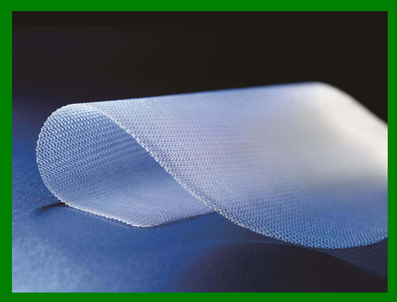

# A prospective clinical trial of a fully resorbable P4HB mesh in high risk hernia repair – Early outcomes in the first 50 patients


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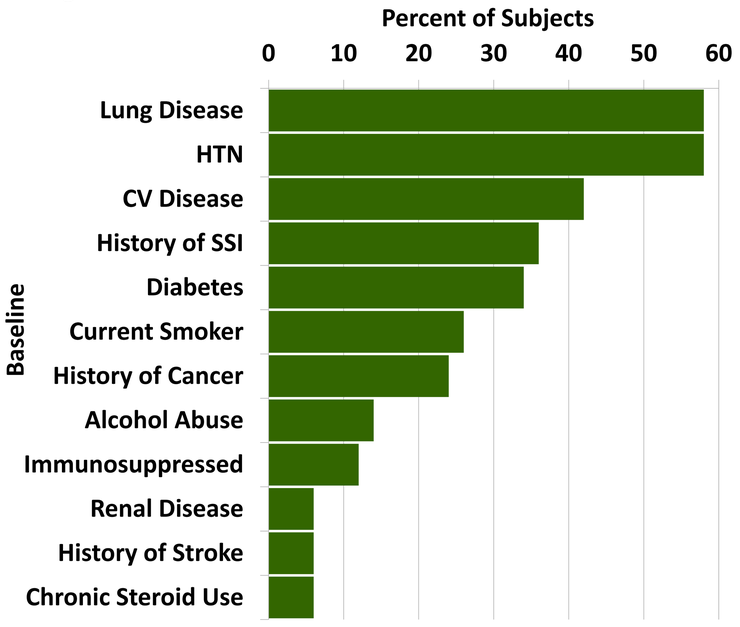
## Introduction

- Long-term, fully absorbable mesh prostheses represent a promising technology in the management of abdominal wall disease.
- Poly-4-hydroxybutyrate (P4HB) mesh is a long-lasting absorbable material with tensile strength exceeding porcine native abdominal wall at time of implantation with full resorption within 2 yrs in preclinical studies.
- This interim review evaluates 6-month outcomes using P4HB material in high risk population undergoing ventral hernia repair.

## Purpose

- The objective of this study was to collect additional data on safety, performance and effectiveness of P4HB Mesh (Phasix™) in subjects requiring primary ventral, incisional or recurrent hernia repair at high risk for complications.

Figure 1. Comorbid Conditions



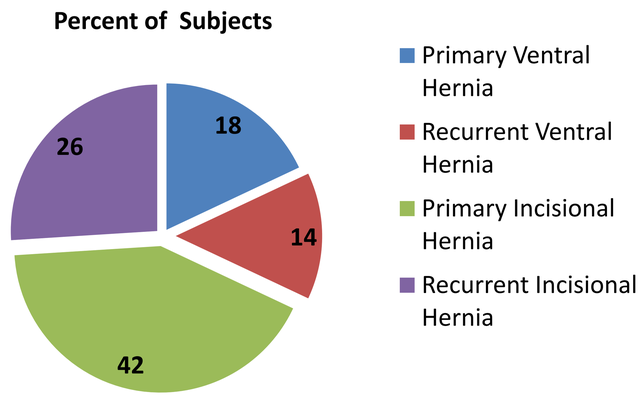

## Methods

- An IRB approved, prospective, multi-center, interventional trial is ongoing.
- Inclusion criteria:
  1. Primary ventral, incisional or recurrent (not to exceed 3) incisional hernias undergoing retro-rectus or onlay repair.
  2. One or more comorbid conditions (obesity, smoking, DM, chronic steroid use, COPD, CAD, immunosuppression, hypoalbuminemia, renal insufficiency, age >75).
  3. Hernia size > 10cm$^2$ and < 350cm$^2$.
  4. CDC Class 1[1] wound.
- Demographics, operative details, QoL surveys, Pain VAS[2,3] scores and postoperative outcomes are collected at 1, 3, 6, 12, 18 and 24 months.

## Study Population

- 112 patients have been enrolled to date, of which 50 (18 Male, 32 Female) have completed 6-month follow-up evaluations.
- At baseline, patients had a mean BMI of 32.31 +/- 4.85 kg/m$^2$, and on average 2 comorbid conditions (range 1-5).
- 32 patients (64%) underwent a retro-rectus repair, 17 (34%) an onlay repair and 1 (2%) preperitoneal repair (right flank hernia).

Figure 2. Hernia Types




## Results

**Pain VAS scores improved following hernia repair:**

Figure 3. Mean Pain Score (10-point VAS)

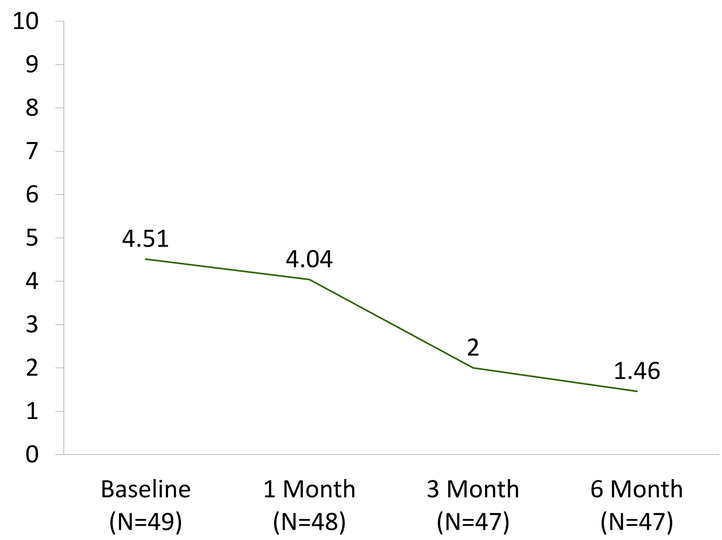



Figure 4: Adverse Events

| Adverse Events of Special Interest | *Percentage of Patients* |
|---|---|
| Skin Dehiscence | 16% |
| Tissue Ischemia | 14% |
| Hematoma | 12% |
| Seroma | 12% |
| Drain Complications | 10% |
| Superficial Infection | 10% |
| Deep Infection | 4% |
| Recurrence | 2%* |
| Wound Cellulitis | 2% |

*Recurrence at 12 months

**One patient had the mesh explanted due to pyrexia of unknown origin which was later determined to be due to pneumonia (resulted in death).**

## Conclusions

**Ventral and Incisional hernia repair in patients with underlying comorbid conditions, can result in frequent complications. In this P4HB mesh study, early recurrences are rare and VAS pain scores improve following hernia repair. Longer term follow-up is ongoing.**

## Disclosures


This study was sponsored by C. R. Bard, Inc. (Davol), Warwick, RI. Authors were reimbursed for expenses related to the conduct of the study. JSR, GJA, JGB, WWH, RGM, MIG, DBE, GJM, JAG, EPD, BJS and GRV are paid consultants for C. R. Bard, Inc. (Davol). The opinions and clinical experiences presented herein are for informational purposes only. The interim results from this clinical study may not be predictive for all patients. Individual results may vary depending on a variety of patient specific attributes.


Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions and instructions for use.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DAV/PHSX/0115/0042a