MULTICENTER HIATAL HERNIA REPAIR (HHR) WITH ABSORBABLE GORE ENFORM MESH

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Introduction

Hiatal hernia repair is commonly performed for symptomatic patients with large paraesophageal hernias or complex type III/IV defects. Achieving a durable repair can be challenging, as recurrence occurs in up to 38% of patients, often resulting in persistent symptoms or reoperation.

Permanent mesh reinforcement can reduce early recurrence rates, but has been associated with erosion, fibrosis, and chronic dysphagia. Bioabsorbable meshes provide temporary support during tissue healing and avoid long-term foreign material. However, outcomes have been variable, and concerns remain regarding early durability with absorbable mesh reinforcement.

Study Objective

The GORE ENFORM Preperitoneal Biomaterial is a fully absorbable mesh designed to reinforce the crura while resorbing over 6-7 months. This study evaluates the perioperative safety, early recurrence, and patient-reported outcomes after hiatal hernia repair reinforced with ENFORM mesh in a multicenter U.S. cohort.

Methods

Study Design

- Multicenter U.S. study (6 academic hospitals)
- Combined prospective (n=60) and retrospective (n=43) cohorts
- Standardized protocol for surgery, follow-up, and data collection; mesh configuration, fixation, and anti-reflux procedures determined by operating surgeon

Inclusion: Adults undergoing hiatal hernia repair with ENFORM mesh reinforcement at hiatus

Data Collected

- Demographics and operative details
- Device- and procedure-related adverse events
- Hernia recurrence
- Patient-reported outcomes (GERD-HRQL)

Follow-Up

- Captured at post-procedure, 6 months, 12 months, and 24 months
- Median follow-up: 24.7 months

Results

Patient Demographics and Select Medical History	Overall N=103
Age at Screening (Years)	63.7 ± 12.8
Sex	
Male	30 (29.1%)
Female	73 (70.9%)
Ethnicity	
Hispanic or Latino	10 (9.7%)
Not Hispanic or Latino	91 (88.3%)
Unknown or Not Reported	2 (1.9%)
Race	
American Indian or Alaska Native	0 (0.0%)
Asian	2 (1.9%)
Black	1 (1.0%)
Pacific Islander	0 (0.0%)
White	93 (90.3%)
Other or Multiple Responses	7 (6.8%)
Body Mass Index (Mean ± Std Dev)	28.2 ± 4.2
Previous Surgeries	
Ventral/incisional hernia	4 (3.9%)
Diaphragmatic/hiatal hernia repair	4 (3.9%)
Inguinal hernia repair	11 (10.7%)
Umbilical hernia repair	1 (0.97%)

Table 1. Demographic characteristics of total cohort (N = 103). Categorical variables are presented as frequency (n) and percentage (%). Continuous variables are summarized as mean ± standard deviation (SD)

Intraoperative Characteristics	Overall N=103
Procedure Time (Minutes)	116.5 ± 43.3
CDC Wound Class	
Clean (Class I)	78 (75.7%)
Clean-contaminated (Class II)	25 (24.3%)
Hiatal Hernia Type	
Type I (sliding)	10 (9.7%)
Type II (classic paraesophageal)	24 (23.3%)
Type III (mixed paraesophageal)	59 (57.3%)
Type IV (giant)	10 (9.7%)
Surgical Approach	
Robotic	45 (43.7%)
Laparoscopic	58 (56.3%)

Table 2. Intraoperative characteristics of total cohort (N = 103). Categorical variables are presented as frequency (n) and percentage (%). Continuous variables are summarized as mean ± standard deviation (SD)

Fig 1. Freedom From Hiatal Hernia Recurrence

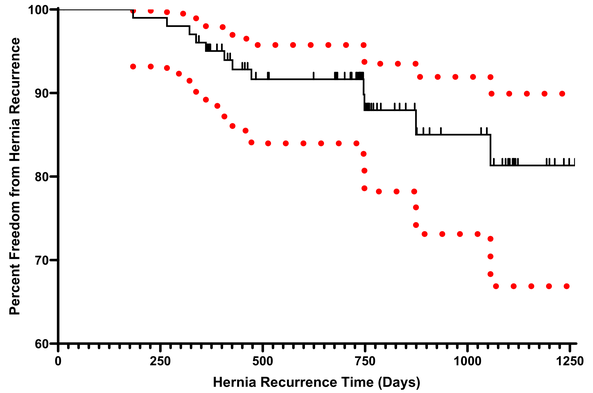

Fig 1. Clinically confirmed hiatal hernia recurrences among all patients through study period (n=103). Vertical dashes represent a censored patient. 95% Confidence Intervals are noted by the red dashed lines.

Time Post-Treatment (Days)	# at Risk at Interval Start	# Failed (Cumulative)	# Censored (Cumulative)	Survival Probability	95% C.I.
0	103	0 (0)	0 (0)	100%	(100.0%, 100.0%)
(0-45]	103	0 (0)	1 (1)	100%	(100.0%, 100.0%)
(45-212]	102	1 (1)	0 (1)	99.0%	(93.2%, 99.9%)
(212-409]	101	5 (6)	8 (9)	94.0%	(87.1%, 97.3%)
(409-790]	88	3 (9)	47 (56)	90.2%	(81.7%, 94.8%)
(790-1262][2]	38	2 (11)	36 (92)	83.4%	(69.0%, 91.5%)

[1]Numbers in parentheses represent cumulative failed or censored subjects through end of interval.
[2]End of window was determined by the most recent contact date of eligible patients.

Fig 2. GERD-HRQL

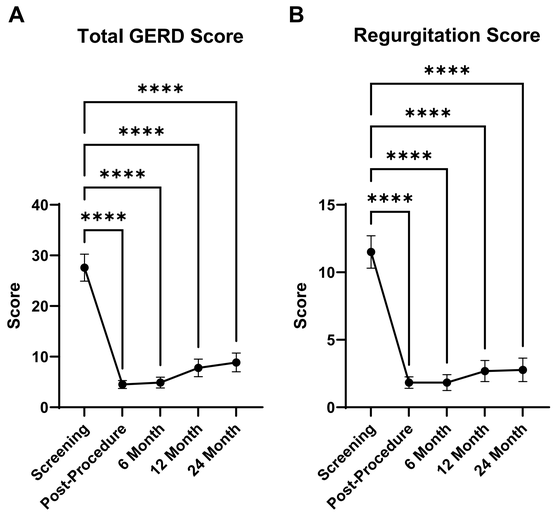

Fig 2. Patient reported outcomes were evaluated using the Gastroesophageal Reflux Disease-Health Related Quality of Life (GERD-HRQL) questionnaire. A) Total score and B) Regurgitation score were longitudinally evaluated. The number of patients evaluated in the current data analysis windows were: screening (n=70), post-procedure (n=58), 6-month (n=53), 12-month (n=51), and 24-month (n=40). Mixed-effects analysis with Geisser–Greenhouse correction was performed in GraphPad Prism. Dunnett's test was used to compare all time points to baseline. ****p<0.0001. Error bars represent mean ± SEM.

Conclusions

In this multicenter U.S. cohort of 103 patients, hiatal hernia repair reinforced with fully absorbable GORE ENFORM mesh demonstrated a favorable perioperative safety profile, including among complex paraesophageal hernias. Procedure-related serious adverse events were rare and resolved without reoperation; no mesh-related complications requiring surgical intervention occurred. Among prospective patients (n=60), 35 have completed 24-month follow-up; the remaining patients have been censored pending follow-up (completion in October 2026).

Over a median follow-up of 24.7 months, the rate of hernia recurrence was 10.7%. After accounting for censoring, the adjusted rate of recurrence was 16.6% at 41.5 months, corresponding to a recurrence-free survival of 83.4%. Only one patient required surgical re-intervention, indicating short- to mid-term durability of repairs. Patients reported substantial, sustained improvements in symptoms, with GERD-HRQL scores decreasing from 27.6 at baseline to 8.9 at 24 months.

These findings support bioabsorbable mesh reinforcement as a balanced approach in elective hiatal hernia repair, providing both anatomic durability and symptom improvement while avoiding the long-term risks of permanent meshes. Longitudinal follow-up will further define long-term recurrence patterns and absorbable mesh durability in foregut surgery.

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