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Improving Hemostasis in Sleeve Gastrectomy With Alternative Stapler

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ABSTRACT

Background: Staple line bleeding can be a major intra-operative complication during laparoscopic sleeve gastrectomy, requiring reinforcing interventions that may diminish the integrity of the staple line and put patients at risk for postoperative hemorrhage or leak. To improve outcomes associated with surgery, surgeons may benefit from an alternative stapler that produces a drier staple line and requires less staple line manipulation.

Methods: Sixty consecutive laparoscopic sleeve gastrectomy procedures were performed by three surgeons; 30 sleeves using the AEON™ Endostapler on THICK MODE and 30 using the Echelon Flex™ Powered Stapler with pulse technique. Stapler performance was measured by incidence and degree of staple line bleeding. Images of the first firing and fundus were taken with the laparoscope 10 seconds after the final firing. Images were evaluated by a third-party blinded evaluator and given a "bleeding score," a qualitative measure of intra-operative staple-line bleeding (1 = no bleeding to 5 = profuse bleeding).

Results: The AEON™ Endostapler demonstrated a lower mean (± standard error) "bleeding score" versus the Echelon Flex™ (2.1 ± 0.1 vs. 2.6 ± 0.1; p = 0.01). The AEON™ Endostapler had 15 cases (50%) with no bleeding at the fundus; the Echelon Flex™ had 7 cases (23%) with no bleeding at the fundus. The AEON™ Endostapler had 0 cases (0%) with profuse bleeding; the Echelon Flex™ had 2 cases (7%) with profuse bleeding.

Conclusion: The AEON™ Endostapler is a significantly drier alternative to the Echelon Flex™ Powered Stapler, producing a much drier staple line and decreasing the need for other bleeding control methods.

Key Words: Surgical stapler, Complications, Hemostasis, Sleeve gastrectomy.

INTRODUCTION

The laparoscopic sleeve gastrectomy (LSG) is an effective primary bariatric procedure for weight loss and the treatment of associated comorbidities. Compared with Roux-en-Y gastric bypass, LSG requires less operative time, is easier to perform, and has 50% fewer complications.[1–3] Its success has rendered it the most common surgical procedure to treat morbid obesity and type-2 diabetes, representing 47% of bariatric procedures worldwide in 2019.[4]

Although recognized for its high efficacy and acceptably low complication rate, LSG is not performed without inherent risk. Intra-operative bleeding can occur when dividing the transverse branches of the lesser curvature arteries during stapling, which is associated with a longer length of stay[5] and a small but non-zero risk of mortality.[6] Bleeding may additionally precipitate the need for transfusion or re-operation and increase the cost of surgery.[7–8]

The dryness of the staple line is indicative of its compressional reliability and may influence the surgeon's confidence during surgery. To mitigate the risk of bleeding, surgeons commonly employ suturing, buttressing, clipping, and/or gluing to reinforce the staple line. However,

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these reinforcement methods have demonstrated mixed success in their ability to reliably reduce bleeding.[9–11] In addition, they are practiced variably among surgeons, increase the cost of surgery, and may instead diminish the integrity of the staple line.[12–14]

The current variability of reinforcement outcomes warrants the need for a stapler that produces a drier staple line and can therefore reduce the need for staple line manipulation. There are currently two legacy brands in the endostapler market with well-established outcomes. A new brand, AEON™ by Lexington Medical (Lexington Medical Inc., Billerica, MA, USA), was recently introduced and has been studied by several prior investigators demonstrating its safety and feasibility.[15–16] Anecdotal evidence from experienced surgeons suggests that the new brand produces an improved, consistent 'B' staple formation and drier stapler lines than existing alternatives. We undertook this clinical trial to test the hypothesis that the new brand with improved 'B' staple formation can lead to better hemostasis in LSG compared to the Echelon Flex™ Powered Stapler by Ethicon (Ethicon Inc., Somerville, NJ, USA).

METHODS

Ethics Approval

This study was approved by and conducted with the accordance of the Aspire Institutional Review Board (IRB study no. 1271222). All patients provided written, informed consent.

Study Design

This clinical trial was a two-group, randomized, multicenter study including 60 obese patients at 3 hospitals in the United States. LSGs were performed consecutively between October 2019 and December 2019 at Southern Surgical Hospital (Slidell, LA, USA), Crescent City Surgical Centre (Metairie, LA, USA), and Avala Hospital (Covington, LA, USA). One-week and one-month follow-ups on adverse effects were performed.

Participants

Patients were screened based on inclusion and exclusion criteria, then randomized by alternating surgery days and assigned one of two stapler treatment groups in a 1:1 ratio: AEON™ Endostapler or Echelon Flex™ Powered Stapler. Patients were included if they were undergoing a planned LSG and gave their informed consent for the study. Patients were excluded if their planned sleeve gastrectomy was open, they had a prior bariatric operation, they were taking anticoagulants, they were under 18 at the time of the surgery, or if their surgery required the use of staple line reinforcement material.

Interventions

Three bariatric surgeons (JR, TL, MF) performed the sleeve gastrectomies. Each surgeon performed at least 5 surgeries using each stapler brand. All firings with the AEON™ Endostapler were done using THICK MODE and conformed to the AEON™ Instructions For Use.[17] All firings with the Echelon Flex™ were done using pulse technique according to the Echelon Flex™ Instructions For Use.[18] Sleeve gastrectomies were performed according to institutional standard-of-care and all subjects underwent standard pre-operative evaluation as well as postoperative care. No sutures, cautery, or clips were applied to the staple line during stapling unless required at the surgeon's discretion.

AEON™ reloads used by surgeons were Purple (4.0 mm open staple height, 1.8 mm closed staple height), Orange (3.25 mm, 1.5 mm), and White (2.5 mm, 1.0 mm) thicknesses. Purple and White reloads were 60 mm in length, and Orange reloads were 45 mm and 60 mm in length. Echelon Flex™ reloads were available to surgeons in Green (4.1 mm, 2.0 mm) and Blue (3.5 mm, 1.5 mm) thicknesses. Green and Blue reloads were 60 mm in length. First firings were performed using AEON™ Purple or Echelon Flex™ Green. Subsequent firings were performed using AEON™ Orange, AEON™ White or Echelon Flex™ Blue.

Using a laparoscope, images of the first firing and fundus were systematically captured 10 seconds following the last stapler firing of each sleeve gastrectomy. Images were then sent to the third-party primary outcome evaluator (TB), a bariatric surgeon with at least 10 years of experience, who was blinded to the surgeon and device used. In the event that staple line bleeding required control prior to the last firing, an additional image was captured before undergoing the necessary intervention.

Outcomes

The third-party primary outcome evaluator assigned each staple line a "bleeding score" on a 5-point Likert-type scale for bleeding severity, a qualitative measure of intraoperative staple-line bleeding (1: No bleeding; 2: Minimal

bleeding; 3: Moderate bleeding; 4: Excessive bleeding; 5: Profuse bleeding) (**Figure 1**). The bleeding scale used in the study was designed by the authors for the purposes of assessing hemostasis in humans after sleeve gastrectomy. This scale was inspired by a similar hemostasis scale developed by Siegel et al. for use in pigs.[19] The primary outcome evaluator evaluated staple line bleeding for each image according to the provided scale (**Figure 1**) as soon as all images became available (March 3, 2020), and scores were tabulated in Excel (Microsoft, Redmond, WA, USA).

Following the surgery, the surgeons reported their satisfaction with the stapler (Dissatisfied, Somewhat dissatisfied, Neutral, Somewhat satisfied, or Satisfied) and the level of control required on staple line bleeding (None, Minimal, Moderate, or Excessive). The surgeons additionally reported any product malfunctions, necessary blood transfusions, and secondary sources of bleeding during the surgery. Patients were contacted one week following the surgery to determine postoperative outcomes on their weight-loss, pain level on a 0 to 10 scale (per standard protocol), and symptoms of dysphagia and nausea. Patients were contacted again one month following the surgery to determine if staple line leakage and/or device-related adverse events had occurred.

Statistical Analysis

Analyses were performed using Excel and summarized using descriptive statistics (for the bleeding score) or frequencies (for case counts). Unpaired, two-tailed t-tests were performed using Excel to test for significant differences in bleeding score between stapler treatment groups. Statistical significance was accepted at $p < 0.05$. Total counts of cases with no bleeding at fundus, cases with no bleeding over the entire staple line, and cases with profuse bleeding were not tested for significance.

RESULTS

Seven patients were excluded from the study: 2 from the AEON™ treatment group and 5 from the Echelon Flex™ treatment group. One AEON™ case and 2 Echelon Flex™ cases experienced technical issues that made it impossible to retrieve staple line images, 3 Echelon Flex™ cases required necessary intervention to reduce bleeding (by mistake, images were not captured before the intervention as required by the protocol), and 1 AEON™ case was performed using the wrong stapler treatment as per their randomized group treatment.

A total of 60 patients were included and received treatment with the AEON™ Endostapler (n = 30) or the Echelon Flex™ Powered Stapler (n = 30). The patient population (mean age, 46 ± 11 years; 72% women; mean BMI, 45 ± 7 kg/m^2) was comparable across both groups in age, gender, and BMI (**Table 1**).

Primary Outcome

During sleeve gastrectomies, the AEON™ Endostapler demonstrated a lower overall mean (± SEM) bleeding score versus the Echelon Flex™. The AEON™ Endostapler also demonstrated a lower bleeding score of fundus firing, but did not demonstrate any significant difference in bleeding score at first firing. These differences are demonstrated in **Table 2**.

Table 3 shows the counts of cases that demonstrated staple line bleeding. The AEON™ Endostapler had 15 cases (50%) with no bleeding at the fundus; the Echelon Flex™ had 7 cases (23%) with no bleeding at the fundus. The AEON™ Endostapler had 3 cases (10%) with no bleeding over the entire staple line; the Echelon Flex™ had 1 case (3%) with no bleeding over the entire staple line. The AEON™ Endostapler had 0 cases (0%) with profuse bleeding; the Echelon Flex™ had 2 cases (7%) with profuse bleeding.

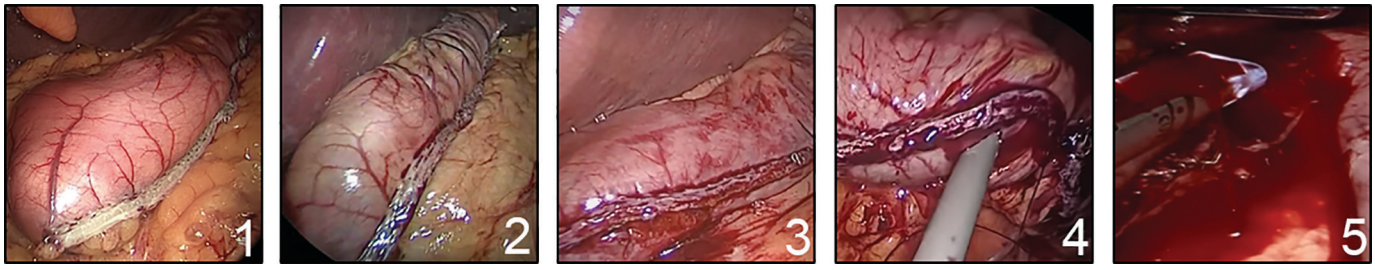

Figure 1. Bleeding Severity Scale. 1: No bleeding at staple line; 2: Minimal bleeding at staple line; 3: Moderate bleeding at staple line; 4: Excessive bleeding at staple line; 5: Profuse bleeding at staple line.

Table 1.
Comparison of Patient Demographics

Variable	AEON™	Echelon Flex™	Total
Patients	30	30	60
Age, y	46 ± 11	45 ± 11	46 ± 11
Sex (male/female)	12 (40 /18 (60)	5 (17)/25 (83)	17 (28)/43 (72)
Body Mass Index, kg/m^2	44 ± 6	46 ± 7	45 ± 7

Data are expressed as mean ± SD or n (%).

Secondary Outcomes

Neither brand saw any product malfunctions, blood transfusions, leakage, or device-related adverse events in the month following the surgery (**Table 4**). Operating room (OR) time did not differ significantly between populations, however, the OR time for 1 AEON™ case and 2 Echelon Flex™ cases was not recorded. There were no significant differences in weight loss, pain level, dysphagia, and nausea at one week following the surgery. At the one-month follow-up, no postoperative staple line leakage or device-related adverse events had occurred. Secondary sources of bleeding were reported in 3 of 30 AEON™ cases and 4 of 30 Echelon cases (**Table 4**).

Both patient populations required a similar quantity of stapler cartridge reloads during surgery (**Table 5**). Both staplers worked as expected in all cases. **Table 6** demonstrates the surgeon-reported satisfaction and level of bleeding control required using both devices. For the AEON™ Endostapler, control of staple line bleeding was not required in 14 cases, required minimally in 15 cases, and moderately in 1 case. For the Echelon Flex™, control of the staple line was not required in 2 cases, required minimally in 22 cases, and moderately in 6 cases. The surgeon was satisfied with the staple line in 29 AEON™ cases and somewhat satisfied in 1 case. Using the Echelon Flex™, the surgeon was satisfied with the staple line in 27 cases, somewhat satisfied in 1 case, neutral in 1 case, and somewhat dissatisfied in 1 case (**Table 6**).

Table 2.
Comparison of Intraoperative Stapler Bleeding Scores

Outcome Measure	AEON™	Echelon Flex™	*p*-value
Overall bleeding score	2.1 ± 0.1	2.6 ± 0.1	0.01
Fundus bleeding score	1.6 ± 0.1	2.3 ± 0.2	0.001
First firing bleeding score	2.6 ± 0.2	2.8 ± 0.2	0.49

Data are expressed as mean ± standard error of the mean.

DISCUSSION

In this randomized clinical study, the new brand demonstrated significantly less bleeding along the fundus and overall staple line compared to the Echelon Flex™ Powered Stapler, though the brands did not differ in bleeding at first firing. Moreover, the AEON™ stapler had fewer cases of bleeding along the fundus over the entire staple line, and no cases with profuse bleeding. Control of the staple line was not required in 14 AEON™ cases compared to 2 Echelon Flex™ cases, and minimally or moderately required in 16 AEON™ cases compared to 28 Echelon Flex™ cases. Surgeons reported consistent staple line satisfaction with the AEON™ device, but were neutral or somewhat dissatisfied with the Echelon Flex™ staple line in 2 of 30 cases.

Staple line bleeding can be a major intraoperative complication during LSG. Baseline factors such as existing comorbidities, hypertension or the use of anticoagulant and antithrombotic drugs can predispose the patient to a greater risk of bleeding. However, during the surgery, stapler misfirings and the use of stapler cartridge heights that are insufficient for the thickness of the tissue can increase the risk of staple line bleeding.[20]

Many surgeons believe that reinforcing the staple line will reduce bleeding. A 2013 consensus summit on sleeve gastrectomy determined that 79% of respondent surgeons

Table 3.
Cases With and Without Staple Line Bleeding

	AEON™	Echelon Flex™
Cases with no bleeding at the fundus	15 (50)	7 (23)
Cases with no bleeding over the entire staple line	3 (10)	1 (3)
Cases with profuse bleeding	0 (0)	2 (7)

Data are expressed as n (%).

Table 4.
Comparison of Postoperative Outcomes

	AEON™	Echelon Flex™
Reported device-related adverse events	0 (0)	0 (0)
Blood transfusions due to staple line bleeding	0 (0)	0 (0)
Blood transfusions within 72 hours of surgery start	0 (0)	0 (0)
Operative time (mins)	51 ± 10	50 ± 13
Weight loss at 1 week (pounds)	14.7 ± 8.8	16.2 ± 8.6
Pain level at 1 week (NRS)	1.8 ± 2.9	1.6 ± 2.7
Dysphagia present at 1 week	4 (13)	2 (7)
Nausea present at 1 week	2 (7)	5 (17)
30-day leakage complications	0 (0)	0 (0)
Intraoperative secondary sources of bleeding	3 (10)	4 (13)

Data are expressed as mean ± standard deviation or n (%).
NRS; numeric rating scale from 1-10.

reinforce the staple line, and of these surgeons, 57% buttress the staple line, and 43% oversew it.[21] Although reinforcement is reassuring, these additional interventions can stress the integrity of the staple line. Due to the severity and increased occurrence of bleeding observed with Echelon Flex™ staplers, the higher rate of subsequent intervention required with these staplers could potentially lead to more staple line leakage and an increased need for transfusion.

Additionally, a surgeon's confidence is dependent on the integrity of their staple line. A bleeding staple line may indicate an increased risk for postoperative stomach line leakage which does not inspire confidence in its strength or reliability. In laparoscopic gastric bypass surgery, intraoperative bleeding is associated with less favorable outcomes such as lower weight loss and a lower quality-of-life 2 years after surgery.[22] Therefore, for the safety of the operation and the ensuing outcome(s), it is ideal to produce a drier, more reliable staple line that reduces the need for reinforcing materials.

Table 5.
Average Stapler Cartridge Counts Used Per Surgery

Stapler Cartridge	AEON™	Echelon Flex™
AEON Purple 60 mm Reloads	1.0 ± 0.0	-
Echelon Flex Green 60 mm Reloads	-	1.0 ± 0.2
AEON Orange 60 mm Reloads	4.2 ± 0.5	
Echelon Flex Blue 60 mm Reloads	-	4.2 ± 0.5
AEON Orange 45 mm Reloads	0.1 ± 0.3	-
AEON White 60 mm Reloads	0.0 ± 0.2	-

Data are expressed as mean ± standard deviation.

Table 6.
Surgeon-Reported Stapler Satisfaction

Satisfaction Query	AEON™	Echelon Flex™
Overall, did the stapler work as expected? (y/n)	30 (100)/0 (0)	30 (100)/0 (0)
Overall satisfaction with the staple line		
Satisfied	29 (97)	27 (90)
Somewhat Satisfied	1 (3)	1 (3)
Neutral	0 (0)	1 (3)
Somewhat Dissatisfied	0 (0)	1 (3)
Dissatisfied	0 (0)	0 (0)
Level of control of staple line bleeding required		
None	14 (47)	2 (7)
Minimal	15 (50)	22 (73)
Moderate	1 (3)	6 (20)
Excessive	0 (0)	0 (0)

Data are expressed as n (%).

Regarding device satisfaction, the surgeons were largely satisfied with the staple lines produced using both devices. However, in 2 of 30 Echelon Flex™ cases, surgeons reported a neutral or dissatisfied rating with the device, whereas surgeons reported no neutral or dissatisfied ratings with the AEON™ stapler. Although these ratings are subjective and the differences are not clinically significant, it is worth considering that the same blinded surgeons rated both staplers. Given that the alternative brand produced significantly less bleeding along the staple line, it is clear that the AEON™ stapler had a positive and measurable effect on the surgeon's confidence level after surgery.

A limitation of this study is our method of evaluation of the staple line. We chose to evaluate the staple line solely on bleeding severity; however, this study could have benefitted from evaluating staple line leak to assess staple line integrity. We chose not to assess staple line leak due to the much larger sample size that would have been required due to the

lower rate of staple line leaks compared to bleeding. Furthermore, we designed and used a bleeding scale that has not been previously validated. We chose to design our own scale because we did not find previously validated hemostasis scales to be appropriate for the assessment of human gastric staple lines. We also chose to use picture stills instead of continuous video clips for evaluating the staple line to maintain consistency between cases and facilitate the reviewing process; however, we may have derived additional benefit from using short video clips to capture the dynamic nature of bleeding.

Another potential critique for this study is the 60 patient sample size used to compare stapler treatment groups. Bleeding complications occur at a relatively high rate during sleeve gastrectomy, therefore a large sample size was not necessary to demonstrate a significant difference between groups. Finally, although our protocol excluded patients using anticoagulants, we did not control for blood disorders that could predispose patients to excessive bleeding, such as hypertension and coagulation disorders.

CONCLUSION

In this study, we demonstrated that an alternative stapler using improved 'B' staple formation can improve staple line hemostasis relative to an existing market stapler, the Echelon Flex™ Powered Stapler by Ethicon. Our findings suggest that the AEON™ Endostapler produces a significantly drier staple line compared to the Echelon Flex™ Powered Stapler and is associated with less interventional control of the staple line.

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