GORE® BIO-A®
Tissue Reinforcement

CLINICAL PERFORMANCE AND QUALITY OUTCOMES IN HIATAL HERNIA REPAIR

Utilizing a 3D PGA:TMC Web Scaffold for Tissue Reinforcement

Together, improving life

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The articles listed here may include outcome descriptions that reflect use of devices outside the approved *Instructions for Use* (IFU), in certain region/country. Gore does not promote the off-label use of devices. Physicians should consult the IFU for complete device information, including contraindications, warnings and cautions.

All studies included are not funded by W. L. Gore & Associates.

Article 1: Long-Term Results After Laparoscopic Sleeve Gastrectomy with Concomitant Posterior Cruroplasty: 5-Year Follow-Up[1]

Cristian Eugeniu Boru, Maria Grazia Coluzzi, Francesco de Angelis, Gianfranco Silecchia

July 2019 in *Journal of Gastrointestinal Surgery*

Study summary

Study type	Prospective study	
Number of patients	**Total of 96 patients** GORE® BIO-A® Reinforcement group: 48	Suture group: 48
Follow-up length	Five years	
Patient complete full follow-up	GORE® BIO-A® Reinforcement group: 95.6%	Suture group: 79.2%
Hernia size	GORE® BIO-A® Reinforcement group: > 4 cm^2	Suture group: < 4 cm^2
Hernia recurrence rate	GORE® BIO-A® Reinforcement group: 4.3%	Suture group: 18.4%
Recurrent GERD	GORE® BIO-A® Reinforcement group: 19.5% ($P = 1.00$), no significant differences	Suture group: 15.7%
Device-related complications	0	
GERD control rate	80% for device group, 85% for suture group ($P > 0.05$, no significant differences)	
Barrett esophagus	0	
Device shape	7 × 10 cm with "U" shape	
Concomitant procedure	Laparoscopic sleeve gastrectomy (LSG)	
Patient postoperative status	All patients declared a non-chronic use of Proton pump inhibitors (PPI). Outcomes of LSG combined with posterior cruroplasty were satisfactory in all patients.	
How hernia recurrence was measured	Radiological, contrast study and CT scan	

Excerpts

"The general trend confirms that reinforced cruroplasty is highly effective in a certain subgroup of patients with weakness of the pillars and "medium" hiatal defect (range 4–8 cm^2), with no side effects or complications related to the use of the totally absorbable synthetic [device]."

PubMed link

https://pubmed.ncbi.nlm.nih.gov/31410817/

Article 2: Simple Versus Reinforced Cruroplasty in Patients Submitted to Concomitant Laparoscopic Sleeve Gastrectomy: Prospective Evaluation in a Bariatric Center of Excellence[2]

Sara Ruscio, Mohamed Abdelgawad, Danilo Badiali, Olga Iorio, Mario Rizzello, Giuseppe Cavallaro, Carola Severi, Gianfranco Silecchia

October 2015 in *Surgical Endoscopy*

Study summary		
Study type	Prospective study	
Number of patients	**Total of 96 patients** GORE® BIO-A® Reinforcement group: 48	Suture group: 48
Follow-up length	Mean 19 (range 10–39 months)	
Hernia size	GORE® BIO-A® Reinforcement group: > 4 cm^2	Suture group: < 4 cm^2
Hernia recurrence rate	GORE® BIO-A® Reinforcement group: 0%	Suture group: 12.5%
Recurrent GERD (symptomatic and radiological)	GORE® BIO-A® Reinforcement group: 0%	Suture group: 10.4%
Device-related complications	0	
GERD control rate	95% for device group, 82.3% for suture group	
Barrett esophagus	0	
Device shape	7 × 10 cm with "U" shape	
Concomitant procedure	Laparoscopic sleeve gastrectomy	
Patient postoperative status	All cases showed symptom remission and gave up PPI within three months after surgery.	
How hernia recurrence was measured	Radiological, contrast study and CT scan and intraoperatively	

Excerpts

"The results of the present study were surprising because in the high risk group for recurrence with larger hiatal defects, we did not observe any clinical or radiological recurrence at 19 months. On the contrary in the low risk group (simple cruroplasty, regular pillar, small hiatus defect), a statistically significant recurrence rate was observed at 21 months (12.5 %). In conclusion, the synthetic absorbable [device] offers an effective option for crural repair during Laparoscopic Sleeve Gastrectomy (LSG) with low recurrence rates at 19 months."

PubMed link

https://pubmed.ncbi.nlm.nih.gov/26428202/

Article 3: Concomitant Hiatal Hernia Repair During Bariatric Surgery: Does the Reinforcement Make the Difference?[3]

Cristian E. Boru, Pietro Termine, Pavlos Antypas, Angelo Iossa, Chiara M. Ciccioriccio, Francesco De Angelis, Alessandra Micalizzi, Gianfranco Silecchia

February 2021 in *Minerva Surgery*

Study summary		
Study type	Prospective study	
Number of patients	**Total of 250 patients** GORE® BIO-A® Reinforcement group: 99	Suture group: 151
Follow-up length	50 months	
Patient complete full follow-up	GORE® BIO-A® Reinforcement group: 95%	Suture group: 93%
Mean hernia size	GORE® BIO-A® Reinforcement group: 6.7 cm^2	Suture group: 3.4 cm^2
Hernia recurrence rate	GORE® BIO-A® Reinforcement group: 4%	Suture group: 8%
How recurrence was measured	Radiological, contrast X-ray	
Device-related complications	0	
Device infection	0	
Device erosion	0	
Device shape	7 × 8 cm with "U" shape	
Concomitant procedure	Predominantly laparoscopic sleeve gastrectomy and R-en-Y gastric bypass	
Patient postoperative status	($P < 0.0003$) "Significantly less patients of GORE® BIO-A® Reinforcement group experienced GERD symptoms postoperatively than those of suture group"	
PPI	GORE® BIO-A® Reinforcement group patients showed a significant decrease in PPI therapy after the surgery	

Excerpts

"An aggressive search for and repair of HH [hiatal hernia] during any bariatric procedure seems advisable, allowing a low HH [hiatal hernia] recurrence rates. Additional measures, like [device] reinforcement of crural closure with biosynthetic, absorbable [device], seem to improve results on long term follow-up, especially in case of larger hiatal defects. In our experience, reinforcement of even smaller defects seems advisable in obese population."

PubMed link

https://pubmed.ncbi.nlm.nih.gov/33006451/

Article 4: A Collective Review of Gore Bio-A Absorbable Synthetic Mesh in Cruroplasty Reinforcement[4]

Michael T. Olson, Sumeet K. Mittal, Ross M. Bremner

September 2020 in *Journal of Laparoendoscopic & Advanced Surgical Techniques*

Study summary	
Study type	Systematic review of studies from January 2008 to December 2019. Eight articles were included: Two prospective and six retrospective studies.
Number of patients	734
Follow-up length	Median clinical follow-up: from 12 (11.6–15.7) months to 47.5 (36–60) months
Hernia size	All hiatal hernia types were included
Hernia recurrence rate	Objective (anatomical) recurrence rate: 7.5%
Reoperation rate	7.9%
Device-related complications	1 (0.17%)
Device erosion	0
Device related mortality	0
Device shape	7 × 10 cm with "U" shape
Concomitant procedure	Fundoplication, Collis Gastroplasty
Patient postoperative status	Symptomatic outcomes were reported by multiple methods across studies including GERD-HRQL Questionnaire or yes/no scoring system, the author concluded "Excellent patient satisfaction and very low morbidity rates" with no mesh-related mortality reported in any of the included studies.

Excerpts

"This collective review offers considerable evidence that the absorbable synthetic [GORE® BIO-A® Tissue Reinforcement] is associated with low morbidity rates, and it may help prevent [device-related] complications over the long term."

"Laparoscopic HH [hiatal hernia] repair with the use of [GORE® BIO-A® Tissue Reinforcement] remains a safe procedure with excellent patient satisfaction and very low morbidity rates."

PubMed link

https://pubmed.ncbi.nlm.nih.gov/32882152/

Article 5: Outcomes of Bariatric Surgery with Concomitant Hiatal Hernia Repair Using an Absorbable Tissue Matrix[5]

Michael W. Love, Daniel F. Verna, Shanu N. Kothari, and John D. Scott

May 2021 in *The American Surgeon*

Study summary				
Study type	Retrospective Study			
Number of patients	420			
Mean follow-up length	26 months			
Mean hernia size	3.2 ± 1.1 cm			
Device shape	"U" shape			
Concomitant procedure	Laparoscopic sleeve gastrectomy or Roux-en-Y gastric bypass			
How recurrence was measured	Physical examination			
Hernia recurrence by group	**420 patients**			
	202 Roux-en-Y gastric bypass (RYGB)*		18 Vertical sleeve gastrectomy(VSG)†	
	188 BIO-A® Reinforcement	14 no device	204 BIO-A® Reinforcement	14 no device
	3.7%	7.1%	0.5%	7.1%
Overall recurrent rate	GORE® BIO-A® Reinforcement group: 2%		Suture group: 7.1%†	
Device-related complications	0			
Rate of reoperation	0			
Patient postoperative status	Total PPI use declining from 41% within the first postoperative year to 9% by the third postoperative year			

Excerpts

"Performing Roux-en-Y gastric bypass or vertical sleeve gastrectomy with concomitant hiatal hernia repair is safe and durable. Employing crural reinforcement with BTM [GORE® BIO-A® Reinforcement] may be of benefit in reducing recurrence rates of hiatal hernia, particularly in sleeve gastrectomy patients."

PubMed link

https://pubmed.ncbi.nlm.nih.gov/34058829/

* $P > 0.05$ no significant difference.

† $P = 0.01$ significant difference.

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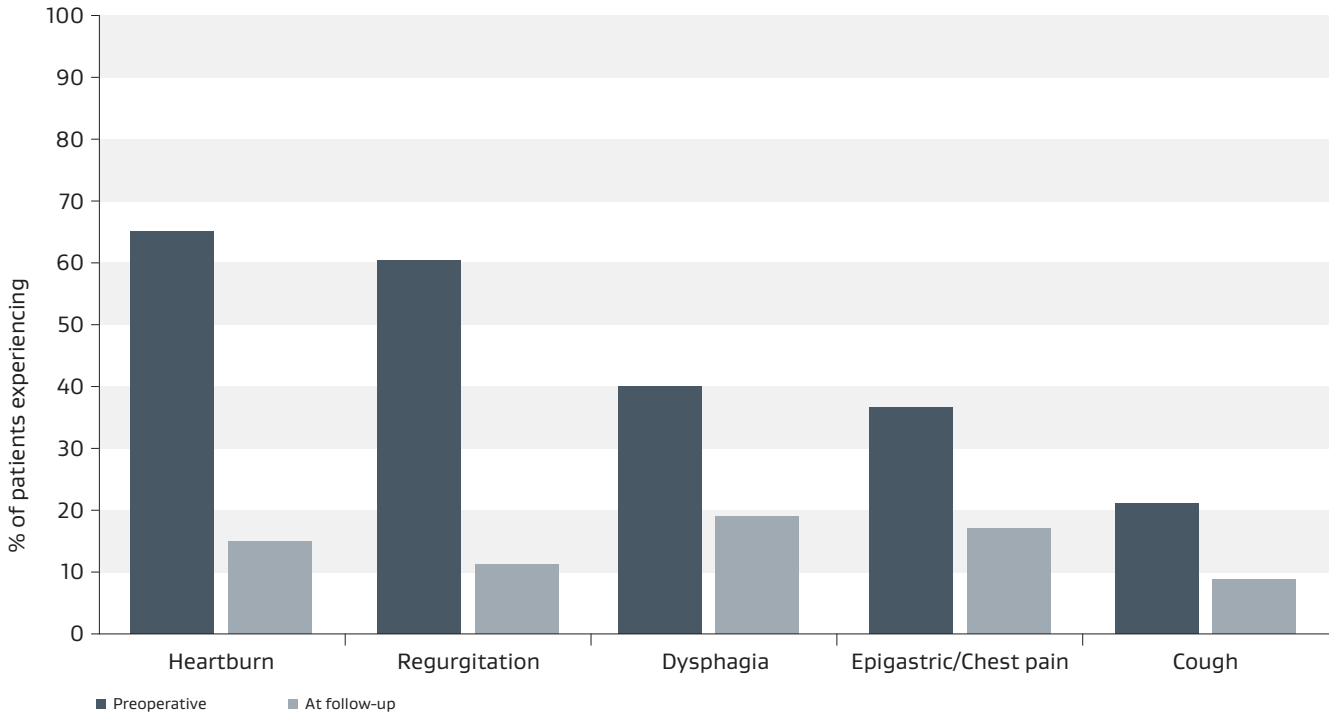
Article 6: Primary Paraesophageal Hernia Repair (PEH) with GORE® BIO-A® Tissue Reinforcement: Long-Term Outcomes and Association of BMI and Recurrence[6]

Michael T. Olson, Saurabh Singhal, Roshan Panchanathan, Sreeja Biswas Roy, Paul Kang, Taylor Ipsen, Sumeet K. Mittal, Jasmine L. Huang, Michael A. Smith, Ross M. Bremner

May 2018 in *Surgical Endoscopy*

Study summary	
Study type	Retrospective Study
Number of patients	399
Follow-up length	Mean 44.7 month (± 22.8)
Patient complete full follow-up	n = 305 (76.4%)
Hernia size	Primary paraesophageal hernias including small (< 3 cm), medium (> 3, < 5 cm), large (> / = 5 cm) hernias and intrathoracic stomach
Hernia recurrence rate	7.9% (24/305) recurrence requiring reoperation
GERD	194/217 patients (89.4%) reported good to excellent satisfaction with the 6-point symptom severity questionnaire
Device-related complications	1 (0.33%)
Device shape	"U" shape
Concomitant procedure	Fundoplication, Collis gastroplasty (one case)
Patient postoperative status	89.4% patients reported good to excellent satisfaction with their PEH repair

Comparison of symptoms at the time of clinical presentation and at long-term follow-up



Excerpts

"This study confirms that laparoscopic primary PEH repair with onlay absorbable biosynthetic [device] [GORE® BIO-A® Reinforcement] combined with fundoplication is a safe and feasible procedure that offers excellent long-term patient-centered outcomes and an acceptable symptomatic recurrence rate."

Additional study information

- No device erosions.
- This study has shown the success of this procedure in a cohort of which nearly half the patients (n = 180; 45.1%) were obese at the time of surgery.

PubMed link

https://pubmed.ncbi.nlm.nih.gov/29761272/

Article 7: Crura Augmentation with BIO-A® Mesh for Laparoscopic Repair of Hiatal Hernia: Single-Institution Experience with 100 Consecutive Patients[7]

E. Asti, A. Sironi, G. Bonitta, A. Lovece, P. Milito, L. Bonavina

April 2017 in *Hernia*

Study summary	
Study type	Retrospective study
Number of patients	100
Follow-up length	Median follow-up was 30 months with multiple patients complete 58 months follow-up
Hernia recurrence rate	9% (eight of the nine patients had a preoperative type III hernia) Kaplan Meier five-year recurrence rate: 16%
Device-related complications	0
GERD control rate	The median GERD-HRQL score[8] was significantly reduced after operation ($P < 0.001$) with GERD-HRQL median scores before hiatal hernia repair was 14 and scores after hiatal hernia repair were two.
Reoperation/surgical revision	0
Device shape	7 × 10 cm with "U" shape
Procedure	Crura reinforcement with GORE® BIO-A® device and Toupet fundoplication
Patient postoperative status	Only two patients had mild reflux symptoms responding to PPI therapy. None of the patients required surgical revision. GERD-HRQL scores were significantly reduced and returned to normal values compared to baseline.
How hernia recurrence was measured	Recurrence hernia ≥ 2 cm, at endoscopy or barium swallow

Excerpts

"The present study confirms that the use of an absorbable synthetic [device] was safe and durable over time in a larger patient population. No infectious or mechanical complication associated to the [device] were observed, and the median GERD-HRQL score significantly decreased over the long-term follow-up."

PubMed link

https://pubmed.ncbi.nlm.nih.gov/28396955/

Article 8: Resorbable Biosynthetic Mesh for Crural Reinforcement During Hiatal Hernia Repair (2014)[9]

Evan T. Alicuben, Stephanie G. Worrell, Steven R. Demeester

October 2014 in *American Journal of Surgery*

Study summary	
Study type	Retrospective study
Number of patients	114
Follow-up length	Median of 12 months
Patient complete full follow-up	99
Hernia type	Sliding hiatal hernia and paraesophageal hiatal hernia
Hernia recurrence rate	0.9% (one patient), identified three years after repair
Reoperation	0
Device-related complications	0
Device erosion	0
Device infection	0
Device shape	Heart-shaped (as described in article)
Concomitant procedure	Fundoplication, Collis gastroplasty
How hernia recurrence was measured	Recurrence was defined as any size hernia visible on videoesophagram or on upper endoscopy.

Excerpts

"At a median follow-up of 12 months, the results with this technique have been excellent with no erosions, minimal complications and objective evidence of an intact repair in 99% patients."

"In this study we show that the use of crural-relaxing incisions and a Collis gastroplasty when necessary in addition to [GORE®] BIO-A® Reinforcement of the primary crural closure allow excellent early results with minimal morbidity and few recurrent hernias by objective evaluation."

PubMed link

https://pubmed.ncbi.nlm.nih.gov/25264654/

Article 9: Mid-Term Safety Profile Evaluation of BIO-A Absorbable Synthetic Mesh as Cruroplasty Reinforcement[10]

Angelo Iossa, Gianfranco Silecchia

January 2019 in *Surgical Endoscopy*

Study summary	
Study type	Retrospective evaluation of prospectively maintained database
Number of patients	120
Follow-up length	Mean follow-up of 41 months
Patient group	**Group A:** 92 obese patients — hiatal hernia repair with GORE® BIO-A® Reinforcement + bariatric procedures (including sleeve gastrectomy, re-LSG and gastric bypass) **Group B:** 28 non-obese patients — hiatal hernia repair with GORE® BIO-A® Reinforcement + antireflux surgery (360° Nissen fundoplication)
Hernia size	Hiatal defect ≥ 4 cm^2
Hernia recurrence rate	Group A: 5.4% Group B: 7.1%
Device-related complications	0
Device infection	0
GERD management	After more than three years of follow-up, 74% of group A and 61% of group B patients are PPIs free with median GERD-HRQL score[8] of four (from 16) and six (from 23), respectively. The difference with pre-operative GERD incidence was statistically significant
Barrett esophagus	0
Device shape	7 × 10 cm with "U" shape
Concomitant procedure	Sleeve gastrectomy, re-LSG, gastric bypass, Nissen fundoplication
How hernia recurrence was measured	X-ray with barium swallow, CT scan, and/or endoscopy

Excerpts

"These results support the use of absorbable [device] for [hiatal hernia repair] (safe profile—0% of complications rate), showing excellent recurrence rate results and good GERD symptoms control."

Additional study information

- There is a need to treat hiatal hernia repair for obese patients:
  - "A correlation between body mass index (BMI) and gastroesophageal reflux disease (GERD) with concomitant hiatal hernia has been reported in up to 50% of morbid obese candidates for bariatric surgery."
  - "Moreover, simple posterior cruroplasty with non-absorbable stitches is accompanied by high hernia recurrence rates (up to 30%) in obese patients (BMI > 30 kg/m2)."
  - "The American Society for Metabolic and Bariatric Surgery (ASMBS) guidelines recommend hiatal hernia repair during all bariatric procedures."
- The authors states that: "This data is much more interesting considering that the device is completely replaced by collagen in six months". This confirmed: 1) All GORE® BIO-A® Reinforcement used were absorbed completely and replaced with quality tissue. 2) The collagen generated provided strong repair which can reduce hernia recurrence for more than three more years.

PubMed link

https://pubmed.ncbi.nlm.nih.gov/30675663/

Article 10: Tissue Reinforcement with Gore BIO-A Matrix in Large Hiatal Hernias. "State Of The Art" in Hiatal Augmentation?[11]

D. Birk

2017 in *Hernia as abstract*

Study summary	
Study type	Prospective study
Number of patients	134
Follow-up length	Median follow-up is 23 months
Patient complete full follow-up	91%
Hernia size	Large hiatal hernia > 4 cm
Hernia recurrence rate	11%
Device-related complications	0
Device shape	7 × 10 cm with "U" shape
Procedure	Laparoscopic crura repair

Excerpts

"The GORE® BIO-A® Reinforcement has so far led to a very favorable clinical outcome. To my knowledge this is the lowest reported recurrence rate after 23 months as compared to similar patient cohorts. This implant may become "state of the art" in hiatal augmentation."

Article 11: The Use of Biosynthetic Mesh in Giant Hiatal Hernia Repair: Is There a Rationale? A 3-Year Single-Center Experience[12]

E. Tartaglia, D. Cuccurullo, L. Guerriero, S. Reggio, C. Sagnelli, P. Mugione, F. Corcione

July 2020 in *Hernia*

Study summary	
Study type	Prospective study
Number of patients	44
Follow-up length	Three years
Patient complete full follow-up	40 (90.9%)
Hernia size	> 5 cm
Hernia recurrence rate	4.5%
Symptoms scores (dysphagia, regurgitation, heartburn, nausea, indigestion)	"Mean preoperative symptoms score analysis was 1.68 ± 0.73. Conversely, the mean scores at each follow-up time (0.27 ± 0.45, 0.55 ± 0.50, 0.59 ± 0.55 at 6, 12 and 36 months, respectively) were significantly improved compared to baseline ($P < 0.05$)"
Device-related complications	0
Device shape	U-shaped 5 × 8 cm
Antireflux procedure	Nissen fundoplication and Toupet fundoplication
Patient postoperative status	Patients' satisfaction rate which was reported as excellent in 51.7%, good in 29.3%, fair in 10.4% and poor in 8.6% of patients
How hernia recurrence was measured	Radiological recurrence with Barium swallow

Excerpts

"The use of Gore biosynthetic [device] [GORE® BIO-A® Tissue Reinforcement] for laparoscopic repair of large hiatal hernias demonstrated to be safe. It confirms low recurrence rate and no [device] complication at 3-year follow-up, with a significant improvement of the symptoms compared to preoperative evaluation."

PubMed link

https://pubmed.ncbi.nlm.nih.gov/32712835/

Article 12: Laparoscopic Mesh Hiatoplasty with Bioresorbable Mesh[13]

Cobb W, Carbonell A, Walton L, Kramp C, Scott J, Bour E, Smith D

2012 in *Hernia* as Abstract

Study summary	
Study type	Retrospective study
Number of patients	148
Follow-up length	Mean follow-up of nine months
Hernia type	Paraesophageal hernia repair (112) Large hiatal hernia repair (14) Recurrent hiatal hernia repair (20) Parahiatal hernia repair (2)
Hernia recurrence rate	7%
Device erosion	0
Concomitant procedure	Laparoscopic crura repair + fundoplication (85% cases)

Excerpts

"Bioresorbable [device] can be safely used to reinforce hiatal closure with a low risk of recurrence. The incidence of postoperative dysphagia is low and no complications of [device] erosion were encountered."

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W. L. Gore & Associates, Inc.
goremedical.com
Asia Pacific +65 6733 2882 **Australia/New Zealand** 1800 680 424 **Europe** 00800 6334 4673
United States Flagstaff, AZ 86004 800 437 8181 928 779 2771