

The Use of Surgisis® Biodesign™ Staple Line Reinforcement to Reinforce the Staple Line during Laparoscopic Roux-en-Y Gastric Bypass

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Introduction

The use of surgical staplers in abdominal procedures, such as Roux-en-Y gastric bypass, has been commonplace for decades. These devices quickly cut and close tissues that previously required suturing—significantly decreasing operating time and tissue handling. Available in various staple sizes and shapes, surgical staplers can be used in both open and laparoscopic procedures for various applications.

The success of laparoscopic Roux-en-Y gastric bypass procedures is dependent on the closure of staple lines. Despite the benefits of decreased operating time and tissue handling with surgical staplers, typical complications include leakage and bleeding. Failures in these procedures have been reported to be between 0.5-6%.¹⁻³ Leakage from the staple line, the most common complication, may lead to significant morbidity by causing peritonitis and septic shock, and if severe enough, death.⁴ Recovery from these complications is often lengthy and expensive. On the other hand, staple line bleeding generally leads to less severe complications. However, this too can lengthen the operating time and can occasionally lead to the need for transfusions and additional surgical procedures.⁵

To decrease the incidence of these complications in Roux-en-Y procedures, materials can be used to reinforce the staple line. Reinforcement of the staple line with a buttressing material can decrease the incidence of leakage and bleeding, as well as reinforce tissue edges that have become frail due to disease. This reinforcement occurs by placing a thin piece of material between the tissue and the stapler. After the stapler is fired, the material can reduce the tension in the staple line, seal the staple holes and reduce the distance between the staples, which ideally mitigates leakage, bleeding and tearing.⁵

Multiple materials, ranging from nonabsorbable polymers, such as expanded polytetrafluoroethylene (ePTFE) to semiabsorbable materials, such as bovine pericardium, to absorbable copolymers, such as polyglycolic acid:trimethylene carbonate, have been

described in the literature for use in laparoscopic gastric bypass procedures. Shikora et al. described using bovine pericardium to reinforce gastric staple lines and to effectively decrease gastric leakage.⁴ Several papers have reported successfully using an absorbable polyglycolic acid:trimethylene carbonate copolymer to reduce leakage and bleeding during laparoscopic gastric bypass.⁶⁻⁹ However, complications, such as erosion, migration, immunological reaction and encapsulation, can occur with these materials.¹⁰⁻¹² Here, we present evidence on the successful use of Surgisis Biodesign Staple Line Reinforcement for support of the staple line during laparoscopic Roux-en-Y gastric bypass.

Surgisis Biodesign Staple Line Reinforcement

Surgisis Biodesign Staple Line Reinforcement is part of a family of devices whose base material is composed of small intestinal submucosa, a naturally derived biologic graft. Surgisis Biodesign is minimally processed to maintain the natural three-dimensional, collagen-rich extracellular matrix (ECM) while removing all cells and nuclear matter. Furthermore, no Surgisis Biodesign products are chemically cross-linked.

Unlike synthetic or cross-linked meshes, Surgisis Biodesign is engineered to facilitate tissue remodeling while being slowly incorporated into the body. Surgisis Biodesign is not merely a passive mechanical structure, but contains a complete and complex ECM, including growth factors and cytokines that modulate cell behavior and aid in the healing process. During the remodeling process, Surgisis Biodesign is infiltrated by host cells, tissues and blood vessels while being slowly resorbed into the body, metabolized, and excreted from the body. Thus, Surgisis Biodesign is not a long-term foreign body, and the problems associated with that—erosion, chronic inflammation and infection—are mitigated.

Surgical Technique

The jejunum was divided 40 cm from the ligament of Treitz using a 60 mm Endo-GIA 3.5 mm stapler (U.S. Surgical Corp., Norwalk, CT) with reinforcement material (Surgis Biodesign Staple Line Reinforcement, Cook Medical, Inc., Bloomington, IN). A 150 cm Roux limb was constructed by creating a side-to-side jejunojejunostomy utilizing a 60 mm Endo-GIA 2.5 mm stapler. The transverse closure of the jejunojejunostomy was then completed with a 60 mm Endo-GIA 3.5 mm stapler and reinforcement material. After opening the pars flaccida, division of the descending branch of the left gastric (lesser omentum) was performed with a 60 mm Endo-GIA 3.5 mm stapler with reinforcement material to further expose the lesser sac and the posterior wall of the stomach. A 20 cc vertical gastric pouch was created based on the lesser curvature. The vertical staple lines of the gastric pouch were reinforced with the Surgis Biodesign Staple Line Reinforcement device. The Roux limb was then brought to the upper abdomen in an antecolic fashion. A 12 mm gastrojejunostomy was created utilizing a linear stapler technique with a 45 mm Endo-GIA 3.5 mm stapler. The redundant overhang of the Roux was transected flush with the gastric pouch utilizing a 60 mm Endo-GIA 3.5 mm stapler with reinforcement material.

Results

A total of 287 laparoscopic Roux-en-Y gastric bypass (RYGB) procedures were completed using Surgis Biodesign Staple Line Reinforcement to bolster the staple lines. Of these cases, 18 were revisional bariatric procedures that were either conversions of vertical banded gastroplasty to RYGB or removals of Lap-Band® followed by RYGB. The mean age of the patient population was 43 years old with a mean BMI of 49.6 kg/m². The group of patients consisted of 221 women and 66 men. In all cases, at least 6 Surgis Biodesign Staple Line Reinforcement devices were used. Minimal intraoperative bleeding was observed, and no reoperations were required due to bleeding. Postoperatively, no staple line leaks have been noted, and a low incidence of 1.6% of postoperative bleeding required blood transfusions, which were treated by holding the postoperative venous thromboembolism chemoprophylaxis of unfractionated heparin and ketorolac prior to their transfusion.

Discussion

While several materials exist to reinforce staple lines, few have indications for use that include gastrointestinal procedures. Ideally, these materials “should be biocompatible and not lead to immunologic reaction or predispose a patient to infection,” and “it should increase the strength of the tissue.”¹³ As evidenced by the published nonclinical data, Surgis Biodesign Staple Line Reinforcement performs, at a minimum, equal to that of other competitor materials and products.¹³⁻¹⁵ The Surgis Biodesign product line has been proven safe and effective through use in multiple controlled trials and case studies comprising various disease states.

The Surgis Biodesign Staple Line Reinforcement is considered unique and represents several advantages over alternative products. This is because it has the ability to provide mechanical support and actively facilitate the remodeling of host tissue at the site of implantation. As the base material contains proteins and regulatory factors that stimulate the body's natural healing processes,^{16,17} Surgis Biodesign acts as a scaffold for guided tissue growth. At the same time that Surgis Biodesign is guiding the tissue remodeling, it is being incorporated into the host system such that no device material permanently remains in the body,¹⁸ reducing the likelihood of discomfort, immunological reaction, encapsulation, expektoration, migration or erosion that may be seen with other biomaterials.¹⁰⁻¹²

Clinically, Surgis Biodesign Staple Line Reinforcement has a uniform thickness, which creates a more secure and stronger staple line. Unlike other staple line reinforcement materials, which have a series of strings attached, the adhesive on the Surgis Biodesign Staple Line Reinforcement holds firmly to the jaws of the stapler, allowing manipulation of the stapler during the procedure. Because minimal, if any, staple line bleeding occurs, it is the quickest and easiest to use. The material, on the whole, embodies many of the characteristics of an ideal tissue engineered biomaterial—acellular, nonpermanent, provides mechanical integrity and facilitates the growth of healthy, properly functioning host tissue. Therefore, Surgis Biodesign Staple Line Reinforcement is an attractive alternative for linear staple line buttressing to decrease the incidence of leaking from the staple line.

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