

Long-Term, Prospective, Multicenter Study of Poly-4-hydroxybutyrate Mesh (Phasix™ Mesh) for Hernia Repair in Cohort at Risk for Complication: 60-Month Follow-Up.

Article Summary

Authors

Roth, John Scott MD, FACS^a; Anthon, Gary J MD, FACS^b; Selzer, Don J MD, FACS^c; Poulouse, Benjamin K MD, FACS, MPH^d; Pierce, Richard A MD, FACS, PhD^e; Bittner, James G MD, FACS^f; Hope, William W MD, FACS^g; Dunn, Raymond M MD, FACS^h; Martindale, Robert G MD, FACS, PhDⁱ; Goldblatt, Matthew I MD, FACS^j; Earle, David B MD, FACS^k; Romanelli, John R MD, FACS^l; Mancini, Gregory J MD, FACS^m; Greenberg, Jacob A MD, FACSⁿ; Linn, John G MD, FACS^o; Parra-Davila, Eduardo MD, FACS^p; Sandler, Bryan J MD, FACS^q; Deeken, Corey R PhD^r; Badhwar, Amit PhD^s; Salluzzo, Jennifer L MD, FACS^t; Voeller, Guy R MD, FACS^u

Journal

Journal of the American College of Surgeons, 2022

Objectives

Evaluate poly-4-hydroxybutyrate mesh (P4HB, Phasix™ Mesh) in comorbid patients with CDC Class 1 wounds.

Study design

Prospective multi-institutional.

Subjects and methods

Patients older than 18 years with primary ventral, primary incisional, or recurrent incisional hernia (not to exceed 3 recurrences) were evaluated for eligibility. Including one or more of the following comorbidities: Class I surgical wound (defined by Centers for Disease Control and Prevention (CDC)), and 10-350 cm² hernia defect suitable for repair by retrorectus or onlay mesh (with or without myofascial release, MR). Primary outcomes included: hernia recurrence and surgical site infection. Secondary outcomes included pain, device related adverse events, quality of life, reoperation, procedure time, and length of stay. Postoperative patient visits were scheduled at 1, 3, 6, 12, 18, 24, 36, and 60 months, a telephone interview was conducted at 30 months.

Results

A total of n= 121 (46 M, 75 F) underwent VIHR with P4HB mesh with a BMI of 32.2 ± 4.5 kg/m². A total of n= 54 (44.6%) patients completed the 60-month follow up. Primary outcomes (Kaplan-Meier estimates at 60-months) include: recurrence (22.0 ± 4.5%; 95% Confidence Interval (CI) 11.7, 29.4%) and SSI (10.1 ± 2.8%; 95% CI: 3.3, 14.0). Secondary outcomes include seroma requiring intervention (n=9), procedure time (167.9 ± 82.5 minutes), length of stay (5.3 ± 5.3 days), re-operation (18/1221, 14.9%), Visual Analog Scale-Pain (change from baseline -3.16 ± 3.35 cm at 60 months; n=52) and Carolinas Comfort Total Score (change from baseline -24.3 ± 21.4 at 60 months; n=52).

Conclusion

The 5-year outcomes following VIHR with P4HB mesh are associated with infrequent complications and durable hernia repair outcomes. This study provides framework for anticipated long-term hernia repair outcomes when utilizing P4HB mesh.

