CLINICAL DISCUSSION

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Long-term results for intraperitoneal biomaterial repair of ventral hernias in a real-world, retrospective, multicenter study

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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

Number of Patients Enrolled	459
Demographics	
Female, n (%)	245 (53.38)
Age (years), mean (SD)	58 (15)
BMI, kg/m^2, mean (SD)	33 (8)
Range	(15, 66)
Medical History	
Tobacco use, n (%)	
Current	86 (18.74)
Former	147 (32.03)
Never	226 (49.24)
Hypercholesterolemia	152 (33.12)
Hypertension	234 (50.98)
Diabetes mellitus	90 (19.61)
Obese	288 (62.75)
Ventral Hernia Characteristics	
VHWG Classification, n (%)	
Grade1: Low- risk	107 (22.7)
Grade 2: Co-morbid	354 (77.1)
Grade 3: Potentially contaminated	1 (0.2)*
Grade 4: Infected	0 (0)
Hernia size (cm^2), mean (SD)	18.9 (31.7)
Hernia length (cm), mean (SD)	4 (4)
Hernia width (cm), mean (SD)	3 (2)
Ventral hernia, incisional only, n (%)	263 (57.3)
Ventral hernia, non-incisional only, n (%)	199 (43.4)

Results: There were 459 patients with 469 ventral hernias with a mean age of 58 ± 15 years and 77% Ventral Hernia Working Group 2 (VHWG2). Mean hernia size was 18.9 cm^2 (Table 1). Laparoscopic or robotic approach were utilized in 95% of patients, incisional hernias accounted for 57%. Mesh location was 75% intraperitoneal† 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 re-operation. 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	453
Subjects with any secondary endpoint event through 12 months*	17/453 (3.75%)
Seroma	0/453 (0.00%)
Fistula	0/453 (0.00%)
SSI	10/453 (2.21%)
SSO	14/453 (3.09%)
Adhesion formation	0/453 (0.00%)
Bowel perforation	0/453 (0.00%)
Unexplained or chronic pain	0/453 (0.00%)

Table 3. Subgroup comparison for all type recurrenceα

Parameter	n/N (%)	Parameter	n/N (%)	p-value
Diabetes	9/70 (12.86)	No Diabetes	17/282 (6.03)	p=.0506
VHWG 2	21/257 (8.17)	VHWG 1	4/81 (4.94)	p=.3323
Obese	17/213 (7.98)	Not Obese	7/118 (5.93)	p=.4911
Never Smoked	10/176 (5.68)	Smoking history	16/176 (9.09)	p=0.2214
Hernia < 9cm^2	12/180 (6.67)	Hernia ≥ 9cm^2	14/172 (8.14)	p=.5974
Incisional	14/189 (7.41)	Non-incisional	11/150 (7.33)	p=.9793
Laparoscopic repair	24/315 (7.62)	Non-Laparoscopic repair	1/24 (4.17)	p=.5328
Midline involvement	25/339 (7.37)	No midline involvement	1/13 (7.69)	p=.9657
Preperitoneal device placement	3/81 (3.70)	Intraperitoneal device placement	22/258 (8.53)	p=.1473
Permanent fixation	11/152 (7.24)	Absorbable fixation only	14/187 (7.49)	p=.9303
Bridging	14/190 (7.37)	Reinforcement	11/149 (7.38)	p=.9961
IPOM with bridging	12/132 (9.09)	IPOM plus (IPOM with reinforcement)	10/120 (8.33)	p=.8315

Results continued: SSO events requiring procedural intervention (SSOPI) were 2.57% through 24-months. An estimated 7% of subjects had hernia recurrence through the study with a mean follow-up of 32-months (14-53 months) using a patient-reported outcome measureβ. 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=.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 VHWG2 population.

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Abbreviations: SD=standard deviation; VHWG=Ventral Hernia Working Group, IPOM – Intraperitoneal Onlay Mesh Technique. *If subject had multiple types of events (e.g. SSI and Ileus) they would only count once for the composite endpoint in this row but would appear in multiple rows below. All rows are counts of subjects with at least one qualifying event, not counts of events. α-All type recurrence: site-reported device-related bowel obstruction, mesh erosion, mesh infection, mesh excision/removal, mesh exposure, device-related fistula, mesh migration, mesh shrinkage, or hernia recurrence prior to day 366 will be counted as events. β"The Patient Reported Outcomes (PRO) subject questionnaire is adapted from a publication on patient reported outcomes following incisional hernia repair - Baucom RB, Ousley J, Feurer ID, Beveridge GB, Pierce RA, Holzman MD, et al. Patient reported outcomes after incisional hernia repair-establishing the ventral hernia recurrence inventory. Am J Surg. 2016;212(1):81-8."

* During procedure, the VHWG Grade 3 patient determined to be CDC class I wound.
† Preperitoneal location was in accordance with *Instructions for Use*.

Fixation methods other than those described in the *Instructions for Use* (IFU), have not been evaluated for use with GORE® SYNECOR Biomaterial. IFU recommends using non-absorbable suture for fixation of GORE® SYNECOR 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 cm^2

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	
Surgical site occurrence (SSO)	3.1%
Surgical site infection (SSI)	2.2%
Surgical site occurrences requiring procedural interventions (SSOPI) 24 months	2.6%

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 cm^2
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 highlights[1–3]
- 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]

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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*[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[5] reported 18% recurrence rate at three years for BD® PHASIX Mesh?
6. What is your experience with defects over 150 cm^2? What recurrence rate have you seen?
7. What are your outcome expectations five years after hernia repairs?

References

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3. Baucom RB, Ousley J, Oyefule OO, *et al*. Evaluation of long-term surgical site occurrences in ventral hernia repair: implications of preoperative site independent MRSA infection. *Hernia*. 2016;20(5):701-710.

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5. Roth JS, Anthone GJ, Selzer DJ, *et al*. Prospective, multicenter study of P4HB (Phasix™) mesh for hernia repair in cohort at risk for complications: 3-year follow-up. *Annals of Medicine & Surgery* 2021;61:1-7.

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