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Original Research Article

Technical details of laparoscopic sleeve gastrectomy with attention to staple line leak and hemorrhage: discussion of 3,031 consecutive cases

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ABSTRACT

Background: Laparoscopic sleeve gastrectomy continues to rise as an effective surgical procedure for weight loss in obese patients. With that, gastric staple line leak and hemorrhage remain the most serious complications and occur in up to 3% of all cases. Each complication is associated with a high degree of morbidity and mortality for the patient as well as substantial cost of care for institutions and payers. Techniques to minimize the risk of sleeve gastrectomy leak and hemorrhage have been published although no universally agreed upon set of techniques exists. This report updates a single-surgeon experience with an approach to sleeve leak and hemorrhage prevention over 10 years.
Methods: 3,031 consecutive sleeve gastrectomy cases between 2012 and 2021 were reviewed retrospectively. Patient characteristics, incidence of leaks and hemorrhage, and percent body weight loss at 6 months were reported for each year. Conceptual and technical changes aimed towards leak and hemorrhage reduction are presented.
Results: With the implementation of the described techniques of sleeve gastrectomy, the rate of sleeve leaks fell from 3.8% in 2012 to 0% in 2015 through 2021, and hemorrhage fell from 1.3% in 2012 to 0.1% in 2018 through 2021. Weight loss remained consistent, as depicted by 6-month change in body weight and percent excess BMI lost.
Conclusion: In this single-surgeon experience, sleeve gastrectomy leak rate fell to 0.0% and staple line hemorrhage rate fell to 0.1% with the implementation of specific technical modifications in the procedure, spanning over 3,031 consecutive cases.

Keywords: Laparoscopic sleeve gastrectomy, Staple line leak, Bariatric surgery, Surgical technique, Complication prevention, Sleeve gastrectomy outcomes

INTRODUCTION

Sleeve gastrectomy has become the most widely performed bariatric surgical procedure, representing 61% of the estimated 199,000 bariatric surgeries performed in 2020 in the United States.[1] Leak at the sleeve staple line has become less common but remains the most serious complication, with reported rates between 1 and 2.4%, proximal more than distal.[2-4] Hemorrhage from the staple line is among the most common complications occurring in 0.6–3% of cases.[2,3,5] It is also associated with a high degree of morbidity for the patient and cost of care for institutions and payers.[6] Reported techniques to minimize occurrence of leak and hemorrhage include changes in calibration tube size, selection of specific staple cartridge, use of fibrin sealants, oversewing of staple line, placement of hemoclip, and use of staple line reinforcement materials.[7-10] In a previous study of leak rate, we implemented use of 40 fr bougie, generous volume around the bougie at the incisura, avoidance of disruption in cardio tuberosity branch arteries to the cardia, angling the linear stapler to the left and more than 15 mm away from the true gastroesophageal junction, using a 3.5 mm tissue stapler on the proximal stomach, application of fibrin glue sealant to the staple line, oversewing the proximal 4 cm of sleeve, apposition of the omentum to the distal staple line, and avoidance of one stage revisional sleeves with band removal.[11] The

previous study showed reduction in gastric staple line leaks, and in this updated analysis, we hypothesized that with five additional years of implementation of these techniques we would see a long-term reduction in both staple line leak and hemorrhage.[11] Additionally, we included the hemorrhage rates over this ten-year period, which we hypothesized would fall via the same interventions to the extent they arose from the staple line. The objective of this study is to test these hypotheses.

METHODS

This was study cases study. Consecutive laparoscopic sleeve gastrectomy cases performed by a single surgeon from January 1, 2012, to December 31, 2021 at Renown Regional Medical Center, Reno, NV were retrospectively reviewed. Since the original publication of 1,070 cases over a five-year period, this review reports an additional 1,961 consecutive cases of sleeve gastrectomy. A comprehensive review of the literature regarding sleeve gastrectomy staple line leak and hemorrhage was conducted. Authors report 3,031 consecutive cases of laparoscopic sleeve gastrectomy and the rate of gastric staple line leak and hemorrhage over a ten-year study period. All cases of laparoscopic sleeve gastrectomy performed by this surgeon during the study period were analyzed. Follow up was obtained for every patient until discharge, 2970 (98%) patients at 30 days, and 2606 (86%) patients at 90 days. Outreach to every patient was attempted at intervals including 6 and 12 months after surgery. The last cases included in the analysis took place in December of 2021 and were monitored for evidence of leaks and hemorrhage through June of 2023.

Surgical details

Each patient underwent preoperative evaluation with either upper GI series or esophagogastroduodenoscopy and responded to clinical questions regarding the presence or absence of GERD symptoms. 18% of patients were diagnosed with hiatal hernia preoperatively and repaired concomitantly with the sleeve, and an additional 10% were diagnosed intraoperatively and repaired. In all cases, the sleeve gastrectomy procedure was performed with laparoscopic technique. After insertion of four bladeless trocars, a Nathanson liver retractor was placed to elevate the left lateral segment of the liver. A bougie calibration tube was placed along the lesser curvature, and the greater curvature attachments were divided with radiofrequency sealing, beginning 4-5 cm from the pylorus. Three Echelon green stapler cartridges were utilized in the antrum, using staple line reinforcement of bovine pericardium (Peristrips Dry with Veritas). The gastric body and fundus were stapled with varying Echelon stapler cartridges, which became consistent after 2014 with two gold cartridges in the mid body followed by two blue cartridges in the proximal fundus. The left crus were fully exposed. The most proximal stapler was angled 2-3 cm away from the esophagus, a measure that may be more than necessary if the staple line is not imbricated. The initial stapler used was the Powered Echelon Flex PSE60A, which was changed to the Powered Plus Echelon Flex PSEE60A in June, 2015 and used until the end of the study. After November of 2016, liberal use of hemoclip on the staple line were utilized to control hemorrhage. After January, 2017, Peristrips were utilized for all staple loads including the most proximal application. The hiatus was repaired with anterior cruroplasty without posterior dissection when a hiatal hernia less than 3 cm was present and with hiatal dissection and anterior and posterior cruroplasty when >3 cm. After January 2017, in all cases, the completed staple line was treated with sprayed fibrin sealant (Tisseel). A methylene blue leak test was infrequently performed in select cases at the end of the procedure. A grant provided by Baxter (Tisseel and Peristrips) was used to pay for the hours of the research effort, data extraction and analysis, and travel support to report findings. The cost of Tisseel ($255) and Peristrips ($258 each, 5 per case) was paid for by the hospitals and their DRG reimbursement. The industry played no role in the clinical practice, study design, data collection or analysis. No company member has had any input into the manuscript other than providing the correct product name and pricing information. The identified technical elements during the reduction in leak and hemorrhage rate were Figures 1–6.

Figure 1: Stomach with 40-french sizing tube within the stomach, positioned along lesser curvature of stomach, in preparation for stapling.

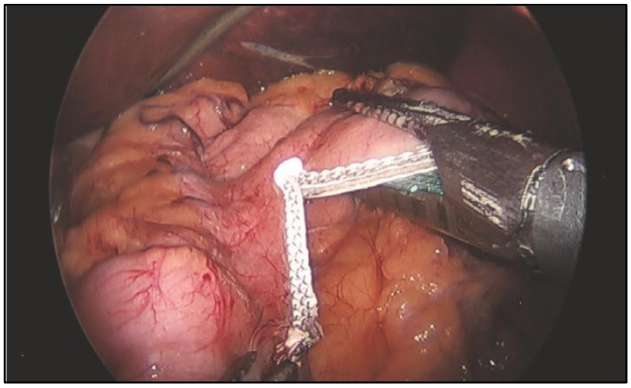

Figure 2: Maintaining a wide berth around bougie at incisura region.

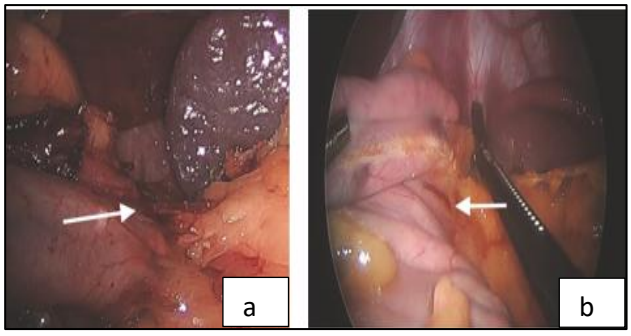

Figure 3: (a) Preserving the proximal posterior attachments and blood supply to the sleeve and (b) preserving the proximal posterior attachments and blood supply to the sleeve.

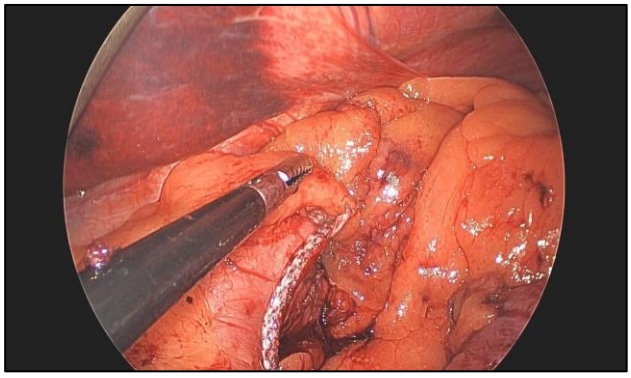

Figure 4: Final stapler loads using 3.5 mm staple height (Echelon Blue Cartridge) with reinforcement material, angled to the left of the fat pad.

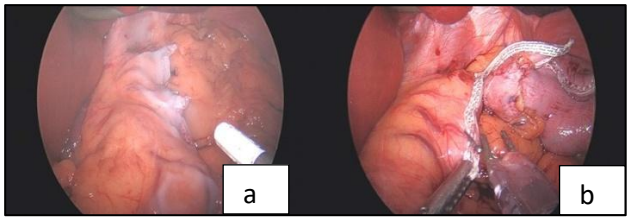

Figure 5: (a) Application of fibrin sealant (Tisseel, Baxter, Corp) along staple line for hemostasis and (b) application of hemoclip along staple line for hemostasis.

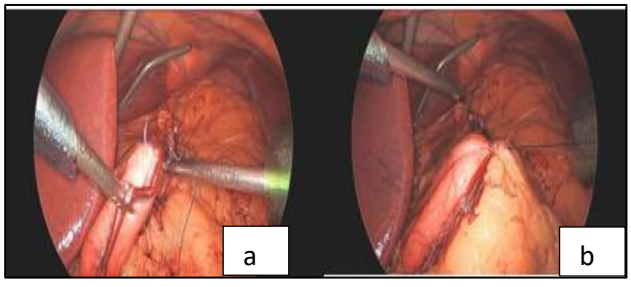

Figure 6 (a and b): Omentoplasty, suturing omentum back to sleeve staple line.

Use of the 40-French sizing calibration tube (Figure 1). Allowing generous volume around the sizing calibration tube at the curve of the incisura (Figure 2). Avoidance of the disruption of cardio tuberosity branch arteries serving as the blood supply to the proximal stomach in the cardia region, especially posteriorly (Figure 3).

Angling the linear stapler to the left and more than 15 mm away from the true gastroesophageal junction. Use of 3.5 mm tissue stapler cartridges in the proximal stomach with staple line reinforcement (Figure 4). Application of spray fibrin glue sealant (Tisseel, Baxter Corp.) to the staple line. (Figure 5a).

Liberal use of hemoclip along staple line to prevent hemorrhage (Figure 5b). Suturing the omentum back to the mid and lower staple line to prevent a potentially obstructing "windsock" deformity (Figure 6). Avoidance of 1-stage revisional sleeves concomitant with band removal.

Ethical approval

This research was deemed HIPAA-compliant and received Institutional Review Board approval. All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Statistical analysis

Data was recorded and results calculated using Microsoft Excel software. Calculations included the incidence of occurrence of both primary outcomes, leak and hemorrhage. Additionally, secondary outcomes of change in BMI, percent excess weight lost, and other study population characteristics were recorded and averaged.

RESULTS

Over the course of ten years, 3,031 consecutive laparoscopic sleeve gastrectomy cases were performed (Table 1). A total of 14 leaks (0.5%) and 15 hemorrhages (0.5%) occurred during the study period. Every leak occurred on the proximal sleeve staple line within 3 cm of the gastroesophageal junction. The leak rate decreased from 3.8% in 2012, to 3.7% in 2013, to 1% in 2014, and to 0% thereafter (Table 2, Figure 8).

A timeline representing the occurrence of leaks and the implementation of the technical changes is displayed in Figure 7. In four cases re-explored for hemorrhage, the source appeared to be the staple line. The rate of hemorrhage decreased from 1.2% in 2012 through 2014, to 0.7% in 2015 through 2017, and to 0.1% from 2018 until 2021 (Table 2, Figure 8).

Table 1: Patient characteristics.

	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021
N	158	164	188	240	320	379	436	421	341	384
Female (%)	74	77	73	75	71	68	74	75	70	74
Male (%)	26	23	27	25	29	32	26	25	30	26
Mean age (in years)	37.7	38.2	39.6	38.9	37.4	45.3	46.7	44.0	45.8	44.5
Mean weight (kg)	125	126	131	128	133	128	132	124	131	122
BMI (kg/m^2)	46	47	49	48	47	49	48	46	47	46

Table 2: Leak and hemorrhage incidence, weight loss results.

Year	Sleeve Cases	Leaks	Hemorrhage	Initial BMI (kg/m^2)	BMI at 6 months (kg/m^2)	Change in BMI (kg/m^2)	6 months Wt. loss change in percentage of body weight (% BW)	6 months percent excess BMI lost (% EBMIL)
2012	158	6 (3.8%)	2 (1.3%)	46	36	10	22	48
2013	164	6 (3.7%)	3 (1.8%)	47	36	11	23	49
2014	188	2 (1.0%)	1 (0.5%)	49	36	13	26	53
2015	240	0	3 (1.3%)	48	37	11	24	50
2016	320	0	3 (0.9%)	47	34	13	26	53
2017	379	0	1 (0.3%)	45	35	10	23	48
2018	436	0	0	46	33	13	26	55
2019	421	0	2 (0.5%)	44	36	11	24	51
2020	341	0	0	45	35	10	23	49
2021	384	0	0	44	32	14	27	56

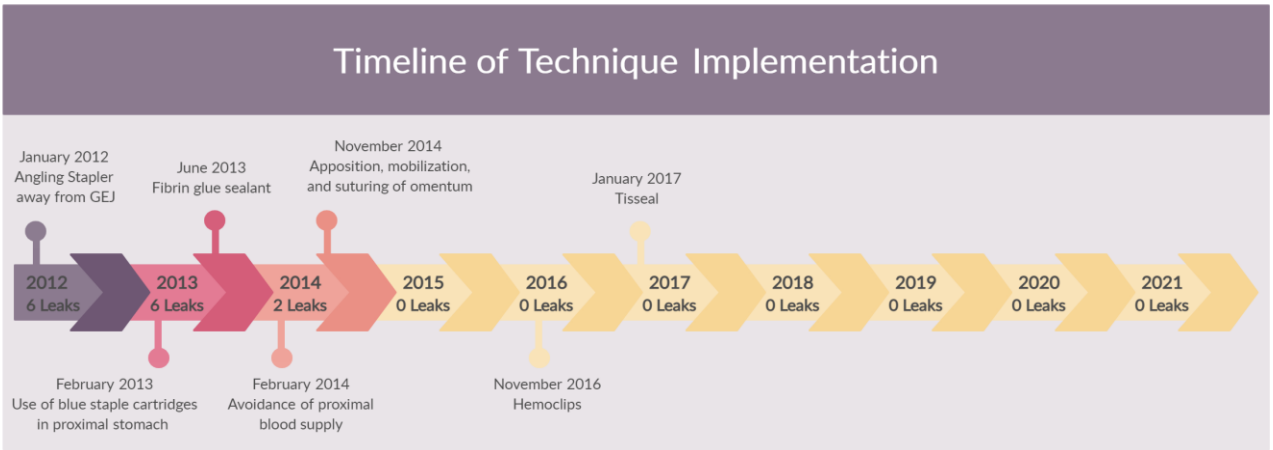

Figure 7: Timeline of technique implementation.

Weight loss results were compared for cases performed from 2012 to 2021, among the 82% of patients who had weight recorded at 6 months of follow-up after their sleeve procedure (Table 2). Weight loss results are reported as lost percentage of body weight (% BW) and percentage excess BMI lost (% EBMIL). The mean percent body weight loss is not significantly different from year to year (p=**0**.35, ANOVA).

All 13 revisional cases in the series included concomitant laparoscopic removal of a gastric band and conversion into a sleeve gastrectomy. Among these, two leaks occurred resulting in a total leak rate of 15% for revisional cases. The last leak occurred in March of 2014 in a revisional case, after which no further revisional band removals with sleeve were performed. Resolution of all leaks occurred after endoscopic stenting or a combination of endoscopic treatments and surgical reoperation.

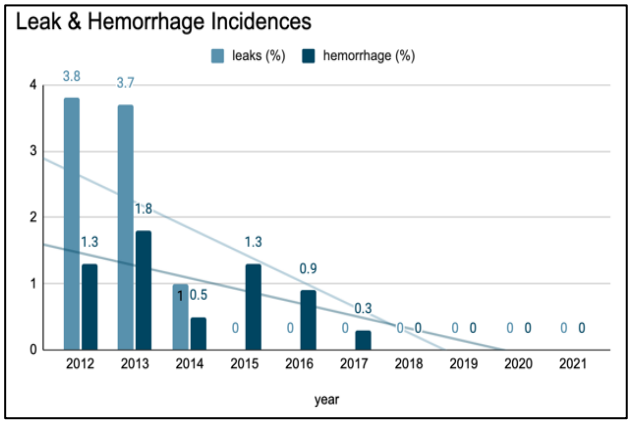

Figure 8: Leak and hemorrhage incidence over time.

One patient had a prolonged stay in the ICU after a leak and reoperative surgery with a recovery of approximately 26 weeks. There was no hospital mortality among any of the 3,031 cases. One patient died at home within 30 days of the procedure. Since March of 2014, 2,521 consecutive laparoscopic sleeve procedures have been performed without a leak and since May of 2019, 900 cases have been performed without hemorrhage.

DISCUSSION

Gastric leak following sleeve gastrectomy remains the most serious complication of sleeve gastrectomy and occurs in approximately 1-2.4% of cases in published reviews.[2,4] Staple line hemorrhage has been reported to occur in up to 3% of cases, with recent large series reporting lower bleed rates of 0.6-1%.[2,3,5,12] Leaks commonly present with an indolent course, weeks, or even months, after the procedure and greater than 90% are diagnosed after discharge.[2] Additionally, 70% of leaks are missed at the first ED visit and untreated leaks are associated with high mortality rates.[13] These findings highlight the necessity of taking proactive measures to prevent leak.

In this study, all of the leaks occurred in the proximal 4 cm or less of the sleeve, which is in agreement with prior literature reporting up to 90% of leaks occur at or near the esophagogastric junction.[2,4,14] Contributing factors can include tissue ischemia, elevated intraluminal pressures, host impaired healing, and suboptimal closure techniques, or hematoma formation. Blood supply, especially to the proximal sleeve, has been long held as a key element in determining staple line and anastomotic integrity.[11,15] Specifically, the disruption of the posterior attachments of the proximal sleeve may be expected to disrupt cardio tuberosity branches of the left gastric artery.[15] The proximal sleeve is vulnerable to compromised blood supply stemming from the division of these small arterioles along the posterior wall of the proximal stomach, which may be visualized intraoperatively within the posterior attachments as the surgeon marches proximally along the sleeve (Figure 3). Preservation of those attachments and vessels may preserve important blood supply to the proximal sleeve and reduce the risks of leak. We made a standardized attempt to visually avoid this risk factor in all procedures, in addition angling the stapler at least 15 mm away from the gastroesophageal junction. This technical element may have played little role, as the leak rate had already fallen prior to its routine implementation. This raises the concern of a possible tradeoff between leak mitigation and weight loss. Future evaluations must consider whether reduced complications may confer a wider benefit to the field and at what cost in terms of long-term weight loss.

Patient selection is an important factor to consider with regard to risk of complications. Those who smoke, use steroids, have medical immunosuppression, require revisional procedures, or exhibit supermorbid obesity have an increased risk of gastric leak.[4,16,17] It is difficult to screen patients with the intent of reducing risk while still maintaining access to surgical treatment as needed. Some ways to improve these and maintain access is to institute preoperative weight loss of at least 10% EBW and focus on improving nutritional status.[18] For the center we insisted on smoking cessation and avoided single stage revisional procedures.

Intraluminal pressure has been cited as a factor that may lead to increased leaks from the staple line, a logical contention and one that is supported by measurements of higher intraluminal gastric pressure within a sleeve than within a gastric pouch following Roux-en-Y gastric bypass.[19,20] Together, gastric outlet obstruction and increased intraluminal pressure may promote staple line leak. In this study we avoided this complication by using a larger bougie to size the gastric sleeve and leaving a generous volume around the incisura. This may have contributed to the decreased incidence of leak and hemorrhage, while still maintaining excess weight lost compared to preintervention values. Previously described stenosis, twist, or “wind-sock” deformity can each lead to gastric outlet obstruction, and each is prevented or minimized by the omentoplasty.[21]

Stapler size selection in this study was maintained at the 3.5 mm cartridge in the proximal stomach, based on IFSO recommendations.[2] However it is important to note that tissue thickness may vary between gender, and between individuals.[22] Additional research is needed to elucidate the ideal staple cartridge size. In the interim, using the smaller staple height on proximal stomach tissues may have played a role in reducing incidence of postoperative leak and hemorrhage rates.

Calibration tube size remains a debated topic among bariatric surgeons, with the consensus panel recommending a bougie size between 32 Fr and 40 Fr.[2] There is more evidence to support preserved weight loss with greater bougie size, and an association of increased complications with smaller bougie size.[7,23] As a result,

there has been a trend toward using larger bougie sizes over time.[2,7,12] This is similar to our practice, in 2013, the cases were performed with 34 Fr bougies; in 2014 a mix of 34 Fr and 40 Fr bougie sizes was utilized, and 2015 onward all cases were performed with a 40 Fr bougie yielding 0 leaks. Fibrin sealants have been promoted for their effectiveness at reducing bleeding from a variety of surgical tissues.[24] A recent systematic review and meta-analysis found that the use of fibrin sealants in bariatric surgery was associated with a decreased incidence of postoperative bleeding (risk ratio=0.42), however it did not have a significant effect in reducing leaks.[25]

In addition to preventing volvulus and wind-sock deformity as previously discussed, the omental apposition, or omentoplasty, to the staple line has the added benefit of enhancing vascularity and helping create a seal over the staple line. This is similar in concept to the widely accepted use of an omental patch on perforated gastric ulcers.[26] A recent study found that omentopexy provides a significant decrease in gastric leak rates and other complications.[27] In this study it was used in conjunction with other interventions to reduce our leak rate. The four cases of hemorrhage that required re-exploration appeared to emanate from the staple line; in the remainder the true source was unknown. There was unanimous agreement among the International Sleeve Gastrectomy Expert Panel that reinforcing the staple-line will reduce bleeding, and studies support over-sewing, buttressing, and applying spray fibrin glue, all of which have a similar effect.[9,12,28-30] A meta-analysis of 41,864 sleeve gastrectomy patients that found no reinforcement had the highest bleed rates (3.45%), and reinforcing with bovine pericardium had the lowest rates (1.23%).[29] In our series, staple line hemorrhage fell from 1.3% in 2012 to 0.1 since 2018 with now 900 cases having been consecutively performed without hemorrhage since the consistent use of a combination of bovine pericardium material (Peristrips, Baxter), liberal use of hemoclip, and spray fibrin sealant (Tisseel, Baxter).

The primary weakness of this observational paper is that all the interventions were non-randomized and made sequentially, and we cannot say which of the nine elements exerted an effect on reducing leak or hemorrhage rate. Changes in technique during 2016 and 2017 may have had an effect and that other intangibles can play a role. While this series represents an attempt to understand the granular elements of "learning curve", these identified elements undoubtedly fail to capture the precise reasons for worldwide trends toward lower complication rates. With further research on each of the many interventions, we expect that near-0% leak and hemorrhage rate may become widespread. Long term weight loss is not reported, so this series relies upon 6-month weight loss data which has historically served as a highly correlated statistical proxy of longer-term weight loss.[31,32] The possibility that a slightly wider sleeve could preserve 6-month weight loss but impair long term weight loss while lowering leak rate deserves consideration.

Technological improvements may play an additional role in the reduction of these complications; notably, there was an evolution of the stapler and improvement in energy devices used during this series. All staple line reinforcement products may not behave the same, and all fibrin glue sealants may not create the same hemostasis on the staple line. Specific commercial devices used may not be available in certain locations, which may limit reproducibility.

While this paper is an attempt to identify the granular elements that define "learning curve" and lead to improved outcomes with experience, the absence of a control group leaves unanswered the potential confounding effect of a more ill-defined learning curve and increased experience of this single surgeon on the results. Such generalized surgeon experience has been previously demonstrated to have an impact.[33] Authors believe the identified elements likely played a role and hope to encourage further discussion and research. Sleeve gastrectomy patients may benefit if external validation of certain elements is achieved through randomized investigations.

Undocumented patient characteristics and premorbid conditions may also have influenced results, but these were not believed to have changed over time. Measures taken to avoid underreporting of complications include outreach to every patient at intervals including 3, 6 and 12 months after surgery. For cases that had a postoperative hemorrhage, it is unknown if bleeding arose from the staple line in cases in which no re-exploration was performed. Despite these weaknesses, observation of reduced hemorrhage and leak rates offers the potential to reduce the fear of complications that routinely hinders patient referral for bariatric surgery, a potentially lifesaving intervention.

A grant from Baxter, the manufacturer of Tisseel and Peristrips supported this work. Measures taken to avoid bias or spin include 10 years of use of Tisseel and Peristrips prior to any engagement with Baxter. Data was maintained prospectively for 10 years, and previously reported, prior to any engagement with Baxter.[11] No company member had any input into the manuscript other than providing the correct product name and pricing information.

CONCLUSION

In this series over a 10-year period, a sequence of technical changes was made in a rigorous effort to prevent the most serious complications of sleeve gastrectomy: staple line leak and hemorrhage. Collectively, these technical elements have succeeded in reducing the leak rate from 3.8% in 2012 to a consistent 0% for 7 years between 2015 and 2021 without a change

in the 6-month weight loss results. Staple line hemorrhage rate fell from 1.3% in 2012 to 0.1% since 2018. More than 2,521 consecutive sleeve gastrectomy procedures have now been performed without a leak, and more than 900 without staple line hemorrhage. While external validation is necessary, implementation of these technical elements may play a role in surgical education and widespread reduction of complications.

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Ethical approval: The study was approved by the Institutional Ethics Committee

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