LEXINGTON MEDICAL

AEON™ ENDOSTAPLER

INNOVATING

MINIMALLY INVASIVE

SURGERY WITH

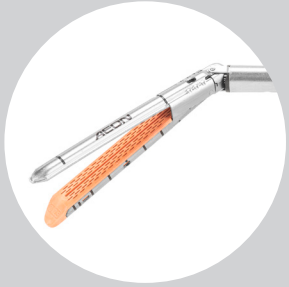
S3 ENGINEERING™

BETTER OUTCOMES

IN

BARIATRIC SURGERY

MADE IN USA



Superior staple lines

Smooth articulation

Multi-speed gear

AEON™ WITH S3 ENGINEERING™

Superior staple lines. Smooth articulation. Multi-speed gear.

50%

lower firing force with multi-speed gear[1]
for better staple formation and superior hemostasis

Smooth articulation

Precise stapler positioning with fluid range of motion

Multi-speed gear

Reduced trigger pull force for thicker tissue

Advanced reload architecture

Integrated I-beam assembly, fixed anvil and teardrop shape anvil buckets

Proprietary tip design

Broadest range of anvil tips to address a wide range of clinical applications

High tech manufacturing

Proprietary manufacturing equipment incorporating AI

WIDEST RANGE OF ANVILS

Regular tip | Short tip | Curved tip

Surgeon Testimonials

Michel Gagner, M.D., FRCSC, FACS, FASMBS
Chief of Surgery, Westmount Square Surgery Center, Montreal, Canada
Professor of Surgery, Herbert Wertheim School of Medicine, FIU
Senior Consultant, Hôpital du Sacre Coeur

"In over 1,000 bariatric cases, we have seen excellent staple formation with the AEON Endostapler. **The unique dual firing gear allows for slow, controlled firing resulting in the best hemostasis I've seen** and a low risk for post-operative complications for our patients.

Furthermore, I think the future is bright for Lexington Medical and it makes a lot of sense for surgeons to partner with them as they deliver top service, consistently respond to surgeon feedback, and offer high quality products."

Christopher Hart, M.D., FACS
Medical Director, Atlanta General & Bariatric Surgery Center, Atlanta, GA
Bariatric Medical Director, (Emeritus) Chief of Staff, Emory Johns Creek Hospital

"Prior to using AEON, we performed testing on excised stomach specimens to evaluate both staple formation and risk of leaks. **The AEON consistently outperformed the other staplers** and we quickly became very comfortable with the product. Our patient results have been fantastic in approximately 1,000 bariatric cases. With the various staple heights made for variable tissue thickness, we have found our staple formation has been consistent even when crossing staple lines.

In addition, **it is refreshing to have a new option in surgical stapling** from a company stirring things up by driving more value and innovation in the market. I've never experienced such responsiveness from a company or openness to feedback."

James Redmann, M.D., FACS
Bariatric Surgeon, Surgical Specialists of Louisiana, Covington, LA
Medical Director, WhyWeight Clinic

"The AEON Endostapler works great. I and my three partners have completed approximately 900 bariatric cases and been **very satisfied with the clean, beautiful staple lines**. Previously, I was frustrated by other companies for their yearly price increases with no real noteworthy product improvements.

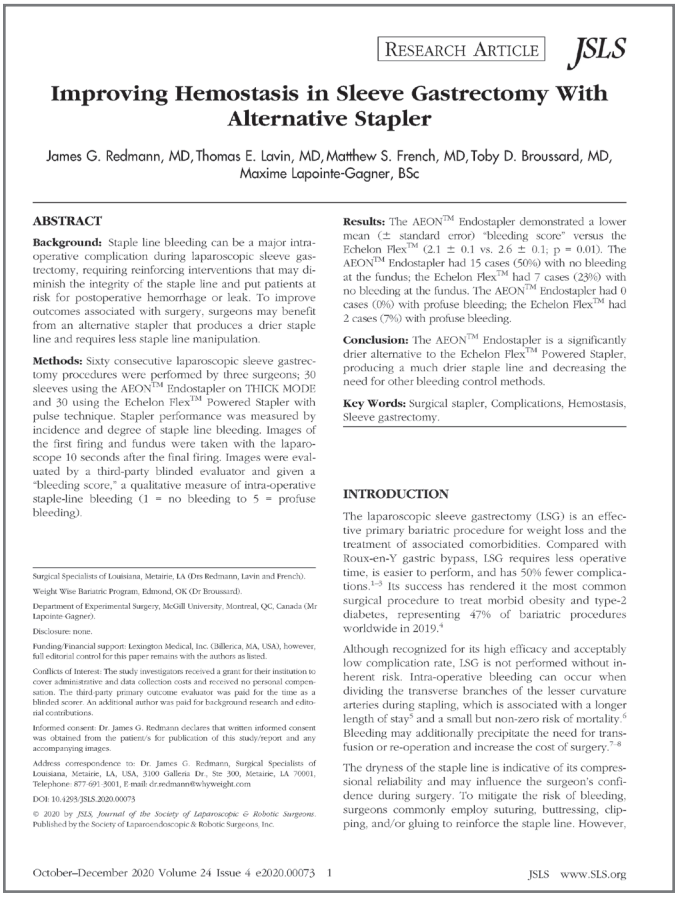
With AEON, we are finding **superior hemostasis** as the fresh blade with each reload makes for a much less traumatic, serosal edge. Other products often required much time spent cauterizing and applying clips to reinforce the staple line. AEON is a **true 'win-win' as it is a high quality product available with excellent service**, we've experienced zero complications, and has resulted in a significant improvements in our procedures."

Greg Walton, M.D., FACS
Bariatric Surgeon, MBS Director, Summit Medical Center, Oklahoma City, OK
Owner, WeightWise Bariatric Program

"As an early adopter of the AEON Endostapler, we've been fortunate to observe and be part of product evolution over a relatively short period of time. Namely, we have found the **new dual firing gear allows for much smoother, easier firing in the thicker tissue of the stomach.**

In addition, my partner and I operate at a physician-owned facility where we have performed over 1,400 bariatric cases with the AEON. We are always looking to optimize safety and patient outcomes and partnering with Lexington Medical has allowed for us to continue to deliver on our track record of optimal patient outcomes."

Clinical Evidence



RESEARCH ARTICLE JSLS

Improving Hemostasis in Sleeve Gastrectomy With Alternative Stapler

James G. Redmann, MD, Thomas E. Lavin, MD, Matthew S. French, MD, Toby D. Broussard, MD, Maxime Lapointe-Gagner, BSc

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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Weight Wise Bariatric Program, Edmond, OK (Dr Broussard).

Department of Experimental Surgery, McGill University, Montreal, QC, Canada (Mr Lapointe-Gagner).

Disclosure: none.

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Conflicts of Interest: The study investigators received a grant for their institution to cover administrative and data collection costs and received no personal compensation. The third-party primary outcome evaluator was paid for the time as a blinded scorer. An additional author was paid for background research and editorial contributions.

Informed consent: Dr. James G. Redmann declares that written informed consent was obtained from the patient/s for publication of this study/report and any accompanying images.

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Significantly drier alternative[2]

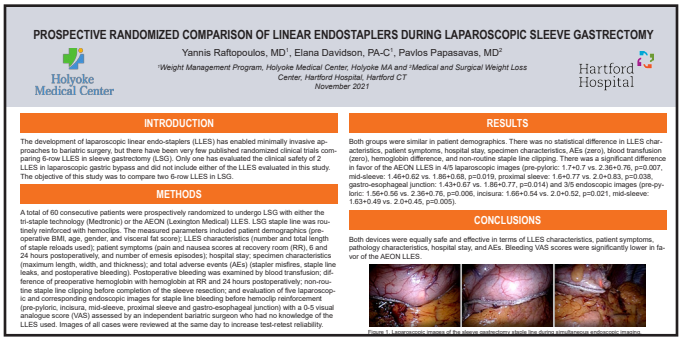
to the Echelon Flex™ Powered Stapler, producing a much drier staple line and decreasing the need for other bleeding control methods

20% reduction in overall bleeding score

comparing AEON™ to Echelon Flex™ (p-value = 0.01)

Significantly lower bleeding scores[3]

comparing AEON™ to ENDO GIA™ in a randomized clinical trial



PROSPECTIVE RANDOMIZED COMPARISON OF LINEAR ENDOSTAPLERS DURING LAPAROSCOPIC SLEEVE GASTRECTOMY

Holyoke Medical Center

Yannis Raftopoulos, MD[1], Elana Davidson, PA-C[1], Pavlos Papasavas, MD[2]

[1]Weight Management Program, Holyoke Medical Center, Holyoke MA and [2]Medical and Surgical Weight Loss Center, Hartford Hospital, Hartford CT

November 2021

Hartford Hospital

INTRODUCTION

The development of laparoscopic linear endo-staplers (LLES) has enabled minimally invasive approaches to bariatric surgery, but there have been very few published randomized clinical trials comparing 6-row LLES in sleeve gastrectomy (LSG). Only one has evaluated the clinical safety of 2 LLES in laparoscopic gastric bypass and did not include either of the LLES evaluated in this study. The objective of this study was to compare two 6-row LLES in LSG.

METHODS

A total of 60 consecutive patients were prospectively randomized to undergo LSG with either the tri-staple technology (Medtronic) or the AEON (Lexington Medical) LLES. LSG staple line was routinely reinforced with hemoclips. The measured parameters included patient demographics (preoperative BMI, age, gender, and visceral fat score); LLES characteristics (number and total length of staple reloads used); patient symptoms (pain and nausea scores at recovery room (RR), 6 and 24 hours postoperatively, and number of emesis episodes); hospital stay; specimen characteristics (maximum length, width, and thickness); and total adverse events (AEs) (stapler misfires, staple line leaks, and postoperative bleeding). Postoperative bleeding was examined by blood transfusion; difference of preoperative hemoglobin with hemoglobin at RR and 24 hours postoperatively; non-routine staple line clipping before completion of the sleeve resection; and evaluation of five laparoscopic and corresponding endoscopic images for staple line bleeding before hemoclip reinforcement (pre-pyloric, incisura, mid-sleeve, proximal sleeve and gastro-esophageal junction) with a 0-5 visual analogue score (VAS) assessed by an independent bariatric surgeon who had no knowledge of the LLES used. Images of all cases were reviewed at the same day to increase test-retest reliability.

RESULTS

Both groups were similar in patient demographics. There was no statistical difference in LLES characteristics, patient symptoms, hospital stay, specimen characteristics, AEs (zero), blood transfusion (zero), hemoglobin difference, and non-routine staple line clipping. There was a significant difference in favor of the AEON LLES in 4/5 laparoscopic images (pre-pyloric: 1.7+0.7 vs. 2.36+0.76, p=0.007, mid-sleeve: 1.46+0.62 vs. 1.86+0.68, p=0.019, proximal sleeve: 1.6+0.77 vs. 2.0+0.83, p=0.038, gastro-esophageal junction: 1.43+0.67 vs. 1.86+0.77, p=0.014) and 3/5 endoscopic images (pre-pyloric: 1.56+0.56 vs. 2.36+0.76, p=0.006, incisura: 1.66+0.54 vs. 2.0+0.52, p=0.021, mid-sleeve: 1.63+0.49 vs. 2.0+0.45, p=0.005).

CONCLUSIONS

Both devices were equally safe and effective in terms of LLES characteristics, patient symptoms, pathology characteristics, hospital stay, and AEs. Bleeding VAS scores were significantly lower in favor of the AEON LLES.

Figure 1. Laparoscopic images of the sleeve gastrectomy staple line during simultaneous endoscopic imaging.

Over 20,000 bariatric procedures

in 29 countries and growing. Ask us about our Bariatric Data Registry to learn how clinicians are using AEON™

Product Offering

The AEON™ Endostapler is versatile and proven to deliver excellent clinical performance and consistent staple formation across variable tissue types.[1]

Reload Type	Cartridge Lengths	Product Codes	Open Height	Closed Height
Gray	30, 45mm	AESR30G, AESR45G	2.0mm	0.75mm
White	30, 45, 60mm	AESR30W, AESR45W, AESR60W	2.5mm	1.0mm
Orange	30, 45, 60mm	AESR30R, AESR45R, AESR60R	3.25mm	1.5mm
Purple	30, 45, 60mm	AESR30P, AESR45P, AESR60P	4.0mm	1.8mm
Black	60mm	AESR60B	5.0mm	2.2mm
Gray Curved Tip	30, 45mm	ASR30GC, AESC45G	2.0mm	0.75mm
White Curved Tip	30, 45, 60mm	ASR30WC, AESC45W, AESC60W	2.5mm	1.0mm
Orange Curved Tip	30, 45, 60mm	ASR30RC, AESC45R, AESC60R	3.25mm	1.5mm
Purple Curved Tip	30, 45, 60mm	ASR30PC, AESC45P, AESC60P	4.0mm	1.8mm
Gray Short Tip	30mm	ASR30GS	2.0mm	0.75mm
White Short Tip	30, 60mm	ASR30WS, ASR60WS	2.5mm	1.0mm
Orange Short Tip	30, 60mm	ASR30RS, ASR60RS	3.25mm	1.5mm
Purple Short Tip	30, 60mm	ASR30PS, ASR60PS	4.0mm	1.8mm

Handle Type	Shaft Length	Product Code
Short	60mm	AESH060
Medium	160mm	AESH160
Long	260mm	AESH260

[1]Data on file. [2]Redmann, et al. (2020). Improving hemostasis in sleeve gastrectomy with alternative stapler. Journal of the Society of Laparoscopic and Robotic Surgeons. (24) 4.https://pubmed.ncbi.nlm.nih. gov/33447003. [3]Raftopoulos, et al. (2021). Prospective randomized comparison of linear endostaplers during laparoscopic sleeve gastrectomy. https://clinicaltrials.gov/ct2/show/study/NCT04617574

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