Analysis of the use of Poly-4-hydroxybutyrate Mesh for Inguinal Hernia Repair: Our first 200 cases

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Introduction

Inguinal hernia repair remains one the most common operation that general surgeons perform on an annual basis. Selection of a tissue based repair versus permanent or biorebsorbable biomaterials still remains an issue for both patients and surgeons when faced with options for inguinal hernia repair. Other studies have demonstrated the long-term strength profile associated with a resorbable mesh comprised of poly-4-hydroxybutyrate, in Ventral Hernia Repair. We however looked at the application of this type of bioprosthetic for use in inguinal hernia repair (IHR).

Data Collection

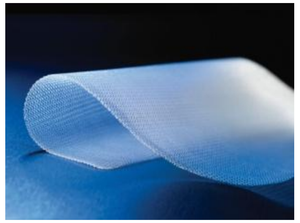
Retrospective review of the data from the Postoperative physical exam, adverse events, recurrence were assessed at:7 , 3, 6, 12, 24 and 36 months, with annual long-term follow-up ongoing.days

Methods

We retrospectively reviewed the continuous application of poly-4-hydroxybutyrate for open inguinal hernia repair at one center in the US.
The study involves IHR with poly-4-hydroxybutyrate mesh in subjects across all types of open inguinal hernia to yield a larger overall, all-comers dataset at a minimum of 12-month postoperative time frame follow up. The trial includes a review comprised of 201 consecutive subjects
Poly-4-hydroxybutyrate plug and patch mesh was utilized in the groin for all primary and recurrent indirect, direct and femoral defects. Hernia complication rates including: recurrence rates, surgical site occurrences (SSO) requiring intervention, surgical site infection (SSI), seroma, wound dehiscence, skin necrosis, hematoma, were reviewed and will be reported.

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*



Phasix™ Mesh

Surgical Outcomes

	Phasix	Other meshes
Patients number	202	124
Duration of FU (Months), mean ± SD	12.22 ± 13.85	10.21 ± 8.64
Median	6	7
IQR	3.00-15.00	3.00-16.00
Minimum	1	1
Maximum	96	36
Complication rate (%)	2 (0.99%)	1 (0.81%)
Infection rate (%)	0	0
Recurrence (%)	1 (0.5%)	0
Time to recurrence (Months)	47	N/A

Conclusions

Intermediate-term outcomes following inguinal hernia repair with poly-4-hydroxybutrate mesh in subjects with a minimum of one year of follow up demonstrate low rates of recurrence and reasonable rates of SSO at the 12-month postoperative timeframe. Longer term follow up is ongoing: Both 3 and 5-year (36,60-month) in the US at the same center and will be reported when complete results are available at a later date.

Study Population

	Phasix	Other meshes
Patients number	202	124
Sex		
Male	196	121
Female	6	3
Age years, mean ± SD	60.68 ± 15.10	52.62 ± 14.15
Median	63	54
IQR	51.25-73.00	43.75-63.00
BMI kg/m2, mean ± SD	26.66 ± 3.85	26.78 ± 3.64
Median	25.8	26.5
IQR	24.03-2.90	24.40-28.50
Hernia Type (%)		
Direct	49 (24.26%)	32 (25.81%)
Indirect	137 (67.82%)	75 (60.48%)
Pantaloon	14 96.93%)	9 (7.26%)
Femoral	2 (0.99%)	0
Right - Direct Left - Indirect	0	1 (0.81%)
Right - Indirect Left - Direct	0	1 (0.81%)
Hernia location (%)		
Left	86 (42.57%)	22 (17.74%)
Right	109 (53.96%)	28 (22.58%)
Bilateral	7 (3.47%)	68 (54.84%)
Approach (%)		
Open	182 (90.10%)	28 (22.58%)
Laparoscopic	20 (9.90%)	93 (75%)

Other mesh types used in the study

Mesh type	
Bard 3D Max	86
Bard 3D Max Light	4
Bard 3D Max and 3D Max Light	1
Bard Soft Mesh and XenMatrix AB	1
Bard 3D Max Anatomic Midway	1
Bard 3D Max and Ventralex ST	2
Ethicon	1
Ethicon UHSOV	4
Meso BioMatrix	1
GORE Bio-A Plug	1
Sutured	1
UHS Oval	1
PHS (Prolene)	2
no-mesh	18

Disclosures

JPK is paid consultants for C. R. Bard, Inc. (Davol).

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