

A Grouped Analysis of Prospective, Multicenter Studies of Poly-4-hydroxybutyrate Mesh for Ventral Hernia Repair: 18-Month Follow-up

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Introduction

Ventral hernia repair remains a clinical challenge, particularly the selection of an appropriate biomaterial. Preclinical studies have demonstrated the long-term strength profile associated with a resorbable mesh comprised of poly-4-hydroxybutyrate (P4HB), making it a promising technology for ventral hernia repair. The current study assessed the clinical performance of P4HB by combining the intermediate-term outcomes of three prospective, multicenter studies performed in the United States and the European Union.

Study Device

- Knitted monofilament of poly-4-hydroxybutyrate (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*



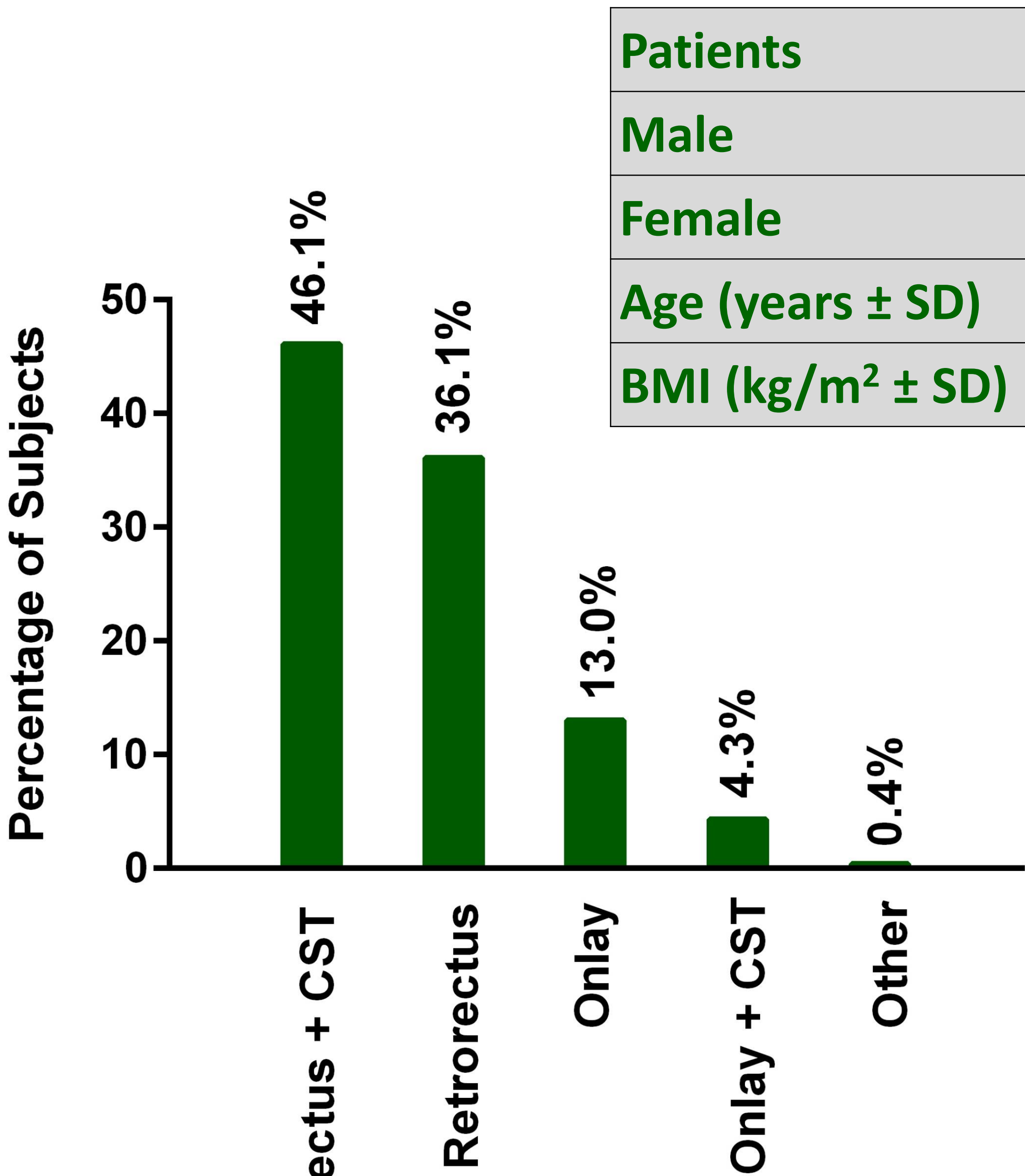
Figure 1: Phasix™ Mesh

Methods

Three prospective, multicenter studies involving ventral hernia repair with P4HB mesh in subjects across all CDC wound classes were combined to yield a larger overall dataset at the 18-month postoperative timeframe. The trials included 2 studies performed in the United States, a pilot study comprised of 25 subjects (Novitsky *et al.*) and a larger study comprised of 121 subjects (Roth *et al.*), as well as a study performed in the European Union comprised of 84 subjects (Jeekel *et al.*). P4HB mesh was utilized in the onlay or retrorectus position, with or without component separation technique (CST). Hernia recurrence rates and surgical site occurrences (SSO) requiring intervention, including surgical site infection (SSI), seroma, wound dehiscence, skin necrosis, hematoma, and fistula for all three studies were combined and reported as a weighted average.

*Preclinical data on file. Results may not correlate to clinical performance in humans.
*No mesh is indicated for use in contaminated or infected fields.

Results



Patients	n=230
Male	n=106 (46.1%)
Female	n=124 (53.9%)
Age (years ± SD)	57.6 ± 13.2
BMI (kg/m² ± SD)	30.4 ± 5.0

Table 1:
Patient Demographics

Figure 2:
Surgical Technique

CST = Component Separation Technique

Table 2:
Postoperative CDC Wound Class Designations

Postoperative CDC Wound Class	Patients (n, %)
Class I-Clean	n=173, 75.2%
Class II-Clean-Contaminated	n=43, 18.7%
Class III-Contaminated	n=12, 5.2%
Class IV-Dirty	n=1, 0.4%
Not reported	n=1, 0.4%

Outcomes

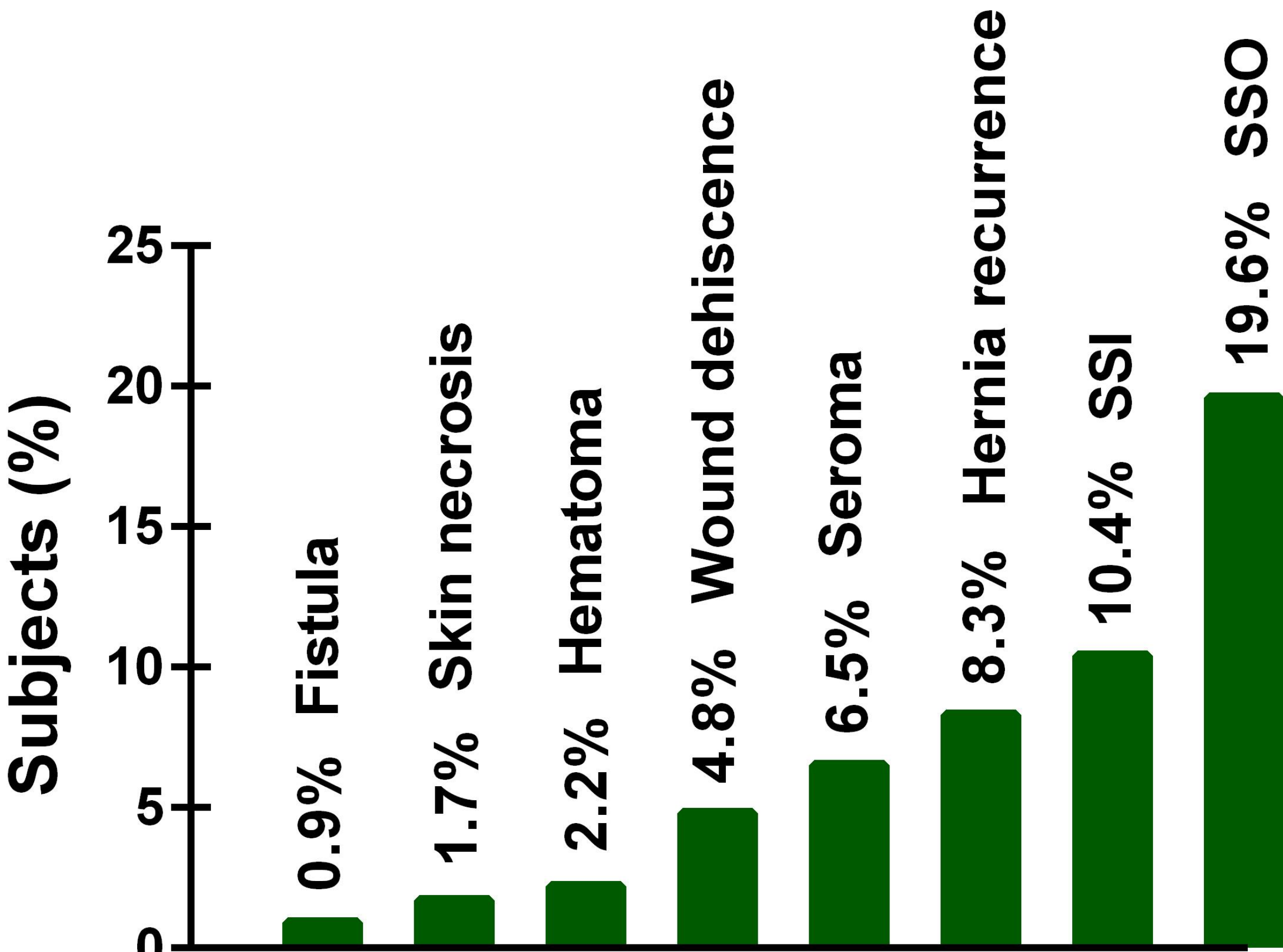


Figure 3: Outcomes at 18 Months (weighted averages)
SSI = surgical site infection & SSO = surgical site occurrence

Conclusions

Intermediate-term outcomes following ventral hernia repair with P4HB mesh in subjects across all CDC wound classes demonstrate low rates of recurrence and reasonable rates of SSO at the 18-month postoperative timeframe. Longer follow up is ongoing: 5-year (60-month) in the United States and 2-year (24-month) in the European Union.

Disclosures

- Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions, and instructions for use.
- This study was sponsored by Davol Inc., a subsidiary of C. R. Bard, Inc. (Warwick, RI.) Bard and Davol have joined BD (Franklin Lakes, NJ).
- JSR and CRD are paid consultants of C. R. Bard, Inc. (Davol).