Comparative Outcomes of Bioabsorbable Poly-4-hydroxybutyrate Versus Synthetic Mesh in Ventral Hernia Repair: A Retrospective Matched Cohort Study

Kartik S Akkihal, Kelly M Dickerson, Anya Ittiruck, Gerald O Ogola, Christine Wang, Mazen Iskander, Steven G Leeds, Marc A Ward, Bola Aladegbami

Baylor Scott & White Baylor University Medical Center Dallas

Texas A&M University College of Medicine

Introduction

The current standard of care to prevent hernia recurrence involves placement of permanent synthetic mesh, which is both durable and cost-effective. *However, synthetic mesh is associated with a significant side effect profile, including:*

- Mesh infection requiring explantation
- Enterocutaneous fistula formation
- Chronic pain and foreign body sensation

To address infection risk in contaminated repairs, biologic mesh was developed. However, randomized controlled trials have demonstrated:

- Approximately 2-3x higher recurrence
- 20-fold higher cost compared to synthetic mesh
- No actual reduction in infection complications

Bioabsorbable Mesh as a Solution:

Poly-4-hydroxybutyrate (Phasix) mesh was developed as a biosynthetic alternative that theoretically combines the benefits of both synthetic and biologic mesh by:

1. Providing mechanical support during the healing phase
2. Completely resorbing over 12-18 months
3. Minimizing chronic mesh-related complications

The Selection Bias Problem:

Emerging evidence shows that Phasix and other biosynthetic meshes are preferentially selected for more challenging cases:

- Larger hernia defects
- Higher Ventral Hernia Working Group (VHWG) grades
- Greater wound contamination (higher CDC wound class)

This systematic selection bias makes direct outcome comparisons with synthetic mesh unreliable, as worse outcomes may reflect case complexity rather than mesh performance.

Study Gap:

Only two prior studies have used propensity score matching to address this bias, with conflicting results. This study aims to provide a more accurate comparison of Phasix versus synthetic mesh performance when case complexity is balanced.

Methods

Study Design: Retrospective cohort study using a prospectively maintained database at a single tertiary-care center

Study Period: 2014 to January 2025

Inclusion Criteria: Adult patients (≥18 years); Underwent ventral hernia repair; Received synthetic, biologic, or bioabsorbable Phasix mesh; Complete perioperative data available

Study Population: A total of 403 patients underwent ventral hernia repair

Phasix mesh: 45 patients

Biologic mesh: 22 patients (excluded from matching due to small sample size)

Synthetic mesh: 336 patients

Variables Collected:

Demographics: Age, sex, body mass index

Comorbidities: Diabetes mellitus, hypertension, COPD, obstructive sleep apnea, inflammatory bowel disease, cancer history, end-stage renal disease, prior thrombosis

Hernia :Characteristics Defect size (cm²), mesh size (cm²), VHWG grade (1-4), CDC wound class (1-4)

Operative Variables: Operative time, mesh type

Primary Outcomes: Hernia recurrence, 30-day postoperative complications

Secondary Outcomes: Mesh infection, Fistula recurrence, Time to hernia recurrence, Specific 30-day complications: SSI, SSO, reoperation, ileus, SBO, renal failure, pulmonary complications, ICU transfer, mortality, readmission

Propensity Score Matching:

One-to-one matching of Phasix to synthetic mesh patients

Matching variables: Age, sex, BMI, diabetes status, CDC wound class, VHWG grade, hernia size

Result: 25 matched pairs (50 total patients)

Balance assessed by comparing baseline variable distributions

Statistical Analysis:

Continuous variables: mean ± SD (normal) or median [IQR] (non-normal)

Categorical variables: frequencies and percentages

Statistical significance: two-sided tests, p<0.05

Software: R version 4.0.3

Results

Unmatched Cohort Demonstrates Selection Bias:

Table 1. Pre-Match Comparison: Evidence of Selection Bias

Variable	Phasix (n=45)	Synthetic (n=336)	p-value
Hernia Characteristics			
Median hernia size	150 cm²	41 cm²	<0.01
Median mesh size	864 cm²	162 cm²	<0.01
VHWG Grade 3-4	43%	6%	<0.01
CDC Class 3-4	24%	1%	<0.01
Operative Complexity			
Mean operative time	308 min	177 min	<0.01
Unmatched 30-Day Complications			
Reoperation	18%	5%	<0.01
Ileus	13%	2%	<0.01
Small bowel obstruction	7%	0.30%	<0.01

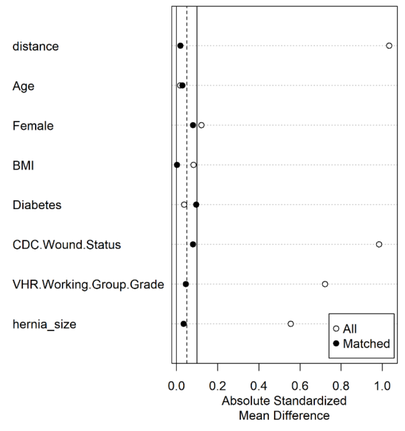
Phasix patients had 3.7× larger hernias, required nearly 5× larger mesh, and experienced significantly longer operative times. The apparent excess morbidity in this unmatched comparison reflects case complexity, not mesh inferiority.

Matched Cohort: Similar Outcomes When Case Complexity Balanced:

Table 2. Primary and Secondary Outcomes After Propensity Matching

Outcome	Phasix (n=25)	Synthetic (n=25)	p-value
Primary Outcomes			
Hernia recurrence	4% (1/25)	8% (2/25)	0.55
Mesh infection	0% (0/25)	8% (2/25)	0.15
Wound Complications			
30-day SSI	**0%** (0/25)	**16.7%** (4/24)	**0.04**
30-day SSO	**4.2%** (1/24)	**33.3%** (7/21)	**0.01**
Other 30-Day Outcomes			
Reoperation	8% (2/25)	12% (3/25)	0.64
Ileus	12% (3/25)	4% (1/25)	0.3
Small bowel obstruction	8% (2/25)	0% (0/25)	0.15
Readmission	12% (3/25)	4% (1/25)	0.3
Mortality	0% (0/25)	4% (1/25)	0.31

Figure 1. Distribution of matching variables before and after propensity score matching:



Key Findings:

1. Comparable recurrence: No significant difference in hernia recurrence between groups (4% vs 8%, p=0.55)
2. Lower wound complications with Phasix: Significantly reduced surgical site infections (0% vs 16.7%, p=0.04) and surgical site occurrences (4.2% vs 33.3%, p=0.01)
3. Similar other complications: Reoperation, ileus, readmission, and mortality rates were statistically similar

Mean Follow-up: 12 months for both groups

Operative Time (Matched): 251 ± 85 min (Phasix) vs 263 ± 119 min (synthetic), p=0.73

Discussion

1. Phasix is Systematically Reserved for Complex Cases

Our institutional experience mirrors national practice patterns.

Phasix was preferentially used in patients with:

- 3.7× larger hernia defects (150 cm² vs 41 cm²)
- Higher contamination (24% vs 1% CDC class 3-4)
- More complex repairs (43% vs 6% VHWG grade 3-4)

This selection bias is consistent with published literature showing 79-90% of biosynthetic mesh is used in high-risk scenarios. The apparent excess morbidity in unmatched Phasix cohorts reflects systematic selection of higher-risk cases, not mesh inferiority.

2. Comparable Recurrence When Case Complexity is Balanced

After propensity matching, Phasix demonstrated:

- Low recurrence rate (4%) comparable to synthetic mesh (8%, p=0.55)
- Performance aligning with synthetic mesh standards
- Substantially better than biologic mesh (typically 20-40% recurrence)

This finding is supported by recent matched analyses (Khan et al. 2025) showing 3-year recurrence rates of 3.3% (Phasix) vs 7.0% (synthetic), despite larger defects in the biosynthetic group.

3. Lower Wound Complications with Phasix

In the matched cohort, Phasix showed:

- Zero surgical site infections vs 16.7% with synthetic (p=0.04)
- 75% reduction in surgical site occurrences (4.2% vs 33.3%, p=0.01)
- Similar rates of other complications

This suggests Phasix may offer advantages in contaminated or high-risk wounds where infection is a primary concern, potentially due to its resorbable nature eliminating long-term foreign body presence.

Clinical Implications:

Phasix mesh represents a reasonable alternative to synthetic mesh when:

- Contamination risk is elevated (CDC class 2-4)
- Wound healing concerns exist
- Patient has high infection risk factors
- Long-term foreign body is undesirable

The comparable recurrence rates suggest Phasix does not sacrifice durability for improved wound outcomes.

Limitations:

- Retrospective, single-institution design
- Modest sample size in matched cohort (n=25 per group)
- Short follow-up (12 months) may not capture late recurrences after complete Phasix resorption (12-18 months)
- Cannot account for unmeasured confounders despite propensity matching
- Findings specific to Phasix, may not generalize to other biosynthetic meshes

Conclusions

✓ Phasix bioabsorbable mesh demonstrates comparable hernia recurrence rates to permanent synthetic mesh when case complexity is balanced through propensity score matching (4% vs 8%, p=0.55)

✓ Phasix offers significantly lower surgical site infections (0% vs 16.7%, p=0.04) and surgical site occurrences (4.2% vs 33.3%, p=0.01) in matched cohorts

✓ The apparent excess morbidity in unmatched Phasix cohorts is driven by selection bias, not mesh inferiority, as Phasix is systematically reserved for larger, more contaminated, and higher-grade repairs

✓ Phasix can be considered a reasonable alternative to synthetic mesh when concern for contamination or early wound complications is high, without sacrificing recurrence outcomes

✓ Larger, multicenter prospective studies with longer follow-up are needed to confirm these findings and refine patient selection criteria for biosynthetic mesh