# INTERIM OUTCOMES FOLLOWING USE OF GORE® ENFORM PREPERITONEAL BIOMATERIAL IN VENTRAL AND INCISIONAL HERNIA REPAIR

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## Abstract

**Introduction:** This study evaluated the safety and clinical outcomes of GORE® ENFORM Preperitoneal Biomaterial (PRE device) in patients undergoing ventral or incisional hernia repair (VHR).

**Materials and Methods:** A multicenter U.S. study including retrospective and prospective cohorts of adults undergoing VHR with the PRE device, a bioabsorbable mesh designed for extraperitoneal reinforcement, was analyzed. Patient characteristics, procedural details, and device- or procedure-related adverse events - including surgical site infection (SSI), surgical site occurrence (SSO), SSO requiring procedural intervention (SSOPI), and hernia recurrence - were assessed. The Carolinas Comfort Scale (CCS) was prospectively collected as a patient-reported outcome (PRO) measure.

**Results:** Ninety-five patients (mean age 58.7 years, 61.1% female; 48 prospective, 47 retrospective) were included. The average body mass index (BMI) was 30.3. Incidence of diabetes was 25.3%. The rate of current smokers within 30 days of the procedure was 3.2%. Former smokers were 45.3% of patients. The average hernia size was 15.0 x 8.6 cm with an average procedure time of 3.1 hours. Twenty-two patients underwent concomitant procedures. The average length of a patient stay was 3.5 days. Recurrent hernias were present in 15.7% of patients. Wound classes included: CDC class I – 69 (72.6%), Class II – 11 (11.6%), Class III –13 (13.7%), and Class IV – 2 (2.1%). Most were VHWG grade 2 or higher (n=74). Meshes were placed extraperitoneally within the retrorectus (n=68) or preperitoneal (n=24). Two meshes were placed as an onlay and one intraperitoneal. Open repairs were performed 91.6% of the time.

Median follow-up was 24.2 months, with an interquartile range (IQR) of 837 days (1207 – 370). Post-procedural follow-up (days 0 to 45) incidence of SSI and SSO were 4.3% and 16.8% respectively, and no device was removed. Thirteen patients (13.6%) experienced a hernia recurrence, median time to recurrence, for these patients, was 7.3 months (Range 3.25 – 27.4). Among patients with a hernia recurrence, the average hernia size was 12.6 x 8.2 cm. Eight patients were designated CDC wound class I, three were class II, 1 class III, and 1 class IV. The average BMI for recurrences was 29.9.

CCS scores indicated a reduction in pain scores and improvement in movement scores from baseline, with minimal increases in mesh sensation scores.

**Conclusions:** High-comorbidity, complex ventral hernia cohort repair with the PRE device is associated with favorable perioperative safety and low rates of wound complications and recurrence. No explants were required. These promising results highlight the safety and performance of this reinforcing bioabsorbable mesh.

## Background

Ventral and incisional hernias remain a challenge in abdominal wall repair, especially in patients with larger defects, previous surgery, or significant comorbidities. Despite progress in surgical technique, wound complications and hernia recurrence continue to patient outcomes. Extraperitoneal reinforcement in the retrorectus or preperitoneal planes is widely used to support the abdominal wall while avoiding direct contact with abdominal organs.

Bioabsorbable materials provide temporary support during healing and gradually resorb, which reduces long term foreign body presence. The GORE ENFORM Preperitoneal Biomaterial was designed for use in extraperitoneal locations to support tissue integration and abdominal wall stability, but real-world data remain limited. This study reports safety, wound related events, recurrence, and patient reported comfort following contemporary ventral hernia repair using this material.

| Patient Demographics and Select Medical History | Overall N=95 |
|---|---|
| Age at Screening (years) | N=95 |
| Mean (Std Dev) | 58.7 (13.5) |
| Median (Min, Max) | 60.0 (24.0, 78.0) |
| | |
| Sex | N=95 |
| Male | 37 (38.9%) |
| Female | 58 (61.1%) |
| | |
| Ethnicity | N=95 |
| Hispanic or Latino | 2 (2.1%) |
| Not Hispanic or Latino | 92 (96.8%) |
| Unknown or Not Reported | 1 (1.1%) |
| | |
| Race | N=95 |
| American Indian or Alaska Native | 1 (1.1%) |
| Asian | 0 (0.0%) |
| Black | 7 (7.4%) |
| Pacific Islander | 0 (0.0%) |
| White | 84 (88.4%) |
| Other or Multiple Responses | 3 (3.2%) |
| | |
| Body Mass Index | N=95 |
| Mean (Std Dev) | 30.3 (4.2) |
| %-iles (Min, 25, 50, 75, Max) | 20.8, 28.0, 31.0, 33.3, 39.3 |
| | |
| Tobacco usage | N=95 |
| Never | 45 (47.4%) |
| Current | 3 (3.2%) |
| Smoking cessation 4 weeks prior to procedure | 4 (4.2%) |
| Former >4 weeks | 43 (45.3%) |
| | |
| Previous Surgeries & Interventions | |
| Previous hernia surgery | 49.5% (47/95) |
| Ventral/incisional hernia | 83.0% (39/47) |
| Diaphragmatic/hiatal hernia repair | 4.3% (2/47) |
| Previous surgery with impact on treatment procedure | 17.0% (8/47) |

## Results

Fig 1. Ventral Hernia Recurrence

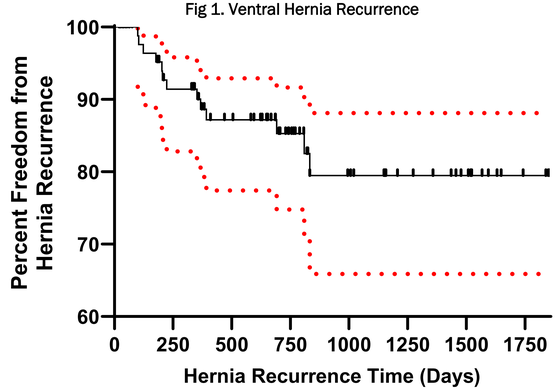


**Fig 1.** Clinically confirmed ventral hernia recurrences among all patients through currently available follow-up (n=95). 95% Confidence intervals are noted by the red dashed lines. See number at risk table below.

| Time Post-Treatment (Days) | # at Risk at Interval Start | # Failed (Cumulative) | # Censored (Cumulative) | Survival Probability | 95% C.I. |
|---|---|---|---|---|---|
| 0 | 95 | 0 (0) | 0 (0) | 100% | (100.0%, 100.0%) |
| (0-45] | 95 | 0 (0) | 7 (7) | 100% | (100.0%, 100.0%) |
| (45-212] | 88 | 6 (6) | 9 (16) | 92.7% | (84.4%, 96.6%) |
| (212-409] | 73 | 4 (10) | 12 (28) | 87.2% | (77.4%, 92.9%) |
| (409-790] | 57 | 1 (11) | 24 (52) | 85.3% | (74.8%, 91.6%) |
| (790-1854][2] | 32 | 2 (13) | 30 (82) | 79.5% | (65.9%, 88.1%) |

[1]Numbers in parentheses represent cumulative failed or censored subjects through end of interval.
[2]This time period is until the time of failure or censor for the subject with longest time.

Fig 2. Carolina Comfort Scale Quality of Life Scores Through Available Prospective Patient Follow-Up

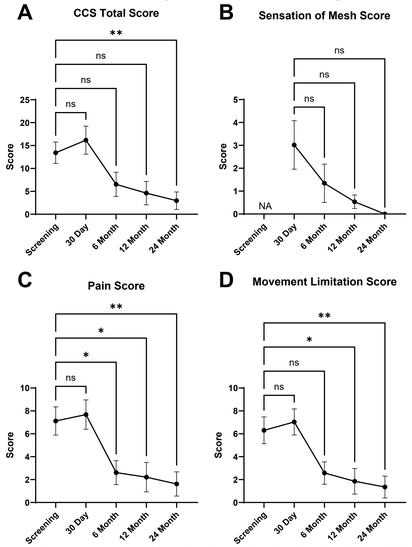


**Fig 2.** Patient reported outcomes were evaluated using the Carolina Comfort Scale (CCS). A) Total score B) Mesh sensation score C) Pain score and D) Movement scores were longitudinally evaluated. Prospective patients were included in this analysis. The number of patients evaluated in the current data analysis window was: screening (n=48), post-procedure (n=46), 6-month (n=29), 12-month (n=28), and 24-month (n=14). Mixed-effects analysis with Geisser–Greenhouse correction was performed in GraphPad Prism. Dunnett's test was used to compare time points to screening or for the 30-day follow-up for mesh sensation. *$p$<0.05; **$p$<0.01. Error bars represent mean ± SEM.

## Conclusions

In this ongoing multicenter study of patients undergoing ventral or incisional hernia repair, use of the GORE® ENFORM Preperitoneal Biomaterial (PRE device) was associated with acceptable perioperative outcomes during the follow-up period available to date. Patients often presented with multiple comorbidities, large defects, or complex wound characteristics, yet observed rates of SSI (4.3%) and SSO (16.8%) were consistent with expectations for similar clinical populations, and no device removals occurred. The unadjusted hernia recurrence proportion was 13.6% (13/95); when accounting for censoring using Kaplan–Meier methods, the estimated hernia recurrence was 14.7% through two years. These results should be interpreted in relation to patient risk factors, including BMI, wound class, prior recurrence, and defect size.

Patient-reported outcomes collected using the Carolinas Comfort Scale indicated decreasing symptom burden over time among respondents, with median Total CCS scores declining from 5.5 at screening to 0.0 at 6, 12, and 24 months. Mean CCS scores followed a similar downward trend, reflecting improvements in pain, movement-related discomfort, and mesh sensation during follow-up. These findings provide insight into clinical and quality-of-life outcomes following extraperitoneal placement of a bioabsorbable reinforcing material, and continued enrollment with extended follow-up will further inform the consistency and generalizability of these observations.

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