

Reinforced Circular Stapler in Bariatric Surgery

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ABSTRACT

Background: Roux-en-Y gastric bypass (RYGBP) is the most common procedure for weight loss surgery but has multiple complications. This study evaluates the use of reinforced circular staplers (RCS) and their effects on reducing gastrojejunal anastomotic complications.

Methods: We conducted a retrospective chart review from January 2007 to November 2008. Laparoscopic RYGBP were performed in 287 patients. A comparison was made of the complications with and without the use of reinforced circular staplers. The comparison was between a nonreinforced circular stapler (NRCS) group comprising 182 patients and an RCS group comprising 105 patients.

Results: Complications at gastrojejunal anastomosis were experienced by 15.3% of the patients; 9.5% were in the RCS group and 18.7% were in the NRCS group ($P=0.026$). Neither group had anastomotic leaks. Bleeding rate was 4.8% in the RCS group vs. 6.6% in the NRCS group. Ulcers occurred in 2.9% of the RCS group vs. 6.0% of the NRCS group. Stricture rate was 1.9% in the RCS group vs. 6.6% in the NRCS group.

Conclusion: The application of RCS reduced the incidence of gastrojejunal anastomotic complications. Patients are twice as likely to develop complications when no RCS device is used (95% CI 1.03, 4.623). Therefore, it is beneficial to utilize RCS for the gastrojejunal anastomosis in RYGBP procedures.

Key Words: Bovine pericardium, Gastrojejunostomy, Complications.

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INTRODUCTION

Sixty-seven percent of the American population is overweight or obese. Approximately 5% of the U.S. adult population struggles with morbid obesity and obesity related diseases.¹ Bariatric surgery effectively provides permanent weight loss and remission of weight-related comorbidities in the majority of patients.^{2,3} Due to the increase in demand for minimally invasive surgery and decreased complication rates, laparoscopic Roux-en-Y gastric bypass (RYGBP) has become the gold standard in weight loss surgery.⁴ However, complications at the gastrojejunostomy including bleeding, strictures, ulcers, and leaks add to the morbidity of the procedure.⁵

Variation in the technique for the gastrojejunal anastomosis exists. Hand-sewn, linear staplers, linear reinforced staplers, circular staplers,⁶ and, recently, reinforced circular staplers have been described in the literature. Previous reports confirm that the application of linear bioabsorbable reinforced staplers reduce anastomotic complications (including bleeding, leaks, fistulas, and strictures).⁷⁻¹² Jones et al⁷ performed a retrospective comparison of 2 consecutive case series with a stapled 25 EEA anastomosis with and without GORE Seamguard reinforcement. Tissue reinforcement decreased complications by 85%. Bleeding, leaks, and strictures were lower in the reinforced group compared with those in the nonreinforced group by 0.7% to 1.1%, 0.7% to 1.9%, and 0.7% to 9.3%, respectively. Other reviews have shown that no difference in leak rates exists with the use of reinforced staplers.¹³ Reports of increased complications with tissue reinforcement also exist. Ibele et al¹⁴ performed a retrospective chart review comparing 419 patients with a 25 EEA stapled anastomosis without reinforcement with 69 patients with a 25 EEA anastomosis with bovine pericardium reinforcement. The no reinforcement group had a 0.7% leak rate compared with a 4.9% leak rate in the bovine pericardium reinforced group. To date, little data are available that evaluate the use of reinforced nonabsorbable circular staplers (RCS) with conventional nonreinforced circular staplers (NRCS) in laparoscopic RYGBP.

This study compared the incidence of complications at the gastrojejunal anastomosis, such as bleeding, stricture, leaks, and ulcer formation, with the use of a bovine

pericardial reinforced circular stapler with a nonreinforced circular stapler at the gastrojejunal anastomosis in the laparoscopic RYGBP.

METHODS

A retrospective chart review was conducted of all the patients who underwent laparoscopic RYGBP procedures from January 2007 to November 2008; 287 laparoscopic RYGBP procedures were performed by the same 2 surgeons. Two consecutive series of patients who underwent laparoscopic RYGBP were compared. Group 1 consisted of the nonreinforced gastrojejunostomies (NRCS), and group 2 consisted of bovine pericardium reinforcement of the stapled gastrojejunostomy (RCS). The NRCS group comprised 182 patients and the RCS group comprised 105 patients. From January 2007 to March 2008, the majority of gastrojejunal anastomoses were created with nonreinforced circular staplers. All gastrojejunal anastomoses between April 2008 and November 2008 were created with bovine pericardial reinforced circular staplers (Peri-Strips Dry, Synovis Surgical Innovations, St. Paul, MN). All data were collected into a Microsoft Access template (Microsoft Corp, Redmond, WA) and analyzed with the SAS system.

All patients were selected for laparoscopic RYGBP according to the 1991 NIH guidelines.²⁷ Mean age was 40.7±10 years, mean BMI was 47.3±10kg/m² (mean weight 278.4lb), and 89.2% of patients were female (**Table 1**). Before the operation, a multidisciplinary team evaluated and informed patients of the risks, benefits, complications, and realistic expectations of the procedure.

Standard 75-cm Roux limbs were constructed, and the gastrojejunostomy was performed using a 25-mm EEA circular stapler (Autosuture, US Surgical, Norwalk, CT). The operations were executed with identical techniques

and equipment. All the patients had intraoperative endoscopy performed by the same surgeon. Patients were followed up postoperatively at 2 weeks, 3 months, 6 months, and 1 year. All patients received fractionated weight heparin preoperatively and postoperatively for deep venous thrombosis prophylaxis. On postoperative day one, patients were started on prophylactic doses of low molecular weight heparin (Fragmin 5000 units subcutaneous every day).

Perioperative and postoperative complications assessed included bleeding, stricture, anastomotic leak, and ulcer formation. Bleeding is defined as evidence of active bleeding at the gastrojejunostomy during the intraoperative endoscopy, requiring endoscopic clip application. Bleeding was additionally defined as hematemesis and a decrease in hemoglobin >2 g/dL, or evidence of intraluminal clot on postoperative endoscopy or Gastrografin UGI. Ulcer formation was defined by endoscopic evidence of gastrointestinal tissue erosion. The definition of stricture was a gastrojejunal anastomotic opening <9mm seen on endoscopy that could not be reversed by the adult endoscope and required dilatation. Anastomotic leaks were evaluated by air insufflation during intraoperative endoscopy and Gastrografin upper gastrointestinal study on postoperative day one (**Figure 1**).

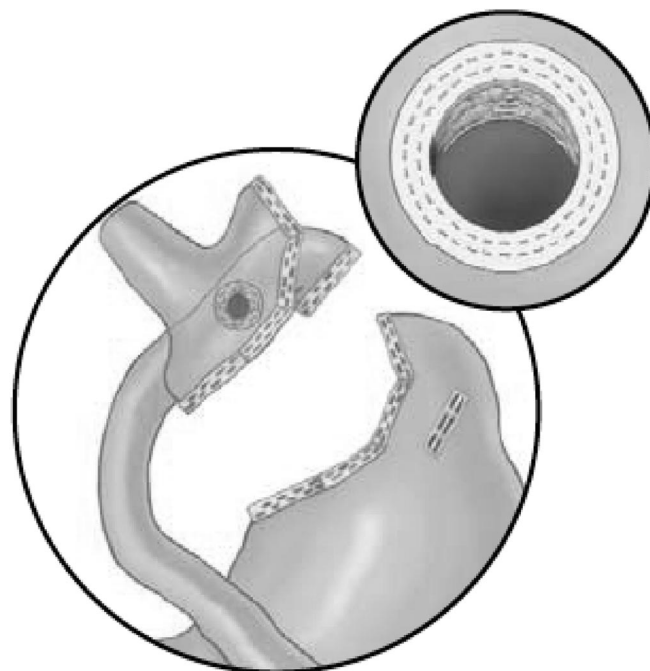


Figure 1. Roux-en-Y gastric bypass created with the reinforced staplers.

Table 1.
Patient Demographics

		Total (n=287)	No Reinforced Circular Staples (n=182)	Reinforced Circular Staples (n=105)
Age	Mean	40.7	39.97	41.97
	Range	18-68	18-65	18-68
BMI	Mean	47.3	46.83	48.34
	Range	36-70	36-69	36-70
	Female	(89%)	(93%)	(86%)
Sex	Male	(11%)	(7%)	(14%)

Statistical Analysis

Statistical analysis compared the RCS and NRCS groups by using SAS system, version 9.2 (SAS Institute, Cary, NC). Univariate analysis was performed. Fisher exact test was utilized. Simple logistic regression was used to decide the benefit of reinforced staples in bariatric surgery. Multiple procedures for variable selection were performed to validate the final model. Modeling the log odds as a function of the covariates age, sex, BMI, weight, and RCS, we have the following model:

$$\log\left(\frac{p(comp)}{p(no\ comp)}\right) = \beta_0 + \beta_{age}AGE + \beta_{sex}I(fem) + \beta_{BMI}BMI + \beta_{weight}Weight + \beta_{RCS}I(RCS = F)$$

Where $I(*) = 1$ if the input is true and zero otherwise (ie, the indicator function). Using proc logistic, we performed the analysis having each variable entered into the model using forward, backward, stepwise, and best 2 variable subset section. In each case, the only variable showing statistical significance was the RCS variable. This results in the final model:

$$\log\left(\frac{p(comp)}{p(no\ comp)}\right) = (-1.86) + (0.39)I(RCS = false).$$

RESULTS

Complications at the gastrojejunal site were experienced by 44 (15.3%) of 287 patients. Based on the statistical analysis, age, BMI, or sex did not appear to play a role in the presence of a complication. No incidences of bovine pericardium infection, migration, or erosion occurred.

From the NRCS group, 34 (18.7%) of the 182 patients had anastomotic complications. In the RCS group, 10 (9.5%) of the 105 patients had anastomotic complications that required perioperative or postoperative intervention. The difference between complications for each group is statis-

tically significant ($P=0.026$). The odds ratio was 2.18 with a 95% confidence interval (1.03, 4.62). We found through logistic regression that patients were 1.96 times more likely to develop complications when no reinforced staplers were used. Neither group presented with anastomotic leaks or deaths, but both RCS and NRCS cohorts developed bleeding, ulcer formation, and stricture formation (**Table 2**).

Bleeding

The bleeding rate was 4.8% in the RCS group vs. 6.6% in the NRCS group ($P=0.36$). In the RCS cohort, during the intraoperative endoscopy, 2 patients had evidence of bleeding at the gastrojejunal anastomosis, which mandated clip application in the operating room. One patient bled 2 days postoperatively. This was diagnosed endoscopically. Treatment required 2 clips and transfusion of 4 units of packed red blood cells (pRBC). One patient presented with hematemesis and a drop in the hematocrit of 4 grams on postoperative day 2. An upper endoscopy performed on postoperative day 3 revealed no evidence of ongoing bleeding, and the patient maintained a stable hemoglobin count. Another patient bled 3 days after surgery and presented at an outside institution with hematemesis. Endoscopy done at the outside institution reported the bleeding was controlled with electrocautery. The patient was then transferred to our institution once hemodynamically stable.

In the NRCS cohort, 9 patients were found to have evidence of bleeding during the intraoperative upper endoscopy. They all required the use of clips for hemostasis. In one of these 9 patients, on postoperative day 1, the hemoglobin fell 3g/dL, and this required 2 units for pRBC transfusion. One patient presented with hematemesis on postoperative day 1. A barium swallow identified a large clot in the gastric pouch, but there were no changes in hemoglobin or hemodynamic stability after 24 hours of

Table 2.
Gastrojejunal Anastomotic Complications

	Total	Reinforced Circular Staples	No Reinforced Circular Staples	P Value
Complications	44 (15.3)	10 (9.5%)	34 (18.7%)	0.0261
Bleeding	17 (5.92%)	5 (4.76%)	12 (6.59%)	0.3618
Ulcer	14 (4.53%)	3 (2.86%)	11 (6.04%)	0.1794
Stricture	14 (4.88%)	2 (1.90%)	12 (6.59%)	0.0622
Leak	0	0	0	

observation. Another patient had a drop in the hemoglobin of 2g/dL and presented with tachycardia that responded to fluids. Endoscopy found clots but no evidence of active bleeding. One patient had bleeding from an ulcer 5 months after surgery. At the time of endoscopy, no active bleeding was seen, and therefore the patient was treated conservatively with a proton pump inhibitor. This episode of bleeding may not be related to the perioperative use of Peri-Strips but was included in the NRCS statistical analysis.

Ulcers

Ulcer formation occurred in 2.9% of the RCS group vs. 6.0% of the NRCS group ($P=0.18$). In the RCS cohort, 3 patients were diagnosed with ulcers, including one with a preoperative *H. pylori* positive test. By using endoscopic confirmation, 1 patient was found to have a simultaneous stricture and an ulcer. All of these patients were medically managed with proton pump inhibitors. Two patients had ulcer formation in <2 months. Time of presentation of the ulcer was the same in both groups.

Eleven patients were diagnosed with anastomotic ulcers in the NRCS group, including 2 who were *H. pylori* positive preoperatively. Seven patients had ulcer formation in <2 months and 4 others presented more than 3 months postoperatively. One patient presented with a perforated ulcer at the gastrojejunal anastomosis about 13 months after the gastric bypass. In this patient, ulcer formation may not have been related to the lack of Peri-Strip reinforcement and might have been related to the use of NSAIDs

Strictures

The stricture rate was 1.9% in the RCS group vs. 6.6% in the NRCS group ($P=0.062$). Two patients presented with strictures in the RCS cohort. They both occurred <2 months postoperatively. Both patients required 2 separate endoscopic dilatation treatments.

In the NRCS cohort, 12 patients developed strictures diagnosed by EGJ. The strictures were identified an average of 40 days (range, 22 to 121) postoperatively. Four of these patients required dilatation only once. The rest of the group needed between 2 to 3 dilatations each.

DISCUSSION

The advances in bariatric surgery with the use of laparoscopic RYGBP have reduced the morbidity and mortality associated with weight loss surgery.^{15,16} However compli-

cations, such as leaks, bleeding, strictures, and ulcers, can occur at the gastrojejunal anastomosis and add to the cost and morbidity of the procedure. The use of reinforced staple lines is reported to increase the staple-line strength while allowing for natural healing to decrease the incidence of complications. At our institution, the bovine pericardium strips (Peri-Stripes Dry with Veritas, Synovis, St. Paul, MN) are used to reinforce the circular stapler line. Previous publications have shown a decreased risk of bleeding and leak rate when tissue reinforcement is used in staple lines. Our study showed an overall decrease in complication rates in the RCS group compared with the NRCS group. Without the use of RCS, patients are twice as likely to develop complications.

A review of the literature shows the leak rate to be 0.8% to 5%. Lujan et al⁶ examined 350 patients who underwent LRYGBP in which a circular stapler was used at the gastrojejunal anastomosis and found the leak rate to be 0.8%. Also, Ibele et al¹⁴ in a retrospective review using reinforcement with bovine pericardium at the gastrojejunal anastomosis found an increase in the incidence of leaks and staple-line failure. The learning curve with the application of new technology may have played a role in these findings. In our review, no leaks occurred in either NRCS or RCS group, which precludes us from making any conclusions with regard to this complication.

Morbidly obese patients are at high risk for deep vein thrombosis and pulmonary embolus and are frequently treated with low-molecular-weight heparin in the perioperative period. This in combination with the popularity of the laparoscopic approach has an increased potential for bleeding from luminal and extraluminal staple lines, as was demonstrated by Bahkos et al.¹⁷ A modality that would decrease the incidence of staple-line bleeding in laparoscopic Roux-en-y gastric bypass would be welcome. It is felt that tissue reinforcement with bovine pericardium through its buttressing effect may be the mechanism by which staple-line bleeding is reduced.¹¹ Studies have shown that reinforced staplers in LRYGBP diminish extraluminal bleeding.¹⁸ An article by Saber et al¹² revealed a lower bleeding rate intraluminally in patients with anastomosis performed using a reinforced stapler. The evidence in our study also verifies that reinforced staplers decrease intraluminal bleeding at the gastrojejunal anastomosis. This finding was not statistically significant, but a decreased incidence of bleeding was present; most of these were observed in the decreased need of clip application during the intraoperative endoscopy, further decreasing the cost of each clip and the potential of delayed

bleeding. Like others, we propose this may be due to the buttressing effect of bovine pericardium.¹¹

With the development of reinforced staplers, stricture rates have decreased. Jones et al⁷ investigated the use of bioabsorbable reinforced staple lines. Although their study did not show a statistically significant decrease with leaks and bleeding, it did reveal a 93% decrease in stricture incidence. This is one of the few previously published studies evaluating circular reinforced staplers in LRYGBP surgery. Prior to the use of reinforced staplers, the stricture rate was 3.2% to 23%.^{19,20} Blackstone et al²¹ found that younger patients and those with GERD were more likely to form strictures. There are also studies which show that using a 25-mm stapler instead of a 21-mm stapler reduces the stricture rate.²² Our institution routinely uses the 25-mm stapler. In our study, the RCS group had a decreased stricture occurrence of 2% compared with 6.5% in the NRCS group. However, this did not reach statistical significance. The decrease in strictures may be due to a reduction in tension at the staple line by the even distribution of forces over the area of buttressing material and decreased collagen formation seen when bovine pericardium reinforcement is used.^{7,23}

Marginal ulceration forms between 2 months and 6 months postoperatively with the majority formed by 12 months. The literature reports that ulcer development occurs between 1% to 20% after LRYGBP.^{24,25} The use of proton pump inhibitors (PPI) is the standard of care for management. Gumbs et al²⁶ recommends prophylactic use of PPI to prevent anastomotic ulceration. In our study, all patients received PPI for 6 months postoperatively. They were also preoperatively screened for *H. pylori* and given appropriate therapy if *H. pylori* was present. Our study shows a decreased incidence of marginal ulcer formation from 6.0% to 2.9% with the use of a reinforced stapler; we hypothesize this may be due to a protective effect from the bovine pericardium that prevents gastric juices from interacting with jejunal mucosa. However, it did not reach statistical significance.

CONCLUSION

Our study showed a statistically significant decrease in overall complications ($P=0.0261$) with the use of bovine pericardium reinforcement at the gastrojejunostomy. Individual complication rates for bleeding, ulcer formation, and stricture formation were not statistically significant. The use of bovine pericardium for the reinforcement of the gastrojejunostomy appears to be safe. Prospective

studies comparing the 2 techniques are indicated. Based on our study, we recommend the use of reinforced circular staplers for the gastrojejunal anastomosis, because it halves the overall complication rate.

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