CLINICAL DISCUSSION


* Funding: The work was supported by W. L. Gore & Associates, Flagstaff, AZ, USA. Written informed consent was obtained from all patients and the study was conducted in accordance with U.S. Federal regulations and with Institutional Review Board approval from each investigative site.
Long-term results for intraperitoneal biomaterial repair of ventral hernias in a real-world, retrospective, multicenter study

Authors: John G Linn1, Carl R Doerhoff2, David W Grantham1, Eric John Mallico2, and Raymond G Washington Jr3


Aim: To analyze device safety and clinical outcomes of ventral hernia repair with a hybrid composite mesh

Material and Methods: This retrospective, multicenter, case review analyzed device/procedure endpoints and patient-reported outcomes in patients treated for hernia repair ≥ 1 year from study enrollment.

Table 1. Patient Demographics, Baseline Medical History, and Baseline Hernia Characteristics of Patients With Ventral Hernia

<table>
<thead>
<tr>
<th>Number of Patients Enrolled</th>
<th>459</th>
</tr>
</thead>
<tbody>
<tr>
<td>Demographics</td>
<td></td>
</tr>
<tr>
<td>Female, n (%)</td>
<td>245 (53.38)</td>
</tr>
<tr>
<td>Age (years), mean (SD)</td>
<td>58 (15)</td>
</tr>
<tr>
<td>BMI, kg/m², mean (SD)</td>
<td>33 (8)</td>
</tr>
<tr>
<td>Range</td>
<td>15 (5.66)</td>
</tr>
<tr>
<td>Medical History</td>
<td></td>
</tr>
<tr>
<td>Tobacco use, n (%)</td>
<td></td>
</tr>
<tr>
<td>Current</td>
<td>86 (18.74)</td>
</tr>
<tr>
<td>Former</td>
<td>147 (32.03)</td>
</tr>
<tr>
<td>Never</td>
<td>226 (49.24)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>234 (50.98)</td>
</tr>
<tr>
<td>Diabetes mellitus</td>
<td>90 (19.61)</td>
</tr>
<tr>
<td>Ventral Hernia Characteristics</td>
<td></td>
</tr>
<tr>
<td>WWG Classification, n (%)</td>
<td></td>
</tr>
<tr>
<td>Grade: Low-risk</td>
<td>107 (22.7)</td>
</tr>
<tr>
<td>Grade 2: Comorbid</td>
<td>354 (77.1)</td>
</tr>
<tr>
<td>Grade 3: Potentially contaminated</td>
<td>1 (0.2%)</td>
</tr>
<tr>
<td>Grade 4: Infected</td>
<td>0 (0.0)</td>
</tr>
<tr>
<td>Hernia size (cm²), mean (SD)</td>
<td>18.9 (31.7)</td>
</tr>
<tr>
<td>Hernia length (cm), mean (SD)</td>
<td>4 (4)</td>
</tr>
<tr>
<td>Hernia width (cm), mean (SD)</td>
<td>3 (2)</td>
</tr>
<tr>
<td>Ventral hernia, incision only, n (%)</td>
<td>263 (57.3)</td>
</tr>
<tr>
<td>Ventral hernia, non-incision only, n (%)</td>
<td>199 (42.6)</td>
</tr>
</tbody>
</table>

Results: There were 459 patients with 469 ventral hernias with a mean age of 58 ± 15 years and 77% Ventral Hernia Repairing Group 2 (VWGH2). Mean hernia size was 18.9 cm² (Table 1). Laparoscopic or robotic approach were utilized in 95% of patients, incisional hernias accounted for 57%. Mesh location was 75% infraperitoneal and bridging repair was performed in 57%. Procedure-related adverse events within 30-days occurred in 5%, including: surgical site infection (SSI), surgical site occurrence (SSO), ileus, readmission, and reoperation. Procedure-related SSI or SSO events were 3.75% through 12-months (Table 2).

Table 2. Procedure-related Events through 12 months

| Subjects eligible for secondary endpoint | Subjects with any secondary endpoint event through 12 months
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Serum</td>
<td>0/453 (0.00%)</td>
</tr>
<tr>
<td>Fatua</td>
<td>0/453 (0.00%)</td>
</tr>
<tr>
<td>SSI</td>
<td>10/453 (2.21%)</td>
</tr>
<tr>
<td>SSO</td>
<td>14/453 (3.09%)</td>
</tr>
<tr>
<td>Adhesion formation</td>
<td>0/453 (0.00%)</td>
</tr>
<tr>
<td>Bowel perforation</td>
<td>0/453 (0.00%)</td>
</tr>
<tr>
<td>Unexplained or chronic pain</td>
<td>0/453 (0.00%)</td>
</tr>
</tbody>
</table>

Subgroup comparison of fixation type (permanent vs absorbable, p=0.93) and repair (bridging vs reinforcement, p=0.99) were conducted for recurrence and were not statistically significant. Diabetes was found to be statistically significant, p=0.0506 (Table 3).

Conclusions: In this analysis, ventral hernia repair with hybrid, composite mesh results in successful outcomes in the majority of patients. This study represents a heterogeneous patient population undergoing repair using various approaches, mesh fixation, and mesh placement locations. These data appear to confirm long-term acceptable safety and device performance with a low rate of recurrence in a predominantly VWGH2 population.

Funding: The work was supported by W. L. Gore & Associates, Flagstaff, AZ, USA. Written informed consent was obtained from all patients and the study was conducted in accordance with U.S. Federal regulations and with Institutional Review Board approval from each investigative site.

Fixation methods other than those described in the Instructions for Use (IFU) have not been evaluated for use with Gore® SYNÈRE Biomaterial. IFU recommends using non-absorbable suture for fixation of Gore® SYNÈRE Biomaterial.
Study overview

Retrospective study
Minimally invasive surgery (MIS) ventral hernia repair (primary or recurrent hernias)
CDC class I wounds – On-label study

High-risk patients, Ventral Hernia Working Group 2 (VHWG 2) (77% VHWG2)
75% intraperitoneal placement
25% preperitoneal/film towards peritoneum
Mean hernia defect size: 18.9 cm²

Mean follow-up time
32 months (2.7 years)
up to 53 months (4.4 years)

Results
- Hernia recurrence via patient-reported outcome measure: 6.8% (23/339)
  - Patient reported outcomes (PRO) is a suggestive estimate of recurrence
- Procedure related adverse events (30 days): 5%

Complication Rates at 12-month follow-up

<table>
<thead>
<tr>
<th></th>
<th>Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surgical site occurrence (SSO)</td>
<td>3.1%</td>
</tr>
<tr>
<td>Surgical site infection (SSI)</td>
<td>2.2%</td>
</tr>
<tr>
<td>Surgical site occurrences requiring procedural interventions (SSOPI) 24 months</td>
<td>2.6%</td>
</tr>
</tbody>
</table>

Conclusion: “These data appear to confirm long-term acceptable safety and device performance with a low rate of recurrence in a predominantly VHWG2 population.”
Key clinical points

One sentence overall summary:
Linn, et al. reported long-term acceptable safety and device performance with a low rate of recurrence in a predominately VHWG2 population undergoing ventral/incisional hernia repair with GORE® SYNECOR Intraperitoneal Biomaterial.
Key clinical points

1. Retrospective, multi-center (4 sites/5 surgeons)
2. MIS ventral hernia repair
3. 459 patients, all with GORE® SYNECOR Intraperitoneal Biomaterial
4. High-risk patients (77% VHWG2)
5. 75% intraperitoneal placement
   25% preperitoneal/film towards peritoneum (on-label)
6. Mean age: 58; Mean body mass index (BMI): 33
7. Mean defect size: 18.9 cm²
8. Mean follow-up time: 32 months (2.7 years) up to 53 months (4.4 years)
Key clinical points

Results
- Hernia recurrence via patient reported outcome: 6.8% (23/339)
  - **PRO is a suggestive estimate of recurrence**
- Procedure related adverse events (30 days): 5%
- Procedure related SSI or SSO events (12 months): 3.75%
- SSOPi (24 months): 2.57%

Other clinical highlights
- All CDC Class I clean cases
- All SSI resolved; one explant, not related to infection
- Intraperitoneal onlay mesh (IPOM) 57%, IPOM Plus 43%
- Laparoscopic or robotic approach used in 95% of cases
- Diabetes found to be only co-morbidity statistically significant for recurrence
- No reports of unexplained or chronic pain

Comparator highlights1–3
- 12% recurrence rate at 12 months for OVITEX® Reinforced Tissue Matrix reported by Parker, et al.
- State-of-the-Art for like devices (Intraperitoneal placement)
  - Hernia recurrence through two-years: 16% [Lavanchy 2018]
  - SSOPi through 2 years: 9.8% [Baucom 2016]

OVITEX is a trademark of TELA Bio, Inc.
What is interesting about this data?

1. What patient characteristics support your choice of mesh material?
2. What length of follow-up do you consider when choosing a mesh material?
3. Have you formerly utilized a hybrid biomaterial/mesh device for complex hernia repairs or abdominal wall reconstruction (AWR)?
4. Are you aware that Burger, et al\textsuperscript{4} reported approximately 28\% recurrence rate at six years for polypropylene mesh in a widely cited randomized controlled trial (RCT) study on mesh repair versus suture paper?
5. Are you aware that Roth et al\textsuperscript{5} reported 18\% recurrence rate at three years for BD\textsuperscript{®} PHASIX Mesh?
6. What is your experience with defects over 150 cm\textsuperscript{2}? What recurrence rate have you seen?
7. What are your outcome expectations five years after hernia repairs?

BD and PHASIX are trademarks of Becton, Dickinson and Company.


Refer to Instructions for Use at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. Rx Only

Products listed may not be available in all markets.

BD and PHASIX are trademarks of Becton, Dickinson and Company.
CAPITAL REGION MEDICAL CENTER is a trademark of Capital Region Medical Center.
NORTHSHORE UNIVERSITY HEALTHSYSTEM is a trademark of NorthShore University HealthSystem.
NOVANT HEALTH is a trademark of Novant Health, Inc.
PINEHURST SURGICAL CLINIC is a trademark of Pinehurst Surgical Clinic.
TELA BIO and OVITEX are trademarks of Tela Bio, Inc.

GORE, Together, improving life, SYNECOR and designs are trademarks of W. L. Gore & Associates.

© 2022 W.L. Gore & Associates, Inc. 22540056-EN AUGUST 2022