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Laparoscopic sleeve gastrectomy using a synthetic bioabsorbable staple line reinforcement material: Post-operative complications and 6 year outcomes

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HIGHLIGHTS

- Laparoscopic sleeve gastrectomy shows sustainable long-term weight loss.
- Laparoscopic sleeve gastrectomy shows excellent resolution of comorbidities.
- The use of a bioabsorbable staple line reinforcement material is safe.

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ABSTRACT

Background: Gastric leak after laparoscopic sleeve gastrectomy (LSG) is a serious complication. Currently, the literature lacks long-term outcomes in LSG and leak rates after reinforcement of the staple line. The aims are two-fold: to present leak rates from using staple line reinforcement and six year outcomes of LSG in relation to resolution of obesity-related comorbidities and long-term weight loss.

Materials and methods: This is a single-institution, retrospectively reviewed study of 204 patient case files. Data from all patients undergoing LSG between December 2007 and May 2013 was collected.

Results: The total complication rate was 6.9% (14/204), with no recorded staple line leaks. The mean postoperative Body Mass Index (BMI) at 1 year, 2 years, 3 years, 4 years, 5 years, and 6 years was 39.3 ± 8, 38.7 ± 8, 40.4 ± 9, 40.5 ± 10, 43.0 ± 10, and 42.4 ± 7, respectively. The mean % excess weight loss at 1 year, 3 years, and 6 years was 48.4 ± 19, 51.7 ± 28, and 41.0 ± 21, respectively. There were no significant differences between follow-ups at year 1 and 3 ($p > 0.05$), and between year 3 and 6 ($p > 0.05$) for the mean % excess weight loss. The resolution rates for all patients were 74%, 61%, 79%, and 90% for hypertension, hypercholesterolemia, diabetes mellitus type 2 and obstructive sleep apnea, respectively.

Conclusion: The synthetic bioabsorbable reinforcement material shows no staple line leaks making it safe to use. LSG as a procedure had a high resolution of obesity-related comorbidities as well as sustainable long-term weight loss.

1. Introduction

Since 2003, laparoscopic sleeve gastrectomy (LSG) has been rising in popularity in Europe, increasing to 127 officially documented operations in 2007 [1,2]. In the United States (US), the number of bariatric surgeries amounted to 179,000 in 2013 with 42.1% of procedures being LSGs while Roux-en-Y gastric bypasses comprised 34.2% of procedures. This now makes LSG the most commonly performed bariatric procedure in the US [3].

Controversy exists regarding the role of staple line reinforcement in preventing gastric leaks [4–6]. Knapps et al. [7] concluded that more studies were needed to assess the safety profile of synthetic bioabsorbable reinforcement materials in LSG. However, Choi et al. [8] and Gagner [15] showed a decreased incidence of leaks when using these materials intraoperatively.

Additionally, long-term outcomes of LSG in general in terms of weight loss are lacking in the literature. Diamantis et al. [9] showed

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that only three studies consisted of patients at the six year follow-up period and only nine studies contained long-term data of patients at the five year follow-up period postoperatively. Several authors have realized this gap in the literature and there are now more papers in the literature with outcomes of LSG spanning 5 years or more [10,11].

The aims of this study are (1): to present our leak rates from using staple line reinforcement and (2) to display six year outcomes of LSG as a procedure in itself in relation to resolution of obesity-related comorbidities and long-term weight loss.

2. Materials and methods

2.1. Study design and data collection

This is a single-institution, retrospectively reviewed study of 204 consecutive patient case files who underwent LSG with reinforcement between December 2007 and May 2013. The data was collected from clinic letters, electronic records and telephone consultations representing a six year series.

Resolution of obesity-related comorbidities (obstructive sleep apnea, diabetes, hypertension, hypercholesterolemia) was noted. Percent excess weight loss (% EWL) and percent excess BMI loss (% EBL) was calculated at each year postoperatively using the ideal body weight estimate with a Body Mass Index (BMI) of 25 as the reference point for normal weight.

Hypertension was defined by a blood pressure greater than 140/90 mmHg and its resolution by a normalized blood pressure and cessation of all blood pressure medications taken preoperatively. Obstructive sleep apnea was diagnosed by a sleep study (polysomnography) and resolution by cessation of the continuous positive airway pressure machine. Diabetes mellitus type II was diagnosed by a fasting blood glucose >7.0 mmol/l (126 mg/dL) or HbA1c > 42 mmol/mol (6 g/dL). Resolution was defined by normalization of one of these laboratory values and cessation of any diabetic medications postoperatively. Lastly, hypercholesterolemia was diagnosed by total blood cholesterol levels >5.2 mmol/l (200 mg/dL) and resolution by stopping medication.

Major complications such as severe vomiting and sleeve stenosis related to LSG in general within the first 30 days postoperatively were recorded. Leaks from the staple line were also recorded using the intraoperative leak test.

Patients who had a primary stand-alone LSG without previous or subsequent weight-loss surgery within the specified time period were included in the study. All patients consented to the collection of data. The study was submitted as an official audit to the institutional review board for ethical approval and registration.

2.2. Materials

The GORE® SEAMGUARD® bioabsorbable staple line reinforcement material (W. L. Gore & Associates, Arizona, USA) has been used at our institution throughout all LSG cases since 2007. The material adds a reinforcement strip to the staple line, which is preloaded onto the stapler, and is eventually absorbed within six months [12].

2.3. Surgical technique

The patient is placed on the operating table in the supine position. The abdominal cavity is entered through a small, transverse left subcostal incision with the bladeless 12 mm trocar, loaded with the 10-mm O-degree laparoscope, and under laparoscopic observation.

The blunt tip retractor is placed below the xiphoid process to retract the left lobe of the liver exposing the gastro-esophageal junction. The lesser sac is entered through the gastrosplenic ligament and the greater curvature of the stomach is freed up to the angle of His. Next, a bougie is passed into the distal stomach and the endostapler loaded with the reinforcement strips is introduced first from the right upper quadrant port to carry out the sleeve gastrectomy. The bougie size used for all operations was 32F. The mean proximal distance from the pylorus used for all operations was 5 cm (standard deviation of 0.69 cm). A mean total of 5 staple firings (standard deviation of 1.04 firings) preloaded with the bioabsorbable material were used for all procedures.

2.4. Statistical analysis

The data were analysed with GraphPad Prism 5.0 (GraphPad Software, La Jolla, CA, USA). Continuous data points are presented as mean ± standard deviation, mean (range), and analysed using the two-tailed paired *t*-test. Statistical significance was defined at a p-value of <0.05.

3. Results

3.1. Patient characteristics

Of a total of 257 patients who had undergone an LSG operation with reinforcement between December 2007 and May 2013, 204 patients (80%) met the inclusion and exclusion criteria. There were 61 males and 143 females. Of the 21/53 patients who were excluded: 16 patients had previously attempted bariatric procedures and 5 patients had subsequent bariatric surgery due to unsatisfactory weight loss. 32/53 patients have also been excluded since they were performed using a different type of staple line reinforcement (Duet TRS by Covidien). These products have been terminated due to major complications associated with their use [13].

3.2. Complication rates, morbidity and mortality

The complications experienced in this study were grouped according to the Clavien-Dindo classification [14]. There were nine Grade I complications (vomiting resolved by antiemetics and sleeve stenoses), three Grade II complications (wound infection requiring antibiotics) and two Grade III complications (major bleeding requiring surgical intervention) (complications displayed in Table 1). The intraoperative leak test was used to determine any potential gastric leaks from the staple line.

In terms of bleeding, there were 2 in the series. The first was taken back to theatre 8 h postoperatively due to tachycardia and a low blood pressure. In theatre, 1.8 litres of clot was seen in left upper quadrant which was removed. No obvious bleeding source was found and the staple lines were dry. The patent was discharged 3 days after the operation.

The second patient had an uneventful postoperative course and was discharged 2 days after the operation. However, this patient

Table 1
Major complication rates related to sleeve gastrectomy within the first 30 days post-operatively.

Complication	Patients (%)
Staple line leak	0/204 (0%)
Severe vomiting	7/204 (3.4%)
Sleeve stenosis	2/204 (0.9%)
Major bleeding	2/204 (0.9%)
Wound infection	3/204 (1.5%)
Death	0/204 (0%)
Total	**14/204 (6.9%)**

presented to the Emergency Room 8 days postoperatively with generalised abdominal pain. A Computed Tomography (CT) scan revealed an intra-abdominal haematoma and the patient was taken to theatre for evacuation of 600 ml of clot. No bleeding source was found and the staple lines were dry. The patient was discharged 3 days later.

There was a statistically significant difference ($p < 0.05$) between pre- and post-operative hemoglobin. The mean hemoglobin was 13.6 g/dL (SD 1.3; Range 9.4–17.3) pre-operatively, dropping to 12.6 g/dL (SD 1.3; Range 8.7–15.8) post-operatively at day 1.

3.3. Weight loss in the short-, mid-, and long-term

Completed weights recorded during each yearly follow-up period are as follows: 148/204 (73%) in the one year period, 128/173 (74%) in the two year period, 81/116 (70%) in the three year period, 49/69 (71%) in the four year period, 24/35 (69%) in the five year period, and 5/8 (63%) in the six year period. Reasons for the remaining incomplete data are due to patients not answering their telephone, incomplete patient notes and undocumented weights in clinic letters.

The mean %EWL was used to see if there were statistically significant differences in weight gain/loss between follow-ups at year one (short-term) and three (mid-term), and between year three and six (long-term). There were no significant differences between follow-ups at year one and three (48.4 ± 18.5 at year 1 *vs.* 51.7 ± 27.9 at year 3; $p > 0.05$), and between year three and six (51.7 ± 27.9 at year 3 *vs.* 41.0 ± 20.5 at year 6; $p > 0.05$) in terms of the mean %EWL (Fig. 1). All results are detailed in Table 2.

3.4. Resolution of obesity-related comorbidities

There were high resolution rates for obesity-related comorbidities: 74% (76/103) of patients with hypertension, 61% (20/33) of patients with hypercholesterolemia, 79% (34/43) of patients with diabetes mellitus type 2, and 90% (54/60) of patients with obstructive sleep apnea.

4. Discussion

4.1. Complication rates for staple line reinforcement materials

Generally, a low rate of total complications after LSG in general has been observed ranging from 3.2% to 14.3% with mortality ranging from 0% to 3.3% [15,16]. This compares with our own experience (total complication rate at 6.9% and mortality rate at 0%).

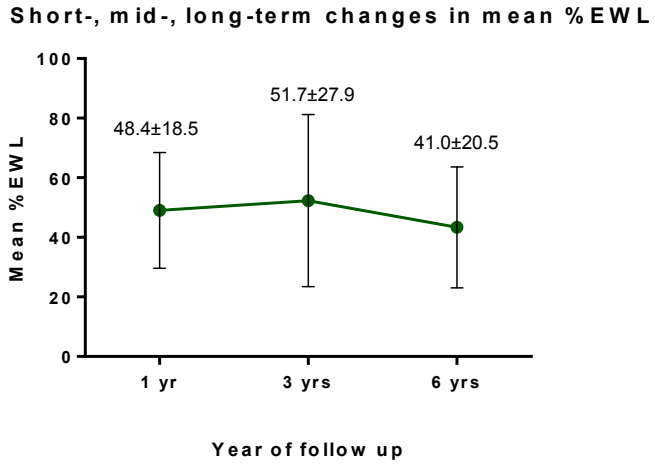

Fig. 1. Mean % Excess Weight Loss (EWL) change over the short-, mid-, and long-term periods of follow-up. No statistical significance was found. The 2-tailed, paired *t*-test was used. Error bars represent standard deviation. The numbers above the points are the mean %EWL ± SD.

In terms of leak rates, which may or may not be influenced by the use of staple line reinforcement material, our study had no leaks. Recently, Gagner et al. produced a systematic review that showed leak rates ranged from 1.09% using bioabsorbable material to 3.3% using non-absorbable material with the total leak rate at 2.1% (n = 191). The leak rate in LSG was significantly lower using bioabsorbable staple-line reinforcement than oversewing, non-absorbable material reinforcement, or no reinforcement [17].

In one of the largest studies of LSG to date encompassing 9991 patients, Parikh et al. conducted a meta-analysis of 112 papers. In 6578 LSG patients, the leak rate was 2.1% (n = 102/4780) when reinforcement was applied and 3.2% (n = 37/1143) when no reinforcement was used. However, the authors concluded that reinforcement does not seem to impact leak rates significantly and that bioabsorbable materials are the most common type used should surgeons want to use reinforcement [18]. Similarly, a meta-analysis of 56,309 patients by Shikora showed that staple line reinforcement with bovine pericardium had the lowest leak rates (2.45%) when compared to buttressing with a biocompatible material (2.61%) and no staple line reinforcement (2.75%) [19].

This important meta-analysis also highlighted the fact that the majority of papers were very small case series that included under 100 patients. Additionally, over half of patients in the staple line reinforcement group in Parikh et al.'s study included biocompatible glycolide copolymer buttresses with either Seamguard (akin to the material used in our study) or Duet. Duet is now withdrawn from the market making any potential widespread use impossible. Finally, the study consisted of papers up until 2011 only. Staple line reinforcement in LSG in terms of popularity and volume load has significantly increased since then, warranting an updated meta-analysis.

The benefits of using staple line reinforcement remain controversial. Several authors have questioned whether the low total complication rate and gastric leak rate seen is due to the use of the material or due to the expertise of the center or surgeon [7,20,21]. A recent survey of expert LSG surgeons showed that 100% of respondents agreed that reinforcement decreased leak rates. However, approximately 20% actually used staple line reinforcement with a bioabsorbable material in their practices. The difference between the actual use of reinforcement and agreement in its use could perhaps be owed to the perceived paucity of published studies establishing a good safety profile in these materials [22]. In the only prospective RCT comparing bioabsorbable staple line reinforcement (SLR) *versus* suturing *versus* no SLR, leak rates were lower with SLR usage. However, the study was underpowered to detect any difference in leak rates in the 3 groups [21]. It will be interesting to see if future RCTs will be conducted to study this further.

In terms of major bleeds, there were two patients enduring significant bleeding postoperatively. These bleeds at the time of relaparoscopy for clot evacuation had stopped and the reinforced staple lines were dry. Possible explanations for the mean drop in hemoglobin include intraoperative bleeding during excision along the greater curvature of the stomach, the hemodilutional effects of intraoperative fluids, and/or a rise in ADH in response to the stresses of surgery.

4.2. Resolution of obesity-related comorbidities

The total resolution rate for hypertension in this series was 74%, which is very similar to the mean resolution rate of 75.9% found by Braghetto et al. in his review of long-term outcomes of LSG [23]. Similarly, resolution rates for diabetes mellitus type 2 vary. The mean resolution rate found in the same review was 78.9% [23],

Table 2
Mean BMI, mean %EBL, mean %EWL, mean %TBWL at different yearly follow-up intervals.

	Pre-operative (n = 204)	1 year (n = 148/204)	2 years (n = 128/173)	3 years (n = 81/116)	4 years (n = 49/69)	5 years (n = 24/35)	6 years (n = 5/8)
Primary LSG							
Mean BMI (kg/m^2)	50.9	39.3	38.7	40.4	40.5	43.0	42.4
SD (kg/m^2)	9.9	7.6	8.1	9.2	10.2	9.5	7.0
Range (kg/m^2)	32–104.4	22–67	19–72	18–76	21–74	26–60	36–54
Mean %EBL	–	48.5	52.1	50.2	50.6	40.0	40.9
SD (%)	–	18.5	21.9	24.4	26.1	21.8	20.5
Range (%)	–	15–123	6–143	−3–151	−22–128	12–98	18–61
Mean %EWL	–	48.4	53.0	51.7	53.1	40.0	41.0
SD (%)	–	18.5	24.4	27.9	31.3	21.8	20.5
Range (%)	–	15–122	6–176	−3–176	−22–176	12–98	18–61
Mean %TBWL	–	23.4	25.4	25.2	25.2	20.6	22.5
SD (%)	–	8.0	9.2	10.0	11.3	11.5	12.0
Range (%)	–	8–47	3–52	2–55	−12–58	7–56	8–35

BMI = Body Mass Index; EBL = Excess BMI Loss; EWL = Excess Weight Loss; SD = Standard Deviation; TBWL = Total Body Weight Loss.

compared to the 79% in this study. For obstructive sleep apnea, resolution rates are generally quite high with a 90% resolution rate shown in this study.

Underlying mechanisms of LSG on the resolution of obesity-related comorbidities exist. It is difficult to compare our resolution rates to that of the literature. Different definitions of diagnosis of comorbidities were used across studies, which can influence resolution rates.

4.3. Long-term weight loss after LSG

Literature reporting on weight loss in the long-term (greater than five years) remains scarce, therefore weight loss reported in this study serves to consolidate the currently limited published results. The reported five year %EWL varies in several papers, ranging from 49.5% to 86% [23–29], and from 52% to 53.3% [23,30,31] in six years. Similarly, our five year mean %EWL was 40% and the six year mean %EWL was 41%. Even so, it is difficult to compare weight loss results across different studies since different bougie sizes were used to create the sleeve. Smaller bougie sizes may result in tighter sleeves, therefore reducing gastric capacity and food intake [32].

We expected that weight loss begins immediately after surgery and remains significantly lower than what it was preoperatively. There were no statistically significant differences between year 1 and year 3, and year 3 and year 6 postoperatively. However, the small number of recorded weights in the six year group (n = 5) may render the year 3 and year 6 comparison for possible weight regain unreliable. The trend for mean %EWL and mean %EBL seems to show that patients maintain their weight loss postoperatively and lose even more weight between year one and year three post-operatively. However, some weight regain occurred between year three and year six postoperatively. Weight loss in the short-to mid-term period may partly be explained by suppression of ghrelin (a hunger-stimulating hormone) obtained by the resection of the gastric fundus in LSG. However, in the mid-to long-term period postoperatively, hyperactivity of previously silent ghrelin-producing cells may cancel the early effect of fundic resection [33]. Late weight regain can be caused by dietary factors as well, such as changes in eating behaviour by moving towards ingesting highly caloric food. Dietary causes may be detected and can potentially be avoided by continuous follow-up appointments aiming at reinforcing patient education and motivation.

4.4. Limitations

There are several limitations. As this is a retrospective review of patients, attrition rates were an important problem. In this study, the attrition rate was highest, at 37%, in patients with recorded weights at the six year follow-up period. This could be attributed to various factors including patient non-compliance to completing their follow-up appointments and may influence long term weight loss outcomes had all patients been analysed for their recorded weights.

Telephone consultations used in obtaining additional information to clinic letters may present its own problems. According to our experiences, telephone consultations are generally considered biased in the sense that patients may underestimate their weight. Therefore, the true final BMI could be even higher than the ones reported in this study.

The documented post sleeve complication rates are free of the limitations mentioned above especially as bleeds and leaks tend to occur in the early postoperative phase. Therefore these complications would have all been captured and our complication rates are true and were achieved.

Additionally, it is important to mention that this study received industry funding. Probst et al. have recently shown that industry bias in surgical research is more likely to be associated with positive findings and significant results [34]. Although this study has shown low complication rates with regards to using the reinforcement material and good long-term outcomes in LSG, our findings have been replicated in other studies that have not received industry funding.

Finally, this study is a retrospective study with no comparator cohort of patients undertaking LSG without staple line reinforcement. The true benefit of staple line reinforcement *versus* no reinforcement can not be commented on although this study serves to show that the use of the GORE® Seamguard was safe to use presenting with no staple line leaks.

5. Conclusion

The GORE® Seamguard material used in this study is safe to use in terms of low complication rates. To effectively elucidate a benefit in using bioabsorbable materials to reinforce the staple line, prospective randomized controlled trials are recommended. LSG also shows good long-term weight loss as well as high resolution rates of obesity related comorbidities. These results add to the currently lacking literature in terms of long-term outcomes in LSG.

Ethical approval

The study was submitted as an official hospital audit to the institutional review board for ethical approval and registration (Trust reference number 1657).

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Author contribution

Authors 1, 2, contributed to the data collection and analysis of data. Authors 1, 2, 3, 4 contributed to the study design and writing of the paper.

Conflict of interest

Authors 1, 2, and 3 have no conflicts of interest to disclose. Author 4 reports grants from WL GORE, personal fees from WL GORE, during the conduct of the study; personal fees from MSD, outside the submitted work. All patients consented to the collection of data.

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Guarantor

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