Prospective Evaluation of Phasix™ Mesh in CDC Class I/High Risk Ventral and Incisional Hernia Repair: 18 Months Follow-up

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Objective

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. The objective of this prospective, multi-institutional study was to evaluate outcomes of VIHR with P4HB mesh in subjects at high risk for postoperative complications.

Study Device

- Knitted monofilament P4HB (Phasix™ Mesh)
- Predictably and gradually degrades via hydrolysis
- Contributes mechanical strength up to 12 months
- Scaffold enables remodeling by host tissue
- Essentially fully resorbed by 18 months

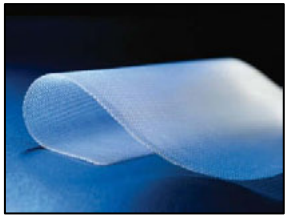

Figure 1: Phasix™ Mesh

Inclusion Criteria

- CDC Class I wounds (clean)
- Hernia defect: 10-350cm^2
- ≤ 3 prior repairs
- ≥ 1 high-risk criteria (depicted in Figure 2)

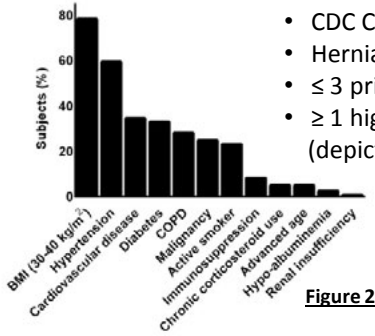

Figure 2: Incidence of high-risk comorbid conditions (%)

Study Population

Subjects enrolled	n=121
Subjects with 18 months follow-up	n=95 (79%)
Sex	n=46 (38%) male n=75 (62%) female
Age (years)	54.7 ± 12.0
Body mass index (kg/m^2)	32.2 ± 4.5
Diagnosis	Primary ventral: 14% Primary incisional: 45% Recurrent ventral: 12% Recurrent incisional: 29%

Table 1: Subject demographics and surgical diagnosis

Surgical Technique

Subjects underwent open ventral hernia repair with retrorectus or onlay placement of mesh (with or without additional myofascial release). Phasix™ Mesh was 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.

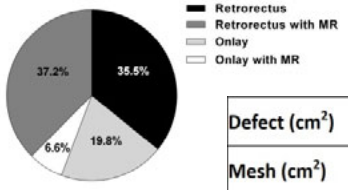

Figure 3: Surgical approach (MR: myofascial release)

Table 2: Operative details

Defect (cm^2)	115.7 ± 80.6
Mesh (cm^2)	580.9 ± 216.1
Surgical procedure time (hrs)	2.8 ± 1.4

Data Collection

Postoperative physical exam and quality of life assessments were performed at 1, 3, 6, 12, and 18 months. Medical history, demographics, and medication usage were also recorded at each visit.

Outcomes

Hernia recurrence	9% (n=11)
Surgical site infection	9% (n=11)
Seroma requiring intervention	6% (n=7)
Rate of reoperation	8% (n=10)
Device-related adverse events	9% (n=11)

Table 3: Postoperative data: Primary and secondary outcomes

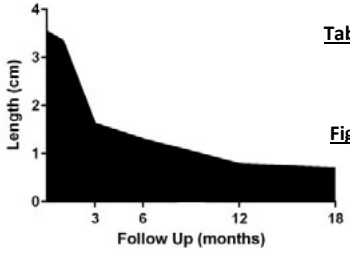

Figure 4: Pain Visual Analogue Scale (VAS) results (cm) depicted over time (months)

Conclusions

High-risk VIHR with Phasix™ Mesh demonstrated positive outcomes and low incidence of hernia recurrence at 18 months. Longer-term, 36-month follow-up is ongoing.

Disclosures

Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions, and instructions for use.
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