaminated fields⁽¹⁸⁾. Furthermore, increasingly comprehensive systematic reviews published in recent years have showed comparable surgical site complication rates between biologic and synthetic meshes in potentially contaminated fields^(19,20). Thus, with a significantly higher cost, questionable bacterial clearance, and a higher-than-expected rate of recurrence, biologic mesh has not been widely adopted^(18,21-24).

Synthetic absorbable meshes, such as P4HB have gained traction as another viable alternative to permanent synthetic mesh in contaminated and clean contaminated fields. P4HB is a synthetic absorbable polymer derived from transgenic *E. coli*. It degrades through natural hydrolysis and is reported to retain its tensile strength for at least 6 months, even in the setting of an active infection^(7,25). It is completely resorbed at 18 months with vascular and tissue incorporation at 52 weeks. This specific property means that the tensile strength of the mesh is greater than the original abdominal wall would be 6 weeks after repair⁽⁸⁾. These characteristics of the biosynthetic implants are especially important in complex repairs in contaminated field or need of previous mesh removal.

In our study, the main indication for the use of P4HB mesh was the presence of a contaminated or infected field. Our most common case scenarios included patients requiring an ostomy, enterocutaneous fistula takedown, hysterectomy, myomectomy, prostatectomy, strangulated omentum, small bowel resection and colectomy. In our cohort there were 29 (57%) patients with clean-contaminated, contaminated or infected wounds (CDC class 2, 3 &

4). Post-operatively, we had 7 (14%) cases of surgical site infection (SSI), six were treated with intravenous antibiotics, four required drainage, one required wound debridement due to skin necrosis, and one required a more extensive wound exploration. There was no infection related need for mesh removal, even with 35 (69%) patients presenting higher risk for SSI (CDC class 2, 3 & 4 and/or VHWG class 2 & 3). This may demonstrate the favorable performance of a biosynthetic mesh in this specific situation.

Patient refusal for permanent mesh was the second most common indication for the use of P4HB mesh in our study. Few patients do not want a synthetic permanent mesh in their bodies for a variety of reasons. A frank and detailed conversation should happen with these patients but ultimately, their wishes should be honored. It is well established that the use of reinforcing mesh is superior to primary sutured repair of incisional and inguinal hernias^(21,26). A biosynthetic P4HB mesh may be offered as an option if its advantages and disadvantages are disclosed and discussed with the patient.

A total of six patients were implanted with P4HB mesh given their exceedingly high pre-operative risk for SSI. We define high-risk patients as those with prior mesh infections, smokers, those with COPD or diabetes mellitus, morbidly obese patients with previous onlay repair, and patients with open abdomen where the mesh was intended to work as a bridge. This classification is with conformity with a grade 2 from the VHWG classification⁽²⁷⁾.

Patients with mesh related chronic pain after permanent mesh use who are presenting with hernia recurrence may also benefit from the use of a biosynthetic mesh. The mesh removal is indicated for pain improvement, but a new mesh repair is needed to approach the recurrence. The option of a tissue repair is possible, but the recurrence rates are extremely high as discussed earlier. The use of a traditional permanent mesh may confuse the outcomes of pain control, once it can be the cause for pain persistence or recurrence. An absorbable mesh may decrease recurrence without the long-term foreign body dilemma for chronic pain. A P4HB mesh may be a cost-effective alternative when compared with biologics. Three patients in our cohort presented with chronic pain and recurrence (two presenting a ventral hernia and one an inguinal hernia).

Protection of a second mesh is another indication for cases where the permanent non-coated mesh was implanted at an extra-peritoneal position, but due to technical difficulties was still exposed and would otherwise be in contact with the abdominal viscera. This usually happens in challenging situations where there is no peritoneal flap to cover the extraperitoneal non-coated permanent mesh due to the nature of the case. To avoid a second permanent coated mesh and its known complications, a P4HB coated mesh with ST barrier was used to protect it in an inlay position to bridge the peritoneal defect.

The last indication of P4HB was in a 12-year-old child with a recurrent inguinal hernia who was being investigated for a connective tissue disorder. Despite his age, the patient had an adult body habitus and the pediatric surgery team felt uncomfortable operating on him. The surgical team discussed with the patient and his family regarding the use of a biosynthetic mesh and the minimally invasive repair. Despite the open repair being the gold

standard in the pediatric population, the laparoscopic approach has been increasing in popularity. A recent meta-analysis has favored laparoscopic approach in shorter operative time for bilateral repair, superior aesthetic results, and lower chances of testicular ascent⁽²⁸⁾. The authors concluded that either technique is appropriate in clinical use and the decision should come from a shared decision-making process between the surgeon and the patient's parents.

In our cohort, we had nine inguinal hernias with no recurrences. There is scarce data in the literature regarding the use of P4HB for inguinal hernia repairs. Aldohayan and colleagues have showed its safety and feasibility in 15 adult patients submitted to a primary laparoscopic TAPP repair⁽¹²⁾. There was no recurrence among these cases at 2 years follow-up.

In our cohort, we had two total recurrences. One was a patient with a ventral hernia measuring 23 x 10 cm with a history of mesh infection. The patient had a retromuscular repair with a 30 x 15 cm mesh what suggest a possible non adequate mesh size for overlap. The recurrence was on the superior border of the previous defect, and it was treated with a new repair with an onlay polypropylene mesh. The second recurrence was in an obese patient with an intra-peritoneal robotic repair with adequate overlap (defect of 7 x 7 cm and a mesh of 25 x 20 cm). The recurrence was in the suprapubic area. This patient is being prepared for a new approach.

Most studies using P4HB mesh have a mean follow-up varying from 18 to 36 months^(7,9) with recurrence rates up to 17%⁽⁷⁾ seroma up to 13% and SSI up to 13%^(1,9). Our median follow-up was 3.5 months (105 days, range 8–648) which does not allow us to evaluate long-term results and complications.

Limitations of the study

This study has several limitations. It is a retrospective, single center study with no comparison group to evaluate outcomes with other types of mesh, a small sample size (n=51) and a short follow up period.

CONCLUSION

This study has demonstrated the versatility of P4HB biosynthetic mesh in a small cohort of patients. P4HB mesh was a safe and viable alternative in complex clinical scenarios with an overall low rate of complications in the short-term.

Author's contribution

Study design: F Malcher, P Sreeramoju, DL Lima. Data collection and analysis: DL Lima, X Pereira, A Estrada, A Alcabes. Manuscript preparation and editing: DL Lima, X Pereira, A Alcabes, P Sreeramoju, A Estrada, F Malcher.

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Lima DL, Estrada A, Pereira X, Alcabes A, Sreeramoujo P, Malcher F. Versatilidade da tela de 4-Polihidroxibutirato (Phasix™) em cirurgia de parede abdominal. *Arq Gastroenterol.* 2022;59(2):226-30.

RESUMO – Contexto – 4-Polihidroxibutirato (P4HB) é um polímero natural derivado da *E. coli* transgênica que tem a mais longa taxa de degradação quando comparado a outros produtos. Este polímero é manufaturado como uma tela bio sintética a ser usada como um reforço no reparo de uma variedade de defeitos de parede abdominal. **Objetivo** – O objetivo deste estudo é descrever nossa experiência inicial com esta tela e discutir suas possíveis indicações. **Métodos** – Estudo retrospectivo e descritivo com pacientes que foram submetidos a cirurgia de reconstrução de parede abdominal de outubro de 2018 a dezembro de 2020 em um grande centro acadêmico. **Resultados** – Cinquenta e um pacientes, média de 54,4 anos (12–89) foram submetidos a reconstrução da parede abdominal com tela de P4HB entre outubro de 2018 e dezembro de 2020. O índice de massa corpórea médio foi de 30,5 kg/m²(17,2–50,6). Vinte e três pacientes (45%) tinham cirurgia prévia de hérnia no mesmo local. Nós agrupamos pacientes em seis diferentes indicações para o uso da tela de P4HB: campo limpo-contaminado, contaminado, infectado (57%), recusa do paciente em telas permanentes (14%), pacientes com alto risco de infecção no pós-operatório (12%), proteção visceral de contato com outra tela (10%), recidiva da hérnia associada com dor crônica relacionada a tela anterior (6%) e pacientes pediátricos (2%). O seguimento mediano foi de 105 dias (8–648). Dois pacientes tiveram recidiva (4%) e 8 (16%) desenvolveram seroma. **Conclusão** – O uso da tela de P4HB se mostrou uma alternativa segura e viável com baixa taxa de complicações para estes pacientes no curto prazo.

Palavras-chave – Hérnia; recidiva; infecção; tela bio sintética; 4-Polihidroxibutirato.

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