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Prospective evaluation of poly-4-hydroxybutyrate mesh in CDC class I/high-risk ventral and incisional hernia repair: 18-month follow-up

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Abstract

Background Long-term resorbable mesh represents a promising technology for complex ventral and incisional hernia repair (VIHR). Preclinical studies indicate that poly-4-hydroxybutyrate (P4HB) resorbable mesh supports strength restoration of the abdominal wall. This study evaluated outcomes of high-risk subjects undergoing VIHR with P4HB mesh.

Methods This was a prospective, multi-institutional study of subjects undergoing retrorectus or onlay VIHR. Inclusion criteria were CDC Class I, defect 10–350 cm^2, ≤ 3 prior repairs, and ≥ 1 high-risk criteria (obesity (BMI: 30–40 kg/m^2), active smoker, COPD, diabetes, immunosuppression, coronary artery disease, chronic corticosteroid use, hypoalbuminemia, advanced age, and renal insufficiency). Physical exam and/or quality of life surveys were performed at regular intervals through 18 months (to date) with longer-term, 36-month follow-up ongoing.

Results One hundred and twenty-one subjects (46M, 75F) with an age of 54.7 ± 12.0 years and BMI of 32.2 ± 4.5 kg/m^2 (mean $\pm$ SD), underwent VIHR. Comorbidities included the following: obesity ($n = 95$, 78.5%), hypertension ($n = 72$, 59.5%), cardiovascular disease ($n = 42$, 34.7%), diabetes ($n = 40$, 33.1%), COPD ($n = 34$, 28.1%), malignancy ($n = 30$, 24.8%), active smoker ($n = 28$, 23.1%), immunosuppression ($n = 10$, 8.3%), chronic corticosteroid use ($n = 6$, 5.0%), advanced age ($n = 6$, 5.0%), hypoalbuminemia ($n = 3$, 2.5%), and renal insufficiency ($n = 1$, 0.8%). Hernia types included

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the following: primary ventral ($n=17$, 14%), primary incisional ($n=54$, 45%), recurrent ventral ($n=15$, 12%), and recurrent incisional hernia ($n=35$, 29%). Defect and mesh size were 115.7 ± 80.6 and 580.9 ± 216.1 cm^2 (mean ± SD), respectively. Repair types included the following: retrorectus ($n=43$, 36%), retrorectus with additional myofascial release ($n=45$, 37%), onlay ($n=24$, 20%), and onlay with additional myofascial release ($n=8$, 7%). 95 (79%) subjects completed 18-month follow-up to date. Postoperative wound infection, seroma requiring intervention, and hernia recurrence occurred in 11 (9%), 7 (6%), and 11 (9%) subjects, respectively.

Conclusions High-risk VIHR with P4HB mesh demonstrated positive outcomes and low incidence of hernia recurrence at 18 months. Longer-term 36-month follow-up is ongoing.

Keywords Hernia repair · Recurrence · Infection · Poly-4-hydroxybutyrate · Mesh · Seroma

Despite significant advancements over the past several decades, ventral hernia repair continues to be plagued by the complex interplay between patient comorbidities, surgical technique, and biomaterial characteristics. Patients with comorbidities such as obesity, diabetes, chronic obstructive pulmonary disease (COPD), coronary artery disease, immunosuppression, smoking, advanced age, hypoalbuminemia, and chronic corticosteroid use experience more frequent complications such as postoperative infection and incur greater costs associated with their care [1–3]. Differences in surgical technique such as fascial closure [4, 5], mesh placement [5–7], and fixation [8, 9] have all been shown to influence outcomes, with no clear consensus on the optimal combination. Over the last decade, the use of biological tissue-derived prosthetics has become increasingly common, particularly in clean-contaminated and contaminated cases [10]. Initially, it was hypothesized that rapid remodeling of these materials would reduce bacterial contamination and prevent wound complications compared to permanent synthetic prosthetics, which are commonly regarded as contraindicated in these settings [3]. However, the substantial cost and unclear clinical benefit ultimately reported for these materials has more recently led surgeons to question their routine use in complex ventral hernia repair [11–13].

As an alternative, resorbable synthetic biomaterials have evolved due to the need for cost-effective, efficacious solutions to repair the abdominal wall in patients in which synthetic mesh materials are not desired. Resorbable synthetic prosthetics comprise a variety of polymers including polyglycolide, polylactide, trimethylene carbonate, silk, and poly-4-hydroxybutyrate [14–18]. These materials, manufactured with consistent material characteristics, lack the issues of disease transmission, allergic reaction, or religious/cultural concerns associated with implantation of human- or animal-derived products [19]. Devices in this category offer short-term mechanical support prior to polymer resorption. As the polymer is resorbed, the load is transferred back to the patient's native tissue. Poly-4-hydroxybutyrate (P4HB) mesh has unique properties with a resorption time of 12–18 months and represents a promising biomaterial for abdominal wall hernia repair [14, 20, 21].

Phasix™ Mesh comprises P4HB fibers that have been knitted to form a mesh construct with preimplantation characteristics similar to commonly used permanent synthetic meshes [14, 21]. Phasix™ Mesh has been evaluated in several preclinical studies in the retromuscular, preperitoneal plane of a large animal model with long-term survival [20–22], in which mesh-repaired sites maintained a consistent strength profile between 6 and 52 weeks that was significantly stronger than the native porcine abdominal wall [20]. Additionally, mesh weight decreased significantly over the course of the 52-week study, indicating active resorption of the polymer. Martin et al. confirmed this finding with observed bulk degradation of the Phasix™ Mesh polymer fibers, a decrease in fiber diameter, and a significant reduction in molecular weight over the course of a 72-week porcine study [21]. Evidence of degradation was visible in specimens retrieved at 48 weeks, and only small fragments were recovered at 72 weeks. Mechanical testing revealed nearly identical strength between the native abdominal wall and Phasix™ Mesh-repaired sites procured at 72 weeks post-implantation, confirming that the mesh did not contribute significantly to the strength of the porcine abdominal wall at that time point. Data from these preclinical studies demonstrate that P4HB mesh contributes mechanical support to the abdominal wall up to approximately 12 months (i.e., 48 and 52 weeks) and continues to resorb until it is essentially fully resorbed at 18 months [20, 21].

Therefore, the objective of this study was to evaluate rates of hernia recurrence, surgical site infection (SSI), and seroma 18 months following ventral hernia repair with Phasix™ Mesh in subjects at high risk for postoperative complications.

Materials and methods

Study design

This study represents a prospective, multicenter, open-label study designed to assess the safety, performance, and outcomes of Phasix™ Mesh (C.R. Bard, Inc., Warwick, RI) for primary ventral, primary incisional, or multiple-recurrent hernia repair in subjects at high risk for complications (ClinicalTrials.gov/NCT01961687). Subjects were considered at

high risk for complications if they had one or more of the following comorbidities: body mass index (BMI) between 30 and 40 kg/m^2 (inclusive), active smokers, chronic obstructive pulmonary disease (COPD), diabetes mellitus, immunosuppression, coronary artery disease, chronic corticosteroid use (> 6 months systemic use), hypoalbuminemia (preoperative serum albumin < 3.4 g/dL), advanced age (≥ 75 years), or renal insufficiency (serum creatinine concentration ≥ 2.5 mg/dL). Subjects, investigators, and surgeons were not blinded to the study treatment. The study was designed to treat 120 subjects at 16 sites throughout the United States, and the protocol was approved by the Institutional Review Board (IRB) at each institution prior to enrolling subjects. All subjects provided informed consent prior to enrollment in the study.

Inclusion/exclusion criteria

Subjects 18 years of age or older, diagnosed with primary ventral, primary incisional, or recurrent incisional hernia (not to exceed three recurrences) were evaluated for study eligibility. Study eligibility includes one or more of the comorbidities listed above, surgical wound described as Class I (defined by the Centers for Disease Control and Prevention (CDC)) [23], and a 10–350 cm^2 hernia defect that was suitable for repair via retrorectus or onlay placement of mesh (with or without additional myofascial release). Subjects were excluded from study enrollment if they met any of the following conditions: four or more previous hernia repairs (of the index repair); peritonitis; on or anticipated to be placed on chemotherapy during the study period; BMI > 40 kg/m^2, cirrhosis of the liver and/or ascites; American Society of Anesthesiology Class 4 or 5; diagnosed human immunodeficiency virus (HIV) infection; life expectancy of less than 2 years at the time of enrollment; planned intra-abdominal mesh placement or bridged repair; surgical wound designated Class II (clean-contaminated), Class III (contaminated), or Class IV (dirty-contaminated) as defined by the CDC [23] (no device is currently indicated for use in contaminated or infected fields); active or latent systemic infection; pregnant or plans to become pregnant during the study period; current breastfeeding; enrolled in another clinical study within the last 30 days; part of the site personnel directly involved with the study; known allergy to the test device or component materials; or any condition that, in the opinion of the investigator, would preclude the use of the study device, or preclude the subject from completing the follow-up requirements.

Surgical technique

All subjects were administered antibiotics according to hospital protocol and underwent open ventral hernia repair. Intraoperative inclusion and exclusion criteria were assessed and documented. Subjects that met the intraoperative eligibility criteria received Phasix™ Mesh positioned with its edges extending beyond the margins of the defect by at least 5 cm. Fixation was achieved with 6–12 resorbable sutures placed at approximately 5–6 cm intervals around the periphery of the mesh. The hernia defect was closed by approximating the fascial edges, including additional myofascial release, if required. The fascial and subcutaneous layers were closed with sutures, and the skin was closed with staples and/or sutures. Operative details including hernia defect size, mesh size, mesh position, repair technique, use of myofascial release, suture type, number of sutures to secure mesh, and procedural time were collected.

Data collection

Postoperative patient visits are scheduled at 1, 3, 6, 12, 18, 24, and 36 months and a telephone interview is conducted at 30 months. Medical history, demographic information, and all current prescription and over-the-counter (OTC) pain medications are recorded at each visit. The Pain Visual Analogue Scale (VAS) and quality of life assessments: Carolinas Comfort Scale® (CCS) and 12-Item Short Form Health Survey® (SF-12) were also completed preoperatively and at all scheduled intervals. At each visit, a physical examination was performed to assess hernia recurrence, surgical complications, and adverse events.

Study endpoints

The primary endpoints of the study include hernia recurrence and surgical site infections (SSI). Hernia recurrence was assessed by physical examination at each study visit. A recurrent hernia was defined as any hernia identified or confirmed by the investigator, during any study follow-up visit, within 7 cm of the repair. Hernia recurrence identified via incidental magnetic resonance imaging (MRI) or computed tomography (CT) scan was evaluated by the operating surgeon for clinical significance and confirmation of hernia recurrence. Surgical site infection was assessed by physical examination with confirmation by gram stain and culture. Superficial and deep surgical site infections were classified according to the CDC guidelines [24]. Device-related complications and reoperations were also recorded.

Analysis population

GraphPad Prism 6.01 statistical software was utilized to generate the descriptive statistics reported below. Frequency counts and percentages are reported for categorical variables, and mean and standard deviation are reported for continuous variables.

Results

Preoperative variables and subject demographics

To date, subjects have completed follow-up visits at 1 month (±7 days), as well as at 3, 6, 12, and 18 months (±30 days). Preoperative variables and subject demographics are shown in Table 1. A total of n = 121 subjects were enrolled in the study, with n = 95 (79%) completing 18-month follow-up to date. The majority were white (n = 115, 95%), not Hispanic/Latino (n = 113, 93%), and female (n = 75, 62%). Subjects had a mean age of 54.7 ± 12.0 years and a mean BMI of 32.2 ± 4.5 kg/m^2. The most common comorbidities included obesity (n = 95, 78.5%), hypertension (n = 72, 59.5%), cardiovascular disease (n = 42, 34.7%), diabetes (n = 40, 33.1%), COPD (n = 34, 28.1%), malignancy (n = 30, 24.8%), active smoker (n = 28, 23.1%), immunosuppression (n = 10, 8.3%), chronic corticosteroid use (n = 6, 5.0%), advanced age (n = 6, 5.0%), hypoalbuminemia (n = 3, 2.5%), and renal insufficiency (n = 1, 0.8%) (Fig. 1). Approximately, 59% of subjects presented with primary hernias (ventral: n = 17 (14%); incisional: n = 54 (45%)), while approximately 41% of the subjects presented with recurrent hernias (ventral: n = 15 (12%); incisional: n = 35 (29%)).

Operative characteristics and postoperative data

Operative characteristics are detailed in Table 2, and postoperative data are reported in Table 3. Less than 5 cm mesh overlap was reported in *n* = 10 (8.3%) subjects. Length of stay ranged from 1 to 35 days with a median of 4 days and a mean of 5.3 ± 5.3 days. NPWT was utilized in *n* = 13 (11%) subjects. Hernia recurrence was observed in *n* = 11 (9%) subjects, with *n* = 5 in the retrorectus group, and *n* = 6 in the onlay group. A total of *n* = 13 surgical site infections were reported in *n* = 11 (9%) subjects, with *n* = 4 characterized as deep infections and *n* = 9 characterized as superficial infections. A total of eight seromas required intervention in *n* = 7 (6%) subjects, with one subject experiencing two separate seromas. Ten (*n* = 10, 8%) subjects required reoperation, and

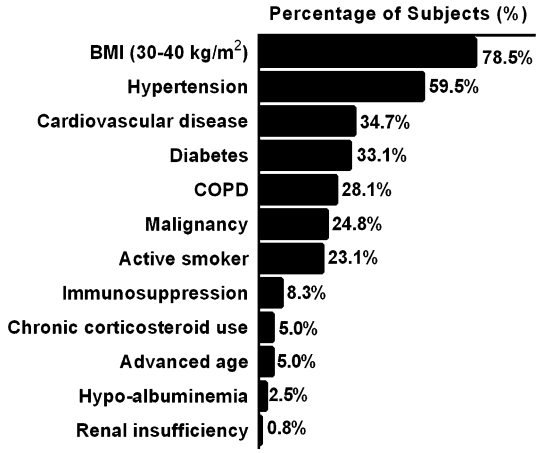

Fig. 1 Incidence of high-risk comorbid conditions (%)

Table 1 Preoperative variables: subject demographics and surgical diagnosis

Subjects enrolled, *n*	121
Subjects with 18-month follow-up, *n* (%)	95 (79%)
Sex	
Male, *n* (%)	46 (38%)
Female, *n* (%)	75 (62%)
Ethnicity	
Not Hispanic or Latino, *n* (%)	113 (93%)
Hispanic or Latino, *n* (%)	8 (7%)
Race	
Black, *n* (%)	5 (4%)
White, *n* (%)	115 (95%)
Other, *n* (%)	1 (1%)
Age (years), mean ± SD	54.7 ± 12.0
Body mass index (kg/m^2), mean ± SD	32.2 ± 4.5
Diagnosis	
Primary ventral hernia, *n* (%)	17 (14%)
Primary incisional hernia, *n* (%)	54 (45%)
Recurrent ventral hernia, *n* (%)	15 (12%)
Recurrent incisional hernia, *n* (%)	35 (29%)

Table 2 Operative characteristics: hernia defect and mesh dimensions, procedure time, and surgical approach

Defect (cm^2), mean ± SD	115.7 ± 80.6
Mesh (cm^2), mean ± SD	580.9 ± 216.1
Surgical procedure time (hrs), mean ± SD	2.8 ± 1.4
Surgical approach	
Retrorectus without MR, *n* (%)	43 (36%)
Rives–Stoppa	41
Other (preperitoneal)	1
Other (retrorectus)	1
Retrorectus with MR, *n* (%)	45 (37%)
Posterior	26
Open or endoscopic	2
Ramirez/open	15
Endoscopic/minimally invasive	2
Onlay without MR, *n* (%)	24 (20%)
Open, perforator preserving	3
Other, unspecified	4
N/A	17
Onlay with MR, *n* (%)	8 (7%)
Ramirez/open	8
Other, *n* (%)	1 (1%)
Rives–Stoppa, open, preperitoneal, right flank	1

MR myofascial release

Table 3 Postoperative data: Length of stay, primary outcomes, and secondary outcomes

Length of stay (days), mean ± SD	5.3 ± 5.3
Negative pressure wound therapy, *n* (%)	13 (11%)
Hernia recurrence, *n* (%)	11 (9%)
Retrorectus, *n*	5
Onlay, *n*	6
Surgical site infection, *n* (%)	11 (9%) 13 total events
Superficial, *n* (events)	9
Deep, *n* (events)	4
Seroma (requiring intervention), *n* (%)	7 (6%) 8 total events
Rate of reoperation, *n* (%)	10 (8%)
Device-related adverse events, *n* (%)	11 (9%)
Incisional hernia	6
Postoperative wound infection	1
Procedural pain	1
Pyrexia	1
Seroma	1
Small intestinal obstruction	1

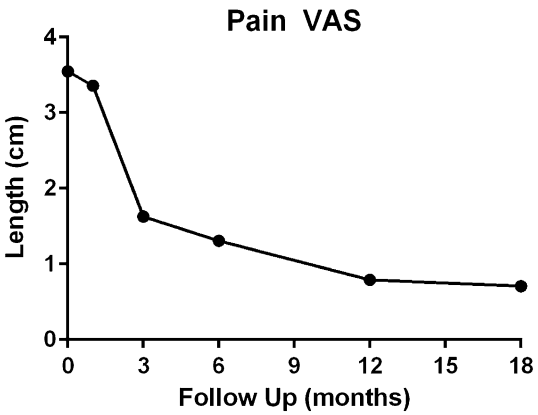

Fig. 2 Pain Visual Analogue Scale (VAS) results (cm) depicted over time (months)

$n = 11$ (9%) subjects experienced adverse events that were characterized as definitely or possibly related to the device. These events included incisional hernia ($n = 6$), postoperative wound infection ($n = 1$), procedural pain ($n = 1$), pyrexia ($n = 1$), seroma ($n = 1$), and small intestinal obstruction ($n = 1$). VAS scores decreased over time (Fig. 2).

Discussion

This prospective, multicenter study described clinical outcomes associated with Phasix™ Mesh after primary ventral, primary incisional, or multiple-recurrent hernia repair in subjects with Class I (clean) wounds at high risk for complications.

Synthetic mesh has been widely accepted as the gold standard for incisional hernia repair following the landmark publication by Burger et al. [25] demonstrating a reduction in recurrence rates in patients with mesh compared to suture. Despite its benefits, synthetic mesh has been associated with complications including infection, migration, erosion, and adhesions which offset the benefits of the reduced incidence of hernia recurrence [26]. Biologic meshes have been advocated by some authors as an alternative to synthetic mesh in selected patient populations, generally in patients with increased risk of wound complications or increased levels of wound contamination [5]. However, the cost of biologic mesh hernia repair is significantly greater than synthetic mesh [27] with tremendous variability in reported outcomes [28, 29]. In a 2016 meta-analysis of biologic mesh hernia repair in potentially contaminated hernia repairs, the recurrence rates between synthetic and biologic mesh were comparable, while surgical site infections were more common in biologic mesh repairs [30]. Studies comparing synthetic and biologic mesh in contaminated fields are lacking, although synthetic mesh use in contaminated hernias has been reported with short-term mesh removal rates of less than 5% [31]. While the majority of patients undergoing contaminated hernia repair may tolerate synthetic mesh placement, those patients with postoperative infections incur significantly greater costs in the perioperative period [32].

The purpose of this study was to evaluate the use of P4HB mesh in patients with a clean wound classification but deemed to be at increased risk of wound complications based upon selected criteria.

Studies with a similar patient population to the current study are lacking, limiting comparisons of the current study to previously reported data. Other groups have reported outcomes (Table 4) associated with resorbable synthetic [7], biological tissue-derived [5], or permanent synthetic meshes [31]. Unlike the current study, however, these studies involved intraperitoneal mesh placement; [5, 7] "bridging" techniques without fascial closure; [5] clean-contaminated [5, 7, 31], contaminated [5, 7, 31], or dirty wounds [5]; and longer follow-up periods [5, 7], limiting comparisons across studies.

A recent publication evaluated the outcomes of a polyglycolic acid/trimethylene carbonate absorbable mesh in the repair of abdominal wall hernias (#NCT01325792) [7]. In this prospective, multicenter study, a synthetic resorbable mesh (Gore® Bio-A® Tissue Reinforcement, W.L. Gore & Associates, Inc., Flagstaff, AZ) was implanted in $n = 104$ subjects in a retrorectus or intraperitoneal fashion in clean-contaminated or contaminated cases. Hernia recurrence, SSI, and quality of life were assessed at 30 days and at 6, 12, and 24 months, with 84% of subjects completing the

Table 4 Comparison of current study to several previous studies

	Roth (current study)	Rosen (COBRA study)	Itani (RICH study)	Carbonell
Number of subjects	121	104	80	100
Type of mesh	Resorbable synthetic	Resorbable synthetic	Biological tissue-derived	Permanent synthetic
Composition of mesh	Poly-4-hydroxybutyrate (P4HB)	67% polyglycolic acid (PGA) 33% trimethylene carbonate (TMC)	Non-crosslinked porcine dermis	Polypropylene (PP)
Trade name	Phasix™ Mesh (C. R. Bard, Inc., Warwick, RI)	Gore® Bio-A® Tissue Reinforcement (W. L. Gore & Associates, Inc., Flagstaff, AZ)	STRATTICE™ Reconstructive Tissue Matrix (LifeCell Corp., Branchburg, NJ)	Ultrapro® (Ethicon Inc., Somerville, NJ) Prolene® Soft (Ethicon Inc., Somerville, NJ) Bard® Soft Mesh (C. R. Bard, Inc., Warwick, RI)
Surgical technique	Retrorectus (73%) Onlay (26%) Fascial closure (94%)	Retrorectus (90%) Intraperitoneal (10%) Fascial closure (100%)	Retrorectus (36%) Intraperitoneal (60%) Fascial closure (80%)	Retrorectus (94%) Fascial closure (91%)
Wound class	Clean	Clean-contaminated Contaminated	Clean-contaminated Contaminated Dirty	Clean-contaminated Contaminated
Comorbid conditions	Obesity (79%) Diabetes (33%) COPD (28%) Active smoker (23%) Coronary artery disease (22%) Immunosuppression (8%) Chronic corticosteroid use (5%) Advanced age (5%) Hypoalbuminemia (3%) Renal insufficiency (1%)	Obesity (34%) Diabetes (18%) COPD (11%) Active smoker (19%) Previous abdominal wall infection (35%) Inflammatory bowel disease (26%)	Obesity (23%) Diabetes (21%) COPD (16%) Active smoker (18%) Previous abdominal wound infection (34%) Past abdominal aortic aneurysm (9%) Prior ventral hernia repair (64%) Enterocutaneous fistula (9%)	Diabetes (24%) COPD (13%) Active smoker (16%) Prior smoker (21%)
Longest follow-up reported	18 months	24 months	24 months	Retrospective 10.8 ± 9.9 months (mean ± SD) range: 1–63 months
Hernia recurrence rate	9%	17%	19% (12 months) 28% (24 months)	7%
Surgical site infection	9%	18%	35%	14% (at 30 days)
Seroma requiring intervention	6%	3%	6%	5% (at 30 days)
Quality of life	Improved over baseline	Improved over baseline	Improved over baseline	Not evaluated
Rate of reoperation	8%	Not reported	9%	12%

24-month follow-up visit. A 17% Kaplan–Meier hernia recurrence rate was reported, along with 18% SSI, and significantly improved quality of life scores at 24 months.

Similarly, Itani et al. reported the results of the Repair of Infected or Contaminated Hernias (RICH) study (NCT#00771407) [5]. This was also a prospective multicenter study. A biological tissue-derived scaffold (non-crosslinked porcine dermis, STRATTICE™ Reconstructive Tissue Matrix, LifeCell Corp., Branchburg, NJ) was implanted in $n = 80$ subjects in a retrorectus or intraperitoneal fashion in clean-contaminated, contaminated, or dirty cases. Hernia recurrence, SSI, and quality of life were assessed at 30 days and at 6, 12, and 24 months, with 75% of subjects completing the 24-month follow-up visit. By 12 months, hernia recurrences were documented in 19% of subjects, and by 24 months, hernia recurrences reached 28%. It should be noted that "bridged" repairs without fascial closure were performed in 20% of subjects in the RICH study. When the recurrences were analyzed by surgical technique, hernia recurrences fell to 23% when fascial closure was

achieved compared to 44% without fascial closure, underscoring the importance of operative technique on outcomes such as hernia recurrence. At 24 months, seromas requiring intervention and surgical site infections were documented in 6% and 35% of subjects, respectively. As with the COBRA study, quality of life scores in the RICH study were also significantly improved over baseline at all follow-up visits.

In a retrospective, multicenter study, Carbonell et al. reported outcomes associated with the use of permanent lightweight polypropylene meshes in n = 100 subjects in clean-contaminated or contaminated cases [31]. Meshes included the following: Ultrapro® (Ethicon, Inc., Somerville, NJ), Prolene® Soft, (Ethicon, Inc., Somerville, NJ), and Bard® Soft Mesh (C. R. Bard, Inc., Warwick, RI). A retrorectus technique was employed, and fascial closure was achieved in 91% of subjects. Recurrences were documented in just 7% of cases. However, the follow-up period was relatively short, with a mean of only 11 months. Similarly, the rate of SSI (14%) and seroma (5%) were reported at just 30 days in the Carbonell study and limit comparisons with other studies with longer follow-up.

In the current study, Phasix™ Mesh exhibited similar rates of hernia recurrence, SSI, and seroma (9, 9, and 6%, respectively) as permanent polypropylene meshes (7, 14, and 5%, respectively) [31], and lower hernia recurrence rate compared to a resorbable synthetic mesh (Bio-A® = 17% at 24 months) [7] and a biological tissue-derived scaffold (STRATTICE™ = 19 and 28% at 12 and 24 months) [5]. Furthermore, Phasix™ Mesh exhibited a lower rate of SSI in the current study compared to a resorbable synthetic mesh (Bio-A® = 18% at 24 months) [7] and a biological tissue-derived scaffold (STRATTICE™ = 35% at 24 months) [5]. However, differences in study design, inclusion/exclusion criteria, and surgical technique in each of these studies limit the ability to draw definitive conclusions regarding the comparative efficacy.

In the current study, the incidence of postoperative surgical site infection was 9%, of which, no patients required mesh removal. Postoperative surgical site infection is the most expensive complication of abdominal wall hernia repair with increasing costs associated with deep and organ space infections [28]. Recognizing the significant costs associated with mesh infections, strategies to identify patients at greatest risk with implementation of strategies to reduce the financial and clinical burden are essential. Although not all postoperative infections are preventable, the use of an absorbable mesh for patients at highest risk for surgical site infections may be part of a strategy to reduce costs associated with mesh infections. Further studies evaluating the economic impact of hernia repair with absorbable meshes are required.

Several limitations of the current study should be acknowledged. First, the lack of a control group prevents direct comparison of the outcomes associated with Phasix™ Mesh to another biomaterial. Second, only Class I (clean) wounds were included in this study. It is unknown how Phasix™ Mesh may perform in clean-contaminated, contaminated, or dirty wounds. Finally, the results of this study are reported after a relatively short 18-month follow-up period. However, preclinical studies have shown that Phasix™ Mesh contributes mechanical support for the first 12 months (48–52 weeks) and is essentially fully resorbed by 18 months [20, 21]. Thus, a follow-up period of 18 months in the current study provides assessment of hernia recurrences 6 months after Phasix™ Mesh is expected to cease providing mechanical support to the abdominal wall.

In conclusion, this prospective, multicenter study demonstrated promising outcomes for Phasix™ Mesh at 18 months post-implantation, with low rates of hernia recurrence, SSI, seroma, reoperation, and adverse events when utilized to repair primary ventral, primary incisional, or multiple-recurrent hernias in subjects at high risk for complications.

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Compliance with ethical standards

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