

Study Stats



Do barbed sutures enable faster enterotomy closure with fewer bleeding complications and correction stitches in Roux-en-Y Gastric Bypass (RYGB)?

A randomized controlled trial (RCT).

Gys B, Gys T, Lafullarde T. *Obes Surg.* 2017;27:2159-2163.

In this novel exploration of barbed suture use for enterotomy closure in RYGB, the authors set out to verify that a single-layer, running closure with STRATAFIX™ Spiral Knotless Tissue Control Device is feasible, safe, and time efficient.



CONCLUSION

Enterotomy closure of the gastrojejunal anastomosis (GJA) and jejunojejunal anastomosis (JJA) with **STRATAFIX Spiral Device was feasible and safe, and led to fewer bleeding complications and correction stitches compared to traditional sutures.**¹



HYPOTHESIS

STRATAFIX Spiral Device can improve the efficiency of enterotomy closure in RYGB compared to traditional sutures without an increase in postoperative complications.



In RYGB, closure of the residual enterotomies is required when using the linear stapled technique to create the GJA or JJA anastomosis.

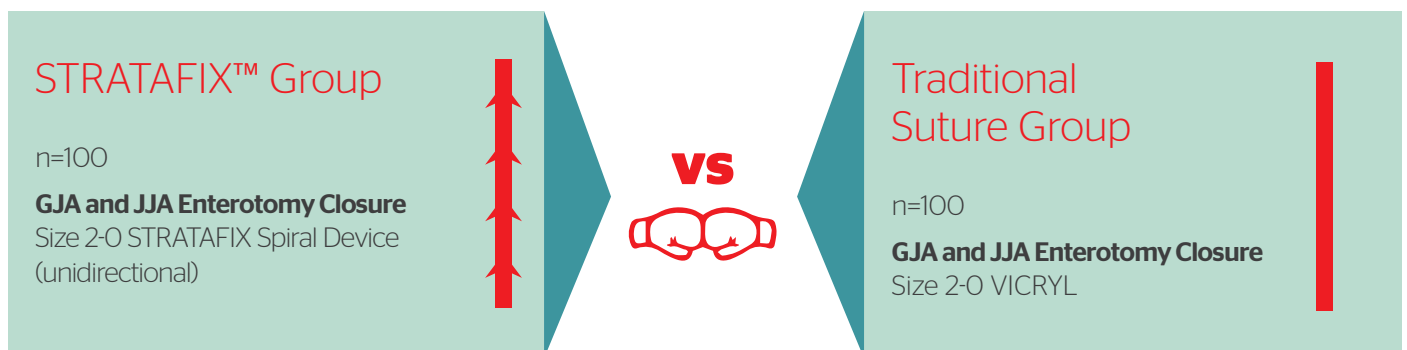
200
LAPAROSCOPIC
RYGBs

METHODS

- Patients were >18 years with an absolute indication for bariatric surgery
- Patients were randomized to either the barbed or traditional suture group
- Standard follow-up at 1 and 6 months post-surgery

Primary Endpoints: Occurrence of anastomosis-related bleeding, stenosis, or gastric fistula formation within 6 months

Secondary Endpoints: Number of correction stitches, enterotomy closure time, and length of stay





RESULTS

Bleeding Complications

No patients in the STRATAFIX™ Spiral Knotless Tissue Control Device group experienced intraluminal bleeding complications within 6 months.



Successful GJA and JJA enterotomy closure is crucial to avoiding complications, but intracorporeal suturing and knot tying is considered one of the most challenging parts of RYGB.

NUMBER OF PATIENTS WHO EXPERIENCED BLEEDING^{1*}

STRATAFIX Spiral Device N=100	Traditional Suture N=100	P value
0	4	.043 [†]

[†]P values <0.05 denote statistical significance.

Stenosis or Gastric Fistula Formation: No patients in the study reported either complication at 6 months postoperatively.¹

Correction Stitches Required

The total number of correction stitches needed in the STRATAFIX Spiral Device group was significantly lower.



At the discretion of the surgeon, a 'correction stitch' was made if a small hiatus at the anastomosis was present after enterotomy closure.

ENTEROTOMY CORRECTION STITCHES¹

	STRATAFIX Spiral Device	Traditional Suture	P value
GJA	8	18	.036 [†]
Total (GJA/JJA)	9	20	.027 [†]

[†]P values <0.05 denote statistical significance.

Enterotomy Closure Time

Statistically significant time savings was seen in GJA enterotomy closure in the STRATAFIX Spiral Device group.¹



By eliminating the need for knot tying and the inconvenience of having a third hand hold constant suture tension after each pass, STRATAFIX Spiral Device has the potential to improve enterotomy closure efficiency.

★ Note on Surgeon Experience

Safety and efficiency outcomes for STRATAFIX Spiral Device were favorable despite a learning curve—the operating surgeon had only minor experience with STRATAFIX Spiral Device in RYGB, but had used Coated VICRYL® (polyglactin 910) Suture in over 3,000 cases.¹

For complete indications, contraindications, warnings, precautions, and adverse reactions, please reference full package insert.

¹Intraluminal bleeding was presumed to be located at the anastomosis in most cases and not at the staple line.

Reference: 1. Gys B, Gys T, Lafullarde T. The use of unidirectional knotless barbed suture for enterotomy closure in Roux-en-Y gastric bypass: a randomized comparative study. *Obes Surg*. 2017;27:2159-2163.