

GORE® SEAMGUARD®

Bioabsorbable Staple
Line Reinforcement



CLINICAL PERFORMANCE WITH STAPLE LINE REINFORCEMENT

Together, improving life



Table of contents

Gastric Bypass Procedures
Data Summary Studies1

Sleeve Gastrectomy Procedures
Data Summary Studies 5

Colorectal Procedures
Data Summary Studies12

Pancreatic Procedures
Data Summary Studies15

Thoracic Procedures
Data Summary Studies 18

Hospital Savings Summary Studies19

References 22

Gastric Bypass Procedures

Use of bioabsorbable staple reinforcement material in gastric bypass: A prospective randomized clinical trial.

Miller KA, Pump A.¹

24 patients with GORE® SEAMGUARD® Reinforcement	24 patients with no SLR	Significance
No leaks	1 intraoperative leak	
Fewer clips used (mean of 2)	Higher clips used (mean of 22)	* $P < 0.0001$
Higher post-operation hemoglobin (12.47 ± 1.7 mg/dL)	Lower post-operation hemoglobin (11.1 ± 1.9 mg/dL)	* $P < 0.05$
No fistulas	12.5% developed fistulas	$P = 0.2$

Excerpts

“Intraoperative staple line bleeding was significantly reduced in our study group, as demonstrated by the significantly lower use of clip instruments in group 1 versus group 2.”

“The avoidance of a single severe complication would make its [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] use worth it.”

Glycolide copolymer staple line reinforcement reduces staple site bleeding during laparoscopic gastric bypass. A prospective randomized trial.

Nguyen NT, Longoria M, Welbourne S, Sabio A, Wilson SE.²

17 patients with GORE® SEAMGUARD® Reinforcement	17 patients with no SLR	Significance
Lower mean blood loss (84 ± 50 ml)	Higher mean blood loss (129 ± 63 ml)	* $P < 0.01$
Fewer staple line bleeding sites (mean: 0–0.4)	Higher staple line bleeding sites (mean: 0.6–2.5)	* $P < 0.01$
Less time to staple line hemostasis (mean: 1.2 min)	Greater time to staple line hemostasis (mean: 10.1 min)	* $P < 0.01$
No transfusions	1 transfusion and reoperation	

Excerpts

“Staple misfire occurred in 1 (0.7%) of 143 total number of stapler loads used in the treatment group compared with 0 of 138 total number of stapler loads used in the control group.”

“Although this study did not conclusively demonstrate that the use of staple line reinforcement sleeves lowers the rate of GI hemorrhage, we found that intraoperative staple line bleeding was significantly reduced. In this trial, we noted an 84% reduction in staple line bleeding sites at gastric tissue, an 83% reduction in staple line bleeding sites at jejunal tissue, and a 100% reduction in staple line bleeding sites at mesenteric tissue with the use of the staple line reinforcement sleeves.”

“The use of glycolide copolymer staple line reinforcement sleeves in patients undergoing laparoscopic gastric bypass is safe and significantly reduces staple line bleeding sites and may reduce the incidence of gastrointestinal hemorrhage.”

* P -values less than 0.05 (* $P < 0.05$) represent statistically significant data.

Comparison of buttressing material in Roux-en-Y gastric bypass.

Zomerlei TA, Brown A, Bajric J, Kemmeter PR.³

142 patients with GORE® SEAMGUARD® Reinforcement	228 patients with SYNOVIS® PERI-STRIPS DRY® Product	Significance
No leaks	5.3% leak rate	* $P < 0.05$

Excerpts

“Despite the EBSG [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] group having a higher rate of comorbidities, the leak rate was lower compared to the PSDV [with SYNOVIS® PERI-STRIPS DRY® Product] group.”

Early experience with intraluminal reinforcement of stapled gastrojejunostomy during laparoscopic Roux-en-Y gastric bypass.

Saber AA, Scharf KR, Turk AZ, Elgamal MH, Martinez RL.⁴

40 patients with GORE® SEAMGUARD® Reinforcement	40 patients with no SLR	Significance
No bleeding	15% intraoperative bleeding rate	* $P = 0.0255$
2.5% stricture rate	10% stricture rate	$P = 0.2007$

Excerpts

“Since most of the cases of bleeding were managed intraoperatively, there was no significant difference between the two groups regarding estimated intraoperative blood loss or postoperative hematocrit values.”

“The use of intraluminal bioabsorbable glycolide copolymer staple line reinforcement significantly reduces the incidence of gastrojejunal bleeding.”

Bioabsorbable glycolide copolymer staple line reinforcement decreases internal hernia rate after laparoscopic Roux-en-Y gastric bypass.

Ahmed AR, Rickards G, Husain S, Johnson J, O'Malley W, Boss T.⁵

354 patients with GORE® SEAMGUARD® Reinforcement	1,350 patients with suture only	Significance
0.8% internal hernia rate	2.9% internal hernia rate	* $P = 0.01$

Excerpts

“In our opinion, SLR (staple line reinforcement) can therefore be used in LRYGBP procedures not only with the objective of decreasing gastrointestinal bleeding but also with the aim of reducing the postoperative IH (internal hernias) rate.”

“It may be argued that the use of SLR is not cost effective, particularly because of the low IH rates in some recent studies. However, the follow-up time in one of these studies was short (9 months). Moreover, our opinion is that, in the light of the costs of hospital or outpatient visits for unexplained episodic abdominal pain, tests ordered to investigate the pain, and, eventually, reoperation, prophylactic use of SLR may save money.”

* P -values less than 0.05 (* $P < 0.05$) represent statistically significant data.

Use of SEAMGUARD [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] in laparoscopic gastric bypass to decrease postsurgical bleeding.

Rodríguez Velasco G, Mendía Conde E, Peromingo Fresneda R, et al.⁶

80 patients with GORE® SEAMGUARD® Reinforcement	45 patients with no SLR
No bleeding	4.44% bleeding rate

Excerpts

“Since we started using [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement], we have no complications in relation to stomach section bleeding.”

Bioabsorbable staple line reinforcement for laparoscopic gastrointestinal surgery.

Nguyen NT, Longoria M, Chalifoux S, Wilson SE.⁷

22 patients with GORE® SEAMGUARD® Reinforcement undergoing Roux-en-Y gastric bypass
No leaks, intra-abdominal abscesses or hemorrhages

Excerpts

“This study demonstrates that bioabsorbable glycolide copolymer staple line sleeves is safe and effective in prevention of intraoperative staple line bleeding and postoperative GI hemorrhage in 44 intra-abdominal GI operations (22 Roux-en-Y procedures).”

Internal hernias after laparoscopic Roux-en-Y gastric bypass are prevented with Bioabsorbable SEAMGUARD® Material.

Allemang MT, Renton DB, Narula VK, et al.⁸

417 patients with GORE® SEAMGUARD® Reinforcement
No internal hernias

Excerpts

“[GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] may be a possible way to prevent retro Roux hernias in patients undergoing laparoscopic Roux-en-Y gastric bypass.”

Foreign material erosion after laparoscopic Roux-en-Y gastric bypass:
Findings and treatment.

Yu S, Jastrow K, Clapp B, et al.⁹

228 patients with GORE® SEAMGUARD® Reinforcement	153 patients with SYNOVIS® PERI-STRIPS DRY® Product	Significance
No erosions	6 erosions (4%)	* <i>P</i> = 0.003

Excerpts

“Non absorbable Peri Strips resulted in erosion.”

“[GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] is preferable because it does not erode.”

* *P*-values less than 0.05 (**P* < 0.05) represent statistically significant data.

SYNOVIS and PERI-STRIPS DRY are trademarks of Baxter Healthcare Corporation.

Sleeve Gastrectomy Procedures

Decreased bleeding after laparoscopic sleeve gastrectomy with or without duodenal switch for morbid obesity using a stapled buttressed absorbable polymer membrane.

Consten, ECJ, Gagner M, Pomp A, Inabnet WB.¹⁰

10 patients with GORE® SEAMGUARD® Reinforcement	10 patients with no SLR	Significance
No leaks		
Lower mean blood loss (120 ± 15 mL)	Higher mean blood loss (210 ± 20 mL)	* $P < 0.05$
	2 had staple line hemorrhages (20%)	
	1 had a subphrenic abscess (10%)	

Excerpts

“These early results may show that [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] reduces staple line hemorrhage and leakage. This may have contributed to shorter hospital stay, decreased costs and lower morbidity after laparoscopic bariatric surgery.”

Strategic laparoscopic surgery for improved cosmesis in general and bariatric surgery: analysis of initial 127 cases

Nguyen NT, Smith BR, Reavis KM, Nguyen XM, Nguyen B, Stamos MJ.¹¹

50 patients with GORE® SEAMGUARD® Reinforcement
(26 were SLIC ‘strategic laparoscopic surgery for improved cosmesis’ patients)

No leaks
No other complications reported

Short-term outcomes of sleeve gastrectomy for morbid obesity:
Does staple line reinforcement matter?

Durmush EK, Ermerak G, Durmush D¹²

332 patients with GORE® SEAMGUARD® Reinforcement	186 patients with no SLR	Significance
No leaks	1.61% (3 patients)	* $P = 0.045$
No bleeds	0.53% (1 patient)	

Excerpts

“Patients in whom synthetic PGA:TMC staple line reinforcement material was applied during LSG had no postoperative leaks or hemorrhages from the staple line. The difference in leak rate between the reinforcement-material group and the no-reinforcement-material group was significant ($P = 0.045$).”

Robot-assisted sleeve gastrectomy for super-morbidly obese patients.

Ayloo S, Buchs NC, Addeo P, Bianco FM, Giulianotti PC.¹³

69 patients with GORE® SEAMGUARD® Reinforcement

No leaks

No other complications reported

Laparoscopic sleeve gastrectomy is a safe and effective bariatric procedure for the lower BMI (35.0–43.0 kg/m²) population.

Gluck B, Movitz B, Jansma S, Gluck J, Laskowski K.¹⁴

204 patients with GORE® SEAMGUARD® Reinforcement

No leaks

1.0% bleeding rate

Single incision laparoscopic sleeve gastrectomy (SILS): A novel technique.

Saber AA, Elgamal MH, Itawi EA, Rao AJ.¹⁵

7 patients with GORE® SEAMGUARD® Reinforcement

No leaks

Early experience with laparoscopic sleeve gastrectomy as a single-stage bariatric procedure.

Lewis CE, Dhanasopon A, Dutson EP, Mehran A.¹⁶

42 patients with GORE® SEAMGUARD® Reinforcement

No leaks

2.38% bleeding rate

How I do it. Laparoscopic sleeve gastrectomy for morbid obesity.

Moy J, Pomp A, Dakin G, Parikh M, Gagner M.¹⁷

135 patients with GORE® SEAMGUARD® Reinforcement

1.5% leak rate

Excerpts

“We believe that use of suture line buttressing material reduces the risk of perioperative bleeding and may reduce the risk of staple line failures resulting in leak.”

Laparoscopic vertical sleeve gastrectomy: Efficacy of using Bioabsorbable SEAMGUARD [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement].

Chiasson PM, Burpee SE.¹⁸

46 patients with GORE® SEAMGUARD® Reinforcement	46 patients with no SLR	Significance
No leaks		
No staple line oozing	13% had staple line oozing (had to oversee)	* $P < 0.05$
No complications	2 patients required blood transfusion therapy	

Excerpts

“The safety and efficacy of the laparoscopic vertical sleeve gastrectomy is enhanced with the use of [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement].”

“Our study suggests that GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement is effective in decreasing bleeding complications related to the long staple line associated with the LVSG.”

Evaluation of the sleeve gastrectomy as a single-stage treatment of morbid obesity.

Topart PA, Chazelet C, Verhaeghe P.¹⁹

49 patients with GORE® SEAMGUARD® Reinforcement	183 patients with no SLR	214 patients with suture
No leaks	4.5% leak rate	3.3% leak rate
No other complications reported		

Excerpts

“Leak rate was reduced with staple line reinforcement (0 vs 4.5%) and oversewing (3.3 vs 6.3%), this was not significant”

“Suture line reinforcement may be useful to reduce this risk”

“Significantly longer op duration (+20min) with suture line inversion”

Comparison of staple line leakage and hemorrhage in patients undergoing laparoscopic sleeve gastrectomy with or without the use of Bioabsorbable Seamguard® [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement]

TSimon TE, Scott JA, Brockmeyer JR, Husain FA, Frizzi JD, Choi YU²⁰

52 patients with GORE® SEAMGUARD® Reinforcement	68 patients with no SLR
1.92% leak rate	5.88% leak rate
0% bleeding rate	0% bleeding rate

* P-values less than 0.05 (* $P < 0.05$) represent statistically significant data.

Laparoscopic single-port sleeve gastrectomy for morbid obesity: Preliminary series.

Gentileschi P, Camperchioli I, Benavoli D, De Lorenzo N, Sica G, Gaspari AL.²¹

8 patients with GORE® SEAMGUARD® Reinforcement

No leaks

No other complications

Single-incision transumbilical laparoscopic sleeve gastrectomy.

Saber AA, El-Ghazaly TH, Eliam A.²²

6 patients with GORE® SEAMGUARD® Reinforcement

No leaks

No other complications

Laparoscopic sleeve gastrectomy: An Indian experience – Surgical technique and early results.

Chowbey PK, Dhawan K, Khullar R, et al.²³

~75 patients with GORE® SEAMGUARD® Reinforcement

No leaks

No bleeds

Excerpts

“Four patients required blood transfusion in the postoperative period for intraluminal bleeding manifested by melena and a fall [in] hematocrit. We have thereafter used [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] to reinforce the staple line. There has since been no evidence of staple line bleed.”

Initial experience with robotic sleeve gastrectomy for morbid obesity.

Diamantis T, Alexandrou A, Nikiteas N, Giannopoulos A, Papalambros E.²⁴

19 patients with GORE® SEAMGUARD® Reinforcement

No leaks

No other complications

Gastroscoically controlled laparoscopic sleeve gastrectomy.

Köckerling F, Schug-Paß C.²⁵

38 patients with GORE® SEAMGUARD® Reinforcement

2.6% bleeding rate

2.6% stenosis

Excerpts

“Thanks to the standardisation of this procedure using staple line reinforcement and intraoperative gastroscopic control, the complication rate can be reduced and the successful outcome of this stand-alone, weight-reduction operation can be optimized.”

“Staple line reinforcement with [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] appears to reduce the risk for bleeding.”

Changes in lipid profiles in morbidly obese patients after laparoscopic sleeve gastrectomy (LSG).

Zhang F, Strain GW, Lei W, Dakin GF, Gagner M, Pomp A.²⁶

45 patients with GORE® SEAMGUARD® Reinforcement

No leaks

No other complications

Laparoscopic sleeve gastrectomy for morbid obesity with intra-operative endoscopic guidance. Immediate peri-operative and one-year results after 25 patients.

Diamantis T, Alexandrou A, Pikoulis E, et al.²⁷

25 patients with GORE® SEAMGUARD® Reinforcement

0% leak rate

0% bleeding rate

Excerpts

“Concerning the measures to reduce the bleeding rate or the chance for a post-operative leakage from the staple line, we regularly use the [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] material, which has been shown to provide effective protection against these fearful complications.”

“Having used this material as of today for all our LSGs and for all of our last LRYGBPs, we have encountered no post-operative bleeding. Last but not least, the post-operative leakage rates from the staple line, which is by far the most fearful complication after LSG, was also zero.”

Laparoscopic sleeve gastrectomy: a retrospective review of 1- and two-year results.

Jacobs M, Bisland W, Gomez E, et al.²⁸

157 patients with GORE® SEAMGUARD® Reinforcement

1.27% leak rate

No post-operative bleeding reported

Laparoscopic sleeve gastrectomy for morbid obesity using a staple line reinforcement material.

Ramon J, Puig S, Pera M, et al.²⁹

17 patients with GORE® SEAMGUARD® Reinforcement

0% bleeding rate

Excerpts

“The absence of hemorrhagic complications in this series may be related to the use of a staple line reinforcement.”

Laparoscopic sleeve gastrectomy: Our first 100 patients.

Nath A, Leblanc KA, Hausmann MG, Kleinpeter K, Allain BW, Romero R.³⁰

100 patients with GORE® SEAMGUARD® Reinforcement

1% leak rate

2% bleeding rate

Comparison of laparoscopic sleeve gastrectomy leak rates in five staple line reinforcement options: A systematic review

Gagner M, Kemmeter P³¹

4,100 patients with

GORE® SEAMGUARD® Reinforcement

0.73% leak rate

16,632 patients with no SLR

1.89% leak rate

Significance

* $P < 0.0001$

Excerpts

“Systematic review of 148 included studies representing 40,653 patients found that the leak rate in LSG was significantly lower using APM [absorbable polymer membrane] staple line reinforcement than over-sewing, BPS [bovine pericardial strips] reinforcement or no reinforcement.”

Clinical and Economic Evaluation of Absorbable Staple Line Buttressing in Sleeve Gastrectomy in High-Risk Patients

Gayrel X, Loureiro M, Skalli EM, Dutot C, Mercier G, Nocca D³²

86 patients with GORE® SEAMGUARD® Reinforcement*	116 patients with no SLR	Significance
2.3% leaks (no surgery required however)	3.5% (3 reoperations required)	
No bleeds	8.6% bleeding	[†] <i>P</i> = 0.005

Excerpts

“It was remarkable that the buttressing group had no bleeding at all and was clearly protected from this complication.”

“Staple line reinforcement with absorbable material reduces bleeding in high-risk population. Therefore, this type of material can also result in cost-savings.”

A comparison of a single center’s experience with three staple line reinforcement techniques in 1,502 laparoscopic sleeve gastrectomy patients

Barreto TW, Kemmeter PR, Paletta MP, Davis AT³³

860 patients with GORE® SEAMGUARD® Reinforcement [‡]	373 patients with imbrication (seromuscular suturing)	269 patients with BPS
0.3% leaks	0.3%	1.5%
5.5% bleeding	3.8%	5.9%

Excerpts

“Although we did not find statistically significant differences in our primary outcome variables of leaks and bleeds, we did see a trend towards a higher leak rate in the [bovine pericardial strips] group, compared to the imbrication or [absorbable polymer membrane] groups (*P* = 0.08).”

“Despite a liberal definition of bleeding, postoperative bleed rates were not statistically different between groups, but did make our rates appear high at 3.8–5.9%.”

* Decreased hospital stay see “Hospital Savings” section.

[†] *P*-values less than 0.05 ([†] *P* < 0.05) represent statistically significant data.

[‡] Decreased reoperation and readmittance rate see “Hospital Savings” section.

Colorectal Procedures

Safety and efficacy of the use of bioabsorbable Seamguard [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] in colorectal surgery at the Texas Endosurgery Institute.

Franklin ME II, Berghoff KE, Arellano PP, Trevino JM, Abrego-Medina D.³⁴

30 patients with GORE® SEAMGUARD® Reinforcement

No leaks, bleeding, or strictures

Excerpts

“It has been used in obesity surgery and pulmonary surgery as staple line reinforcement with good results. As such, we believe that [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] may be ideal to use in colorectal surgery as an aid during the healing process of an anastomosis and may help prevent anastomotic bleeding and staple line disruption.”

“There were no clinical leaks, no strictures, and no bleeding in our early postoperative follow-up period. The use of [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] as a staple line reinforcer appears to be safe and may be useful in preventing anastomotic leakage, bleeding, and intraluminal stenosis.”

Bioabsorbable staple line reinforcement to reduce staple line bleeding in the transection of mesenteric vessels during laparoscopic colorectal resection: A pilot study.

de la Portilla F, Zbar AP, Rada R, et al.³⁵

25 patients with GORE® SEAMGUARD® Reinforcement

No bleeding or other complications during the surgical procedure

Excerpts

“Cost of [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] may be offset by avoiding extra time to oversee bleeding sites and the possible cost of treating intraabdominal hemorrhage that may include blood transfusion and prolongation of hospital stay.”

Pancreatic Procedures

Staple line reinforcement reduces postoperative pancreatic stump leak after distal pancreatectomy.

Jimenez RE, Mavanur A, Macaulay WP.³⁶

13 patients with GORE® SEAMGUARD® Reinforcement	18 patients with no SLR	Significance
No leaks	39% leak rate	* $P = 0.025$

Excerpts

"We conclude that staple line reinforcement is a simple and effective method of reducing pancreatic stump leakage after distal pancreatectomy."

"We believe that the standard individual staples by themselves can "cut" through the pancreatic tissue without effectively achieving any compression or seal. The reinforcement acts as a scaffold for the individual staples, preventing them from cutting through the tissues and allowing even tension distribution along the closure line."

"Staple line reinforcement is a simple and effective method of reducing pancreatic stump leakage after distal pancreatectomy. The economic impact of lower leak rates is reflected in significantly shorter hospital stays."

Laparoscopic distal pancreatectomy. A retrospective review of 14 cases.

Pugliese R, Maggioni D, Sansonna F, et al.³⁷

7 patients with GORE® SEAMGUARD® Reinforcement	7 patients with no SLR	Significance
No leaks at 30 days post-op	57% leak rate	* $P = 0.0349$

Excerpts

"It should be emphasized that after introducing reinforcement of the staple line with [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] in this study, no leak has been observed within 30 days from surgery."

Absorbable mesh reinforcement of a stapled pancreatic transection line reduces the leak rate with distal pancreatectomy.

Thaker RI, Matthews BD, Linehan DC, Strasberg SM, Eagon JC, Hawkins WG.³⁸

29 patients with GORE® SEAMGUARD® Reinforcement	11 patients with no SLR	Significance
3.5% leak rate	36% leak rate	* $P = 0.005$

Excerpts

"Mesh reinforcement of the stapled pancreatic transaction line reduced the pancreatic leak rate after distal pancreatectomy."

"We conclude that incorporation of mesh into the stapled transection line is safe and holds considerable promise as a method to reduce the pancreatic leak rate after open and laparoscopic distal pancreatectomy."

Totally laparoscopic Roux-en-Y duct-to-mucosa pancreaticojejunostomy after middle pancreatectomy.

Rotellar F, Pardo F, Montiel C, et al.³⁹

7 patients with GORE® SEAMGUARD® Reinforcement	2 patients with no SLR
No leaks or fistulas	2 fistulas

Excerpts

“Buttressing the staple line with absorbable material seems to be effective in preventing pancreatic fistula after distal pancreatectomy when compared with standard stapling alone.”

Use of Seamguard [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] to prevent pancreatic leak following distal pancreatectomy.

Yamamoto M, Hayashi MS, Nguyen NT, Nguyen TD, McCloud S, Imagawa DK.⁴⁰

47 patients with GORE® SEAMGUARD® Reinforcement	38 patients with no SLR	Significance
4% leak rate	26% leak rate	* <i>P</i> = 0.01

Excerpts

“In our 2 leaks with use of [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement], 1 patient eventually required another operation to close an unresolved leak, and oversewing of the stump remnant was used. The other patient was treated nonoperatively without incident.”

“The use of [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] is quickly becoming a common adjunct in distal pancreas resections. Our study shows a lower incidence of pancreatic leak after distal pancreatectomy with the use of this staple line-reinforcing product.”

Staple line reinforcement reduces postoperative pancreatic stump leak after distal pancreatectomy.

Mavanur A, Takata M, Macaulay WP, Orlando R III, Piorkowski RJ, Jimenez RE.⁴¹

10 patients with GORE® SEAMGUARD® Reinforcement	18 patients with no SLR	Significance
No leaks	33% leak rate	<i>P</i> = 0.062

Excerpts

“Staple line reinforcement is a simple and effective method of reducing pancreatic stump leakage after distal pancreatectomy. The economic impact of lower leak rates is reflected in significantly shorter hospital stays.”

Laparoscopic distal pancreatectomy results on a consecutive series of 58 patients.

Melotti G, Butturini G, Piccoli M, et al.⁴²

7 patients with GORE® SEAMGUARD® Reinforcement	51 patients with no SLR
No fistulas	31% developed fistulas

Excerpts

“In 7 patients treated with a linear stapler associated with [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement], we obtained a good postoperative course without fistula.”

Staple line reinforcement in laparoscopic distal pancreatectomy diminishes pancreatic duct leak and hemorrhage.

Consten ECJ, Gagner M.⁴³

Case study with GORE® SEAMGUARD® Reinforcement
No bleeding or leaks

Excerpts

“Bioabsorbable staple line reinforcement material [GORE® SEAMGUARD Reinforcement] provides staple line reinforcement without requiring the implantation of a permanent prosthetic material. It diminishes perioperative bleeding and possibly pancreatic duct leaks. Concerns over possible long-term complications such as migration, erosion, calcification and infection are reduced.”

Thoracic Procedures

Reducing airleaks in lung volume reduction surgery: is there a difference between two different buttresses?

Abunasra H, Oey I, Simpson L, Solly S, Martin-Ucar A, Waller DA.⁴⁴

23 patients with GORE® SEAMGUARD® Reinforcement	59 patients with SYNOVIS® PERI-STRIPS DRY® Product	Significance
No leaks requiring reoperation	3.4% leak rate – required reoperation	
7 day average air leak duration	12 day average air leak duration	<i>P</i> = 0.08

Excerpts

“The perioperative cost-effectiveness of LVRS can be improved by technical modifications including the change of stapling practice and buttressing material.”

Video-assisted thoracic surgery (VATS) lobectomy: 13 years’ experience.

Congregado M, Merchan RJ, Gallardo G, Ayarra J, Loscertales J.⁴⁵

237 major pulmonary resections – Most with GORE® SEAMGUARD® Reinforcement
No direct comparison results

Excerpts

“Another potential cause of morbidity is air leakage, the water-seal test should always be performed to check that the bronchial suture is watertight, and reinforcement can be used where necessary. In our opinion, adoption of [GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement] could minimize this complication. . .”

Hospital Savings

Clinical and Economic Evaluation of Absorbable Staple Line Buttressing in Sleeve Gastrectomy in High-Risk Patients

Gayrel X, Loureiro M, Skalli EM, Dutot C, Mercier G, Nocca D³²

Economic Analysis Characteristics	86 patients with GORE® SEAMGUARD® Reinforcement	116 patients without SLR	Significance
Hospital stay (day)	4.2 ± 0.9	5.2 ± 3.8	* <i>P</i> = 0.005
Operative time (min)	155 ± 29	142 ± 29	* <i>P</i> = 0.002
Buttressing cost (€)	746 ± 137	0 ± 0	* <i>P</i> < 0.001
Intraoperative costs (€)	1,678 ± 315	1,546 ± 316	* <i>P</i> = 0.002
Extraoperative costs (€)	3,384 ± 766	4,479 ± 4,734	* <i>P</i> = 0.0035
Overall cost during initial stay (€)	5,808 ± 844	6,026 ± 4,756	* <i>P</i> < 0.001
Rehospitalization costs (€)	5,043 ± 6,240	6,394 ± 4,986	<i>P</i> = 0.53
Overall cost (€)	5,984 ± 1,658	6,246 ± 4,986	* <i>P</i> < 0.001

Note: A French retrospective, observational and comparative study, that was conducted at Montpellier University Hospital, France.

Excerpts

“Regarding overall costs, the use of absorbable buttressing membranes seems to bring another economic benefit in high-risk population. Indeed, control group costs were higher even when rehospitalizations for complications within six months were included in the analysis.”

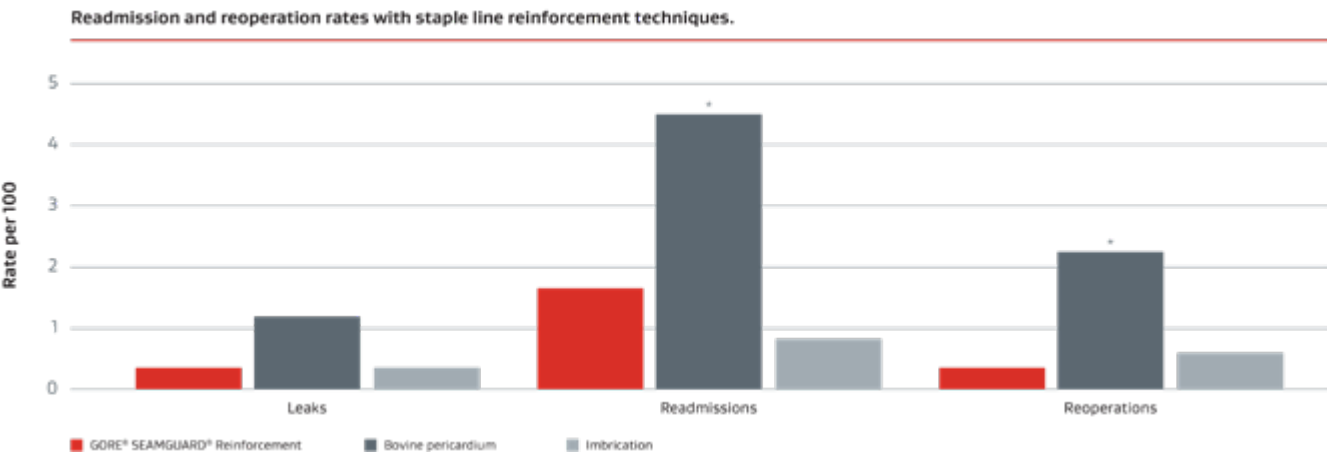
“SLR can be considered a cost-effective measure and this does not include the social costs of leak and bleeding to the patient.”

A comparison of a single center’s experience with three staple line reinforcement techniques in 1,502 laparoscopic sleeve gastrectomy patients

Barreto TW, Kemmeter PR, Paletta MP, Davis AT⁴⁶
Mercy Health Saint Mary’s and Spectrum Health hospitals in Grand Rapids, Michigan, US

1,502 PATIENTS FROM THE SAME INSTITUTION WERE COMPARED

373 patients (24.8%) reinforced with imbrication
269 patients (17.9%) reinforced with bovine pericardial strips (BPS)
860 patients (57.3%) reinforced with GORE® SEAMGUARD® Reinforcement (APM)



Rates of adverse events by percent of gastric leaks ($P = 0.08$), hospital readmissions ($P = 0.001$), and reoperations ($P = 0.01$). Bovine pericardium use resulted in significantly higher readmissions and reoperations compared to the other two techniques.

Excerpts

“Additionally, our study demonstrated statistically higher rates of reoperation and readmission in the BPS group, with leak being the primary indication for reoperation and >25 % of readmissions being related to a leak.”

“This study demonstrated that BPS is associated with significantly higher readmission and reoperation rates with a trend towards a higher leak rate.”

Bioabsorbable Glycolide Copolymer is Effective in Reducing Staple Line Bleeding in Sleeve Gastrectomy.

Iannelli A, Chierici A, Castaldi A, Draï C, Schneck A⁴⁷
CHU Nice – France

418 consecutive patients undergoing sleeve gastrectomy from November 2012 to April 2019.

In the Top-only group only the top staple shot was realized with reinforced material (GORE® SEAMGUARD® Reinforcement).

	Top-only group (n = 145)	Bottom-to-Top group with full GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement (n = 303)	Significance
Mild bleeding	0 (0)	1 (0.3)	<i>P</i> = 1.000
Severe staple line bleeding*	4 (2.8)	0 (0)	<i>P</i> = 0.004
Reoperations for staple line bleeding	3 (2.1)	0 (0)	<i>P</i> = 0.033
Lesser curvature perforated ulcer†	0 (0)	1 (0.3)	<i>P</i> = 1.000
Mild staple line leak‡	3 (2.1)	0 (0)	<i>P</i> = 0.033
Severe staple line leak§	1 (0.7)	0 (0)	<i>P</i> = 1.000
Spleen ischemia	3 (2.1)	1 (0.3)	<i>P</i> = 0.102
Length of hospital stay (d)	5 (4–6)	4 (3–5)	<i>P</i> = < 0.001

Categorical variables are expressed as n (%), continuous variables as median (IQR).

Excerpts

“High leak has appeared as a main concern for the complex management required for healing and because the mechanisms leading to it have not been entirely elucidated so far. The reinforcement of the staple line with buttressing material has been thus proposed to reduce it⁵⁴.”

“The most interesting result of the present study is the reduced rate of bleeding we found since the policy of reinforcing the whole staple line had been adopted.”

“Conclusions: This study provides evidence that the use of a bioabsorbable membrane (GORE® SEAMGUARD® Reinforcement) on the whole staple line is effective in reducing the incidence of staple line bleeding in SG.”

* All four patients required two units of blood each in the Top-only group and the patient in the Bottom-to-Top group was managed conservatively and did not require blood transfusion.

† Bleeding due to a perforation on the lesser curvature into the left gastric artery that required emergency surgery for hemorrhagic shock after failure of endoscopic treatment.

‡ No evidence of oral contrast extravasating from the sleeved stomach, management consisted of antibiotics and nil by mouth.

§ The leak was managed by interventional radiology, endoscopy, nil by mouth and antibiotics.

References

1. Miller KA, Pump A. Use of bioabsorbable staple reinforcement material in gastric bypass: a prospective randomized clinical trial. *Surgery for Obesity & Related Diseases* 2007;3(4):417-422.
2. Nguyen NT, Longoria M, Welbourne S, Sabio A, Wilson SE. Glycolide copolymer staple-line reinforcement reduces staple site bleeding during laparoscopic gastric bypass. A prospective randomized trial. *Archives of Surgery* 2005;140(8):773-778.
3. Zomerlei T, Brown A, Bajric J, Kemmeter P. Comparison of buttressing material in Roux-en-Y gastric bypass. Abstract presented at Grand Rapids Medical Education Partners (GRMEP) Research Day; April 25, 2012; Grand Rapids MI.
4. Saber AA, Scharf KR, Turk AZ, Elgamal MH, Martinez RL. Early experience with intraluminal reinforcement of stapled gastrojejunostomy during laparoscopic Roux-en-Y gastric bypass. *Obesity Surgery* 2008;18(5):525-529.
5. Ahmed AR, Rickards G, Husain S, Johnson J, O'Malley W, Boss T. Bioabsorbable glycolide copolymer staple-line reinforcement decreases internal hernia rate after laparoscopic Roux-en-Y gastric bypass. *Obesity Surgery* 2008;18(7):797-802.
6. Rodríguez Velasco G, Mendiá Conde E, Peromingo Fresneda R, et al. Use of Seamguard in laparoscopic gastric bypass to decrease postsurgical bleeding. Abstract presented at the 9th SECO Congress (Spanish Society for the Surgery of Obesity); March 7-9, 2007; Getafe-Madrid. *Obesity Surgery* 2007;17(2):282. Abstract P9.
7. Nguyen NT, Longoria M, Chalfoux S, Wilson SE. Bioabsorbable staple line reinforcement for laparoscopic gastrointestinal surgery. *Surgical Technology International* 2005;XIV:107-111.
8. Allemang MT, Renton DB, Narula VK, et al. Internal hernias after laparoscopic Roux-en-Y gastric bypass are prevented with Bioabsorbable Seamguard® Material. Poster presented at the 2007 Scientific Session of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES); April 18-22, 2007; Las Vegas, NV. *Surgical Endoscopy* 2007;21(Supplement 1):S372.
9. Yu S, Jastrow K, Clapp B, et al. Foreign material erosion after laparoscopic Roux-en-Y gastric bypass: findings and treatment. *Surgical Endoscopy* 2007;21(7):1216-1220.
10. Consten, ECJ, Gagner M, Pomp A, Inabnet WB. Decreased bleeding after laparoscopic sleeve gastrectomy with or without duodenal switch for morbid obesity using a stapled buttressed absorbable polymer membrane. *Obesity Surgery* 2004;14(10):1360-1366.
11. Nguyen NT, Smith BR, Reavis KM, Nguyen XM, Nguyen B, Stamos MJ. Strategic laparoscopic surgery for improved cosmesis in general and bariatric surgery: analysis of initial 127 cases. *Journal of Laparoendoscopic & Advanced Surgical Techniques* 2012;22(4):355-361.
12. Durmush EK, Ermerak G, Durmush D. Short-term outcomes of sleeve gastrectomy for morbid obesity: does staple line reinforcement matter? *Obes Surg.* 2014 Jul;24(7):1109-16.
13. Ayloo S, Buchs NC, Addeo P, Bianco FM, Giulianotti PC. Robot-assisted sleeve gastrectomy for super-morbidly obese patients. *Journal of Laparoendoscopic & Advanced Surgical Techniques* 2011;21(4):295-299.
14. Gluck B, Movitz B, Jansma S, Gluck J, Laskowski K. Laparoscopic sleeve gastrectomy is a safe and effective bariatric procedure for the lower BMI (35.0–43.0 kg/m²) population. *Obesity Surgery* 2011;21(8):1168-1171.
15. Saber AA, Elgamal MH, Itawi EA, Rao AJ. Single incision laparoscopic sleeve gastrectomy (SILS): a novel technique. *Obesity Surgery* 2008;18(10):1338-1342.
16. Lewis CE, Dhanasopon A, Dutton EP, Mehran A. Early experience with laparoscopic sleeve gastrectomy as a single-stage bariatric procedure. *American Surgeon* 2009;75(10):945-949.
17. Moy J, Pomp A, Dakin G, Parikh M, Gagner M. How I do it. Laparoscopic sleeve gastrectomy for morbid obesity. *American Journal of Surgery* 2008;196(5):e56-e59.
18. Chiasson PM, Burpee SE. Laparoscopic vertical sleeve gastrectomy: efficacy of using Bioabsorbable Seamguard. Abstract presented at the 25th Annual American Society for Metabolic & Bariatric Surgery Meeting (ASMB5); June 15-20, 2008; Washington, DC. *Surgery for Obesity & Related Diseases* 2008;4(3):332-333.
19. Topart PA, Chazelet C, Verhaeghe P. Evaluation of the sleeve gastrectomy as a single-stage treatment of morbid obesity. Poster presented at the 2010 Scientific Session of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES); April 14-17, 2010; National Harbor, MD. *Surgical Endoscopy* 2010;24 (Supplement 1):S298. Poster P001.
20. Simon TE, Scott JA, Brockmeyer JR, Husain FA, Frizzi JD, Choi YU. Comparison of staple-line leakage and hemorrhage in patients undergoing laparoscopic sleeve gastrectomy with or without the use of Bioabsorbable Seamguard®. Poster presented at the 2010 Scientific Session of the Society of American Gastrointestinal and Endoscopic Surgeons (SAGES); April 14-17, 2010; National Harbor, MD. *Surgical Endoscopy* 2010;24 (Supplement 1):S331. Poster P048.
21. Gentileschi P, Camperchioli I, Benavoli D, De Lorenzo N, Sica G, Gaspari AL. Laparoscopic single-port sleeve gastrectomy for morbid obesity: preliminary series. *Surgery for Obesity & Related Diseases* 2010;6(6):665-669.
22. Saber AA, El-Ghazaly TH, Eliam A. Single-incision transumbilical laparoscopic sleeve gastrectomy. *Journal of Laparoendoscopic & Advanced Surgical Techniques* 2009;19(6):755-759.
23. Chowbey PK, Dhawan K, Khullar R, et al. Laparoscopic sleeve gastrectomy: an Indian experience-surgical technique and early results. *Obesity Surgery* 2010;20(10):1340-1347.
24. Diamantis T, Alexandrou A, Nikiteas N, Giannopoulos A, Papalambros E. Initial experience with robotic sleeve gastrectomy for morbid obesity. *Obesity Surgery* 2011;21(8):1172-1179.
25. Köckerling F, Schug-Paß C. Gastroscoopically controlled laparoscopic sleeve gastrectomy. *Obesity Facts* 2009; 2(Supplement 1):15-18.
26. Zhang F, Strain G, Lei W, Dakin G, Gagner M, Pomp A. Changes in lipid profiles in morbidly obese patients after laparoscopic sleeve gastrectomy (LSG). *Obesity Surgery* 2011;21(3):305-309.
27. Diamantis T, Alexandrou A, Pikoulis E, et al. Laparoscopic sleeve gastrectomy for morbid obesity with intra-operative endoscopic guidance. Immediate peri-operative and one-year results after 25 patients. *Obesity Surgery* 2010;20(8):1164-1170.
28. Jacobs M, Bisland W, Gomez E, et al. Laparoscopic sleeve gastrectomy: a retrospective review of 1- and 2-year results. *Surgical Endoscopy* 2010;24(4):781-785.
29. Ramon J, Puig S, Pera M, et al. Laparoscopic sleeve gastrectomy for morbid obesity using a staple line reinforcement material. Abstract presented at the 3rd Congress of the International Federation for the Surgery of Obesity and Metabolic Disorders-European Chapter (IFSO-EC); April 17-19, 2008; Capri, Italy. *Obesity Surgery* 2008;18(4):467. Abstract 136.

30. Nath A, Leblanc KA, Hausmann MG, Kleinpeter K, Allain BW, Romero R. Laparoscopic sleeve gastrectomy: our first 100 patients. *Journal of the Society of Laparoendoscopic Surgeons* 2010;14(4):502-508.
31. Gagner M, Kemmeter P. Comparison of laparoscopic sleeve gastrectomy leak rates in five staple-line reinforcement options: a systematic review. *Surgical Endoscopy* 2020;34(1):396-407.
32. Gayrel X, Loureiro M, Skalli EM, Dutot C, Mercier G, Nocca D. Clinical and economic evaluation of absorbable staple line buttressing in sleeve gastrectomy in high-risk patients. *Obesity Surgery* 2016;26(8):1710-1716.
33. Barreto TW, Kemmeter PR, Paletta MP, Davis AT. A comparison of a single center's experience with three staple line reinforcement techniques in 1,502 laparoscopic sleeve gastrectomy patients. *Obesity Surgery* 2015;25(3):418-422..
34. Franklin ME II, Berghoff KE, Arellano PP, Trevino JM, Abrego-Medina D. Safety and efficacy of the use of bioabsorbable Seamguard in colorectal surgery at the Texas Endosurgery Institute. *Surgical Laparoscopy, Endoscopy & Percutaneous Techniques* 2005;15(1):9-13.
35. de la Portilla F, Zbar AP, Rada R, et al. Bioabsorbable staple-line reinforcement to reduce staple-line bleeding in the transection of mesenteric vessels during laparoscopic colorectal resection: a pilot study. *Techniques in Coloproctology* 2006;10(4):335-338.
36. Jimenez RE, Mavanur A, Macaulay WP. Staple line reinforcement reduces postoperative pancreatic stump leak after distal pancreatectomy. *Journal of Gastrointestinal Surgery* 2007;11(3):345-349.
37. Pugliese R, Maggioni D, Sansonna F, et al. Laparoscopic distal pancreatectomy. A retrospective review of 14 cases. *Surgical Laparoscopy, Endoscopy & Percutaneous Techniques* 2008;18(3):254-259.
38. Thaker RI, Matthews BD, Linehan DC, Strasberg SM, Eagon JC, Hawkins WG. Absorbable mesh reinforcement of a stapled pancreatic transection line reduces the leak rate with distal pancreatectomy. *Journal of Gastrointestinal Surgery* 2007;11(1):59-65.
39. Rotellar F, Pardo F, Montiel C, et al. Totally laparoscopic Roux-en-Y duct-to-mucosa pancreaticojejunostomy after middle pancreatectomy. A consecutive nine-case series at a single institution. *Annals of Surgery* 2008;247(6):938-944.
40. Yamamoto M, Hayashi MS, Nguyen NT, Nguyen TD, McCloud S, Imagawa DK. Use of Seamguard to prevent pancreatic leak following distal pancreatectomy. *Archives of Surgery* 2009;144(10):894-899.
41. Mavanur A, Takata M, Macaulay WP, Orlando R III, Piorkowski RJ, Jimenez RE. Staple line reinforcement reduces postoperative pancreatic stump leak after distal pancreatectomy. Abstract presented at the 87th Annual Meeting of the New England Surgical Society; September 15-17,2006; Groton, CT.
42. Melotti G, Butturini G, Piccoli M, et al. Laparoscopic distal pancreatectomy results on a consecutive series of 58 patients. *Annals of Surgery* 2007;246(1):77-82.
43. Consten ECJ, Gagner M. Staple line reinforcement in laparoscopic distal pancreatectomy diminishes pancreatic duct leak and haemorrhage. Video abstract presented at the 13th International Congress of the European Association for Endoscopic Surgery and other Interventional Techniques (EAES); June 1-4, 2005; Venice Lido, Italy. *Surgical Endoscopy* 2006;20(Supplement 1):S244.
44. Abunasra H, Oey I, Simpson L, Solly S, Martin-Ucar A, Waller DA. Reducing airleaks in lung volume reduction surgery: is there a difference between two different buttresses? Abstract presented at the 16th European Conference on General Thoracic Surgery; June 8-11, 2008; Bologna, Italy. *Interactive CardioVascular & Thoracic Surgery* 2008;7(Supplement 2):S156.
45. Congregado M, Merchan RJ, Gallardo G, Ayarra J, Loscertales J. Video-assisted thoracic surgery (VATS) lobectomy: 13 years' experience. *Surgical Endoscopy* 2008;22(8):1852-1857.
46. Zambelli-Weiner A, Brooks E, Brolin R, Bour ES. *Total charges for post-operative leak following laparoscopic sleeve gastrectomy*. Presented at Obesity Week 2013; November 11-16, 2013; Atlanta, GA. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2013. [Poster]. AS2047-EN1.
47. Iannelli A, Chierici A, Castaldi A, Draï C, Schneck A. Bioabsorbable glycolide copolymer is effective in reducing staple line bleeding in sleeve gastrectomy. *Obesity Surgery* 2022;32(8):2605-2610.

INDICATIONS FOR USE

GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement is indicated for use in surgical procedures in which soft tissue transection or resection with staple line reinforcement is needed. GORE® SEAMGUARD® Bioabsorbable Staple Line Reinforcement can be used for reinforcement of staple lines during lung resection, bronchial, bariatric, colon, colorectal, gastric, mesentery, pancreas, and small bowel procedures.

 Consult Instructions
for Use
eifu.goremedical.com

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.

BAXTER, SYNOPSIS and PERI-STRIPS DRY are trademarks of Baxter Healthcare Corporation.

ETHICON and VICRYL are trademarks of Ethicon, Inc.

MEDTRONIC is a trademark of Medtronic, Inc.

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

© 2021, 2022, 2023 W. L. Gore & Associates GmbH 23868106-EN JULY 2023

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 86003 800 437 8181 928 779 2771

