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Research Paper

Biologic staple line reinforcement for laparoscopic sleeve gastrectomy: A case series

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ABSTRACT

Background: Laparoscopic Sleeve Gastrectomy (LSG) is currently the most common bariatric procedure worldwide. Staple Line Reinforcement (SLR) with biological or synthetic material has been recommended to reduce complications such as staple line bleeding and leakage following LSG. SLR devices have been studied and have shown varied results in reducing these complications.
Objective: The aim of this study was to evaluate the rate of postoperative bleeding and staple line leakage associated with LSG when using a SLR material made from porcine small intestinal submucosa.
Setting: Community Hospital.
Methods: This was a single surgeon retrospective case review of all patients who had undergone LSG to treat severe obesity at our institution between January 2012 and August 2016 and had their staple line reinforced with a SLR device made from porcine small intestinal submucosa. Postoperative complications within the 30-day postoperative window, including bleeding and staple line leakage, were recorded.
Results: A total of 722 procedures were performed (female, 77%; age, 48.7 ± 13.2 years; preoperative Body Mass Index, 43.9 ± 7.6 kg/m^2). The mean operative time was 109 ± 40 min and average length of stay was 1.5 days. Postoperative bleeding was noted in 9 patients (1.2%); 2 patients (0.3%) required re-operation for bleeding. Four (0.6%) post-operative staple line leaks were recorded. There was one post-operative death of indeterminate etiology.
Conclusions: Staple line reinforcement with porcine small intestinal submucosa has leak and bleed rates comparable to those reported for other staple line reinforcement devices.

1. Introduction

Obesity is a leading cause of preventable death that afflicts over 300 million individuals worldwide. Obesity increases the risk of diabetes, hypertension, hyperlipidemia, heart disease, osteoarthritis, sleep apnea, gallbladder disease and premature death [1]. Bariatric surgery has been shown to be the most effective and long-lasting treatment for this disease [2].

Most bariatric surgical procedures, such as gastric bypass and sleeve gastrectomy, involve the use of linear cutting/stapling devices to effectively and efficiently divide and close tissues. Compared to suture (i.e., handsewn) techniques, mechanical staplers reduce tissue manipulation and shorten operation time [3,4]. However, complications may occur and result in significant morbidity [3]. Staple line bleeding and staple line leaks are the main complications following bariatric procedures using staplers [4,5] with average incidences of staple line leaks and bleeding of 1.17% and 3.5% [6].

Laparoscopic sleeve gastrectomy (LSG) is currently the most common surgery performed for obesity in the U.S. and worldwide [2]. In LSG, 75%–80% of the stomach is removed, leaving a narrow gastric tube or "sleeve." The staple line used to seal the stomach is the longest staple line of any bariatric procedure performed currently. Therefore, staple line bleeding and staple line leakage are predominant postoperative concerns.

Staple line reinforcement or buttressing devices have been introduced as an attempt to decrease the incidence of staple line bleeding and staple line leaks. Given the frequent use of

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endomechanical staplers, it is important that the staple line supports the tissue during wound healing and provides an adequate seal to reduce the risk of bleeding and leakage [3–5]. Ideally, staple line reinforcement reduces tension in the staple line, seals staple holes, and reduces the space between staples, thereby reducing the incidence of staple line bleeding and leak, particularly in fragile and/or diseased tissue [3].

The Biodesign® Staple Line Reinforcement (SLR) (Cook Medical, Bloomington, IN) is an absorbable biomaterial strip composed of collagen-based extracellular matrix derived from porcine small intestinal submucosa (SIS) that is pre-coated with an adhesive. The pre-coated adhesive eliminates the need for a separate adhesive (e.g. hydrogel) to affix the device to the surgical stapler cartridge. Upon implantation, the Biodesign® SLR device is integrated between the surgical staples and tissue to reinforce staple line integrity and subsequently reduce the incidence of staple line bleeding and leak. The Biodesign® SLR device incorporates into the body over time such that no graft material is left behind.

In this single-surgeon retrospective case series, we present our experience on the successful use of Biodesign® Staple Line Reinforcement during LSG.

2. Materials and methods

2.1. Protocol registration

This retrospective case series follows the Preferred Reporting of Case Series in Surgery (PROCESS) guidance statement for reporting surgical case series [7]. This study was registered with the ResearchRegistry. Its unique identifying number is researchregistry4609.

2.2. Study design

This retrospective data collection was undertaken as a research audit for quality improvement in our practice. Medical records of all patients undergoing laparoscopic sleeve gastrectomy (LSG) by a single surgeon at our institution who received the SLR device between January 2012 and October 2016 were retrospectively examined. Charts were reviewed for patient demographics, comorbidities, diagnosis, and previous surgeries. Concomitant procedures, such as hiatal and incisional hernia repairs, were also captured. Clinically relevant outcome measures of staple line leaks and postoperative bleeding were assessed during the 30-day postoperative window, along with any other intraoperative or postoperative complications. For the purposes of this data collection, a leak was defined as any demonstrated gastric staple line disruption or any perigastric abscess, regardless of whether a leak was demonstrated. Postoperative bleeding was defined as any case of hemoperitoneum diagnosed on clinical signs (tachycardia, pallor, hypotension), laboratory values (>10% drop in the hematocrit), or on the nature of the drain output.

2.3. Preoperative evaluation

Preoperative evaluation was dependent on the patient's age and associated comorbidities, but typically included a comprehensive history and physical examination, cardiac stress test and echocardiogram, pulmonary function testing, upper endoscopic examination and a screening colonoscopy if over age of 50 years. Sleep studies were also preformed if they were recommended by a pulmonologist or if the patient was at high risk for obstructive sleep apnea. All patients were placed on a very low-calorie liquid protein diet for at least two weeks prior to surgery to decrease liver size.

2.4. Surgical intervention and application of the SLR

All LSGs were performed using an Echelon 60 Endopath Stapler (Ethicon Inc., Somerville, NJ), with a combination of black, green or gold cartridges depending on perceived stomach thickness, using the Biodesign® (porcine small intestine submucosa) staple line reinforcement (SLR). The SLR was applied to the jaws of the loaded surgical stapler pre-warmed in a sterile saline bath warmed to 49 °C (120 °F). The SLR was then pulled out of the tray by the finger grips on the wings of the applicator and placed on the surface of the cartridge side of the open stapler. The stapler was used within 20 min after applying the SLR.

The LSGs were performed by first dividing the gastroepiploic tributaries and short gastric vessels present along the greater curvature using a Harmonic scalpel (Ethicon Inc., Somerville, NJ). Using a 40F bougie as a guide and starting 4 cm from the pylorus, the sleeve was constructed with multiple firings of the Echelon 60 stapler, hugging the bougie and ensuring that staple lines overlapped on the sleeve side. A leak test was performed by insufflating the sleeve with an orogastric tube after upper abdomen was filled with saline. Any bleeding from the staple line was controlled with endoclips. The resected stomach was removed using a specimen retrieval bag (Applied Medical, Rancho Santa Margarita, CA). A 10-mm Jackson-Pratt drain was placed in the left subphrenic space in all patients and was left in place for 24 h to observe for bleeding and leakage.

2.5. Post-operative care

On post-operative day 1, a gastrografin upper gastrointestinal (UGI) series was performed to check for leaks or obstruction. After the UGI series, patients typically were started on clear fluids and discharged to home after tolerating fluids, unless there was a complication. Routine post-operative supplements include a multivitamin, sublingual Vitamin B12, as well as calcium supplements with vitamin D and iron. Patients were routinely followed for complications at 1-week and at 30-days post-surgery. Patients were also seen for routine post-operative evaluation at 3, 6, 9 and 12 months in the first year. Bi-annual health check-ups are typical during the second year, and then annually thereafter.

2.6. Statistical analysis

Continuous variables were summarized using means and standard deviations, and categorical variables were summarized with frequencies and percentages.

3. Results

This series included 722 patients who underwent LSG surgery procedures using the porcine small intestinal submucosa SLR. The mean age of the patient population was 48.7 ± 13.2 years (range: 16–77 years) with a mean Body Mass Index (BMI) of 43.9 ± 7.6 kg/m^2 (range: 27.0–79.4). There were 557 (77.1%) women and 165 (22.9%) men. Sixty-three (8.7%) patients currently smoked at the time of the procedure, while 242 (33.5%) were former smokers and 417 (57.8%) had no previous smoking history. A complete listing baseline characteristics and comorbidities is presented in Table 1.

Mean operative time was 109 ± 40 min, mean blood loss was 5.7 ± 45.6 ml, and mean hospital stay was 1.57 ± 1.46 days. A total of 88 patients had a concomitant hiatal hernia repair procedure and 31 patients had concomitant removal of a gastric band at the time of surgery. There were no conversions to open surgery.

Postoperative bleeding was monitored via drain output and complete blood count (CBC) looking specifically at hemoglobin and

Table 1
Baseline patient characteristics and comorbidities.

Age (years)	48.7 ± 13.2
Gender (n, %)	
Male	165 (22.9)
Female	557 (77.1)
Ethnicity	
Caucasian	579
African American	126
Hispanic	4
Other/mixed	13
Body Mass Index (BMI)	43.9 ± 7.6 kg/m^2
Diabetes, Type II (n, %)	245 (33.9)
Hypertension (n, %)	410 (56.8)
Hyperlipidemia (n, %)	324 (44.9)
Gastroesophageal Reflux Disease (n, %)	328 (45.4)
Sleep Disorders (n, %)	489 (67.7)
Renal insufficiency/failure	40 (5.5)
Gastrointestinal disease	119 (16.5)
Hiatal hernia	67 (9.3)
Liver disease	45 (6.2)
Other	7 (1.0)
Osteoarthritis/joint pain	212 (29.3)
Depression (n, %)	211 (29.2)
Previous Gastric Surgery (n, %)	33 (4.6)
Smoking Status (n, %)	
Current Smoker	63 (8.7)
Past Smoker	242 (33.5)
Never smoked or unknown	417 (57.8)
Concomitant Hiatal Hernia Repair (n, %)	88 (12.2)
Concomitant Gastric Band Removal (n, %)	31 (4.3)
Operative time	109 ± 40 min
Blood Loss	5.7 ± 45.6 ml
Hospital stay	1.57 ± 1.46 days

hematocrit levels. A total of 9 patients experienced post-operative bleeding. Two patients were returned to the operating room for post-operative bleeding and needed transfusions. There were 4 delayed post-operative staple line leaks, all of which were successfully treated non-operatively with antibiotics and in 3 patients radiologic percutaneous drainage. These and additional complications are included in Table 2. There was one post-operative death that occurred after a fall two weeks postoperatively.

4. Discussion

Studies showing positive results in staple line reinforcement with the use of buttressing materials have increased awareness of these materials within the medical community, leading to a rise in their use. However, the results of using staple line reinforcement (including buttressing strips, suture oversewing, and sealants) in bariatric procedures are inconsistent. Meta-analyses of staple line reinforcement in bariatric procedures, including LSG and Roux-en-Y gastric bypass, show a significant decrease in the incidence of overall complications and hemorrhage [8,9] and a significant reduction in operating time [8], perioperative complications, leak, and use of hemostatic clips [10] when staple line reinforcement devices are used. One meta-analysis of randomized controlled trials evaluating the efficacy of staple line reinforcement during sleeve gastrectomy reported that staple line reinforcement was associated with a lower risk of staple line hemorrhage ($p = 0.003$) and overall complications ($p = 0.006$) [8]. On the other hand, other meta-analyses show no clinical or statistical benefit with the addition of staple line reinforcement in bariatric procedures in comparison to standard staple lines or suture closure [11,12].

Table 2
LSG + SLR-related complications.

Complication	Number, n (%)
Dehydration	23 (3.2)
Bleed	9 (1.2)
Leak	4 (0.6)
Wound Infection	3 (0.4)
Pneumonia	3 (0.4)
Pancreatitis	2 (0.3)
Elevated BUN and creatinine	2 (0.3)
Splenic injury	1 (0.1)
Dysphagia	1 (0.1)
Death (unrelated)	1 (0.1)

Staple line complications, though rare, are a significant cause of morbidity and mortality in patients undergoing bariatric surgery. Staple line leaks after LSG can cause chronic fistulas, sepsis, prolonged recovery times, and even mortality if not adequately addressed post-operatively. In addition to the adverse effects on the patient, costs of caring for patients with staple line bleeds or leaks have been reported to be between €1524-€125,684 (between approximately US $1600-$134,000) in 2014 figures [13], which places a tremendous burden on the health care system; most of these costs are related to prolonged hospitalization and intensive care unit stay. Many patients can benefit and costs to the health care system can be reduced if a reliable means of preventing staple line complications following LSG can be developed.

Many materials have been developed and marketed to reinforce staple lines; however, few have indications for use in the gastrointestinal tract. The staple line reinforcement material should be biocompatible, help to increase the strength of the tissue, and should maintain the appropriate staple line tension to provide a watertight seal. Additionally, the material should not lead to immunologic reaction or predispose a patient to infection [4,14]. Here, we have successfully used a porcine SLR material in 722 patients undergoing LSG surgery.

Biodesign® SLR is a distinctive material that possesses several advantages over alternative products including the ability to provide mechanical support and facilitate tissue remodeling at the site of implant. Because the base material contains proteins and growth factors that stimulate the body's natural healing processes [15,16], it simultaneously acts as a scaffold for guided tissue regeneration and is incorporated into patient tissue such that no device material permanently remains in the body [17]. This reduces the likelihood of discomfort, immunological reaction, encapsulation, expectoration, migration, or erosion that may be seen with permanent materials [15,18–20]. The uniform thickness of the Biodesign SLR, coupled with its tissue remodeling ability, enables the creation of a more secure and stronger staple line to prevent gastric leak, excessive bleeding and other complications. During the procedure, the pre-coated adhesive on the device holds it firmly in the jaws of the stapler, which allows for easier tissue manipulation of the stapler as compared to other available products.

In addition to SLR, other techniques were devised to reduce staple line complications after sleeve gastrectomy, one of which is the staple line inversion and distal fixation to the transverse mesocolon. In a recent study of 252 patients where this technique was described, Abdallah et al. [6] reported staple line leak and bleeding rates to be 2% and 1.2%, respectively.

In this retrospective case series, we report a staple line leak rate of 0.6% and a re-operation rate for post-operative staple line bleeding of 0.3%, which is comparable to other reports of staple line reinforcement found in the literature [13,21]. Additionally, these numbers compare favorably to those recently reported in the Metabolic and Bariatric Surgery Accreditation and Quality Improvement Program (MBSAQIP), which reported a 0.96% leak rate with reinforcement and a 0.65% leak rate with no reinforcement. The MBSAQIP reported the rates of post-operative bleeding requiring re-intervention to be 0.75% with reinforcement and 1.0% without [22]. We also report a mean hospital length of stay of 1.5

days, which is much lower than reported elsewhere in the literature [21]. We attribute these results to the fact that we operate with a single, consistent, operative team and pay meticulous attention to detail during these surgical procedures. This attention to detail may result in the longer operative times seen in this series than are typically reported in the literature; however, other local factors, such as the fact that only one stapler was available for most cases could have significantly impacted the operative time recorded.

There are weaknesses associated with this retrospective review. First, all 722 procedures were performed by a single surgeon at a single institution with an operating staff that works together daily. Because the process of adhering the device to the stapler can take some practice, ease of use of the device can be challenging and deployment may result in inadequate staple line reinforcement. The single center experience prevents us from analyzing comparative results from other institutions. Additionally, the retrospective nature of the study meant that no comparison could be made to either oversewing the staple line with another staple line reinforcement technique or with no reinforcement at all, meaning that randomized clinical studies are needed to verify the advantages of the Biodesign SLR over other similar materials and techniques.

5. Conclusions

This retrospective case series demonstrates that the Biodesign® SLR is safe and effective when used during LSG. Staple line bleed and leak rates compare favorably to results achieved with other reinforcement materials. Additional randomized studies should be performed to determine how the use of Biodesign SLR compares to no SLR or oversewing of the gastric staple line.

Ethical approval

N/A.

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Author contribution

MJW: Project concept and design, acquisition of data, data interpretation, drafting of manuscript, critical review of manuscript and final approval of manuscript.

JPH: Project concept and design, data interpretation and statistics, drafting of manuscript, critical review of manuscript and final approval of manuscript.

EC: Project concept and design, acquisition of data, critical review of manuscript and final approval of manuscript.

LC: Project concept and design, acquisition of data, critical review of manuscript and final approval of manuscript.

Conflicts of interest

JPH is employed by Cook Biotech Incorporated. **MJW, EC**, and **LC** have nothing to disclose.

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