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Original article

Staple line reinforcement with new biomaterial increased burst strength pressure: an animal study

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Abstract

Background: Most bariatric operations rely on stapler devices. Although today staplers are extremely safe, efficient, and reliable, a potential risk exists for staple line failures, leading to three complications: leaks, fistulas, and bleeding. Porcine small intestinal submucosa strip applied over the staple line suture might help prevent these problems.

Methods: Forty animals (canine model developed at the University of São Paulo, São Paulo, Brazil) underwent general anesthesia and laparotomy. One nonreinforced staple line suture and one staple line suture reinforced with Surgisis SLR was created in each animal. The burst strength pressure of the 80 staple line sutures was obtained. Suture line bleeding and the ease of use of the membrane were also noted. The data were compared (Student's *t* test). The dogs were euthanized after the procedure. Two surgeons with experience in stapler devices performed all procedures.

Results: The mean ± SD burst pressure was 209.26 ± 76.41 mm Hg and 441.33 ± 128.64 mm Hg for the stapler line without and with the biodegradable membrane, respectively. The difference was statistically significant ($P = .002$). No in vivo suture line bleeding occurred. The biodegradable membrane was easy to use.

Conclusion: The biodegradable membrane was able to increase the burst strength pressure of the bowel segment staple line. It might help prevent some causes of staple line leaks.

Keywords: Burst pressure; Staple line failure; Biodegradable membrane; Test of anastomosis; Bariatric surgery

With the number of laparoscopic bariatric procedures growing throughout the world, it is important that surgeons continue to evaluate methods to improve surgical outcomes. Most bariatric operations rely on stapler devices. Although today staplers are extremely safe, efficient, and reliable, a potential risk exists for staple line failures [1]. Staple line failures can lead to three complications: leaks, fistulas, and bleeding [2–4].

Leaks can lead to life-threatening sepsis in the immediate postoperative period or to delayed presentations with fistulas. A high incidence of mortality has been reported (15–30% of cases) [5,6]. Equally as significant, survivors can bear lifelong consequences, with a slow and costly recovery.

Gastrogastric fistulas between the gastric reservoir and distal stomach can also occur after laparoscopic Roux-en-Y gastric bypass. They can present as intractable marginal ulcers and weight regain. The incidence has been reported in 3–6% of cases [7].

The incidence of intra-abdominal and gastrointestinal hemorrhage after laparoscopic Roux-en-Y gastric bypass ranges from as low as 0.8% to as much as 9.4%. The most common cause of gastrointestinal hemorrhage after laparoscopic Roux-en-Y gastric bypass is bleeding at the staple lines [8]. It is generally of less consequence, but can eventually lead to the need for blood transfusion or surgical

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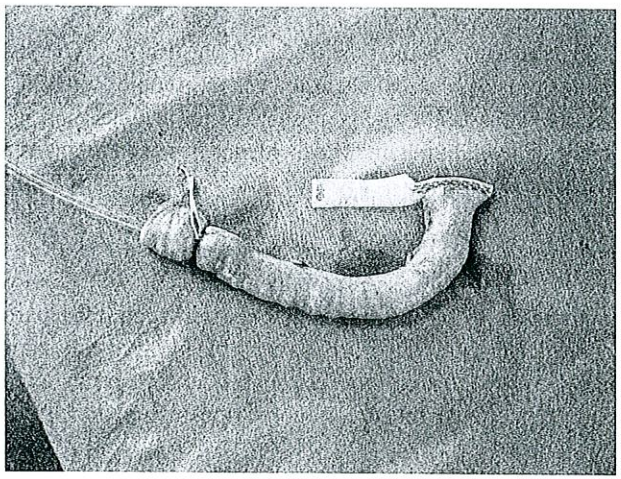
would be of great benefit. The porcine small intestinal submucosa strip (Surgisis SLR, Cook, Bloomington, IN) is extracted in a manner that removes all cells, but retains the complex and acellular matrix. It consists of a mixture of structural and functional proteins arranged in an ordered and organized architecture. After Surgisis is implanted, the tissues adjacent to it deliver cells and nutrients, and fibroblasts rapidly invade the Surgisis material. Capillary growth soon follows, and even more nutrients are provided to the tissue. Surgisis is remarkably strong at implantation, but gradually degrades as the host system reinforces and replaces it with native tissue. Surgisis eventually becomes indistinguishable from the surrounding tissue. No harmful immunologic response has been noted in humans. Thus, this biodegradable, nonimmunogenic, collagen-rich, and relatively acellular material has potential as a staple line reinforcement material.

The most important aim of this study was to evaluate the ability of Surgisis to significantly increase the staple line burst pressure. The secondary aims were to evaluate its ease of use and its ability to reduce staple line bleeding.

Methods

Forty animals (canine model developed at the University of São Paulo, São Paulo, Brazil) underwent general anesthesia. Two surgeons with experience with stapler devices performed all procedures. A midline laparotomy was performed in all animals, and a segment 20-cm distal to the ligament of Treitz was identified. A 45-mm linear stapler (EndoGIA, AutoSuture, U.S. Surgical, Norwalk, CT) with a blue cartridge (3.5-mm staple depth) was fired to divide the small intestine. The small bowel 10 cm proximal to the staple line was occluded with three surgical knots. A 14F nasogastric tube was inserted in this bowel segment through an opening in the bowel wall. An airtight pursestring suture was performed around the tube. The tube was connected to a manometer. The bowel segment was placed under a 5-cm column of sterile water. Continuous intraluminal pressure was monitored during insufflation of air with a manual pumping device. Air insufflation continued until air bubbles were visible from the staple line or bowel wall. The burst pressure was recorded. Then, in the same animal, a segment 30 cm from the ligament of Treitz was identified. Surgisis membrane was placed over both sides of the surgical stapler, as described by the manufacturer. A segment of bowel was divided, and the burst pressure was tested exactly as described previously. Suture line bleeding and the ease of use of the membrane were noted. The dogs were euthanized after the procedure. Fig. 1 shows the bowel segment with Surgisis and nasogastric tube. The Animal Care Committee approved all procedures. The burst strength pressure of the staple line sutures with and without Surgisis was compared (Student's t test).



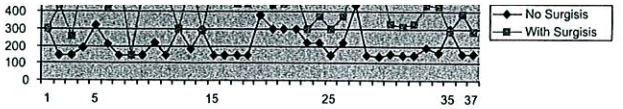


Fig. 2. Burst pressures with (squares) and without (diamonds) Surgisis. X axis: case number; Y axis: burst pressure in millimeters of mercury.

Results

We studied 40 staple line sutures created without Surgisis and 40 staple line sutures created with Surgisis. In three bowel segments with Surgisis, the rupture occurred through the bowel wall and not through the staple line. These data were excluded from the final statistical analysis.

The mean burst pressure was 209.26 ± 76.41 mm Hg of the stapler line without Surgisis and 441.33 ± 128.64 mm Hg with Surgisis. Fig. 2 shows the burst pressure results. The difference was statistically significant ($P = .002$).

No in vivo suture lines bleeding occurred in either group. The biodegradable membrane was easy to use, after an extremely short learning curve.

Discussion

The ideal method or material to prevent staple line complications should be easy to use and not increase the operative time; be biocompatible, behaving better during infection than other synthetic materials; increase tissue strength (assessed by burst strength experimental test), protecting the staple lines; not add to tissue thickness, preventing anastomotic occlusion; not result in stapler malfunction; and be cost effective.

A variety of methods have been used to prevent suture line failures, including oversewing the staple line, using tissue sealants, and buttressing the staple line with nonab-

even increase the risk of staple line failure [9]. Animal and clinical studies focusing on the use of fibrin sealants in staple lines were unable to produce definite conclusions regarding their role in increasing tissue strength or decreasing staple line leaks [10–13]. Testing an anastomosis or suture line is difficult. A variety of methods (mechanical, biochemical, and microscopic) are available, each with its own advantages and drawbacks. Testing an in vivo suture line is even harder. The measurement of burst strength pressure is one the most used, most reliable, and probably the paramount experimental test for evaluating tissue, suture, and anastomosis strength. Even though it does not specifically assess the cause of the leak, it evaluates the efficacy of the anastomosis and, most importantly, it allows comparisons among different suture techniques and different leak-preventing devices.

In our study, the staple lines reinforced with Surgisis had significantly greater mean burst pressures than did the nonbuttressed staple lines. Our experience is similar to that of other experimental studies with buttressing materials. Arnold and Shikora [14] reported that gastrointestinal staple lines buttressed with bovine pericardial strips (Peri-Strips Dry, Synovis Surgical Innovations, St. Paul, MN) were able to maintain seam integrity at significantly greater intraluminal pressures compared with nonbuttressed gastrointestinal staple lines in animal models (rabbits and pigs).

Downey et al. [15] also found greater burst pressures in staple lines reinforced with Surgisis compared with nonreinforced staple lines in a porcine model. Their study also suggested that staple lines with bovine pericardial strips might withstand greater intraluminal pressures than staple lines supported with Surgisis. Our data showed that the mean burst pressure in staple lines buttressed with Surgisis (441.33 mm Hg) was actually greater than that of the staple lines reinforced with pericardial strips (125 mm Hg for swine and 115 mm Hg for rabbits). The disparity in the animal models might account for these differences.

In our study, we always used the more proximal jejunum (20 cm from the ligament of Treitz) for the control samples and slightly more distal jejunum (30 cm from the ligament of Treitz) for the buttressed samples because of technical issues. Not alternating or randomizing the intestinal segments might have introduced a bias in the analysis. However, as in humans, the canine anatomy is well studied, and these two points do not represent different anatomic sites. Because the bowel wall thickness and intraluminal diameter are not different between these two points (20 and 30 cm), it is improbable that the difference observed in burst pressure resulted from this situation.

Both surgeons found Surgisis easy to handle and to apply

ing any analysis.

In three bowel segments, rupture occurred through the bowel wall and not through the staple line. Even though no differences were present in the membrane placement, stapler device used, or amount of pressure used to reach rupture, we preferred to exclude these three bowel segments to not jeopardize the final statistical analysis.

Conclusion

The porcine small intestinal submucosa (Surgisis) membrane was able to significantly increase the burst strength pressures of the stapler line sutures. This material might help prevent suture line complications.

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