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ORIGINAL CONTRIBUTIONS

Safety and Feasibility of a Lower-Cost Stapler in Bariatric Surgery

Kurt E. Roberts[1] · L. Renee Hilton[1,2] · Danielle T. Friedman[1] · Joel S. Frieder[3] · Xuchen Zhang[4] · Andrew J. Duffy[1]

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Abstract

Background Laparoscopic staplers are integral to bariatric surgery. Their pricing significantly impacts the overall cost of procedures. An independent device company has designed a stapler handle and single-use reloads for cross-compatibility and equivalency with existing manufacturers, at a lower cost.

Objectives We aim to demonstrate non-inferior function and cross-compatibility of a newly introduced stapler handle and reloads compared to our institution's current stapling system in a large animal survival study.

Setting University-affiliated animal research facility, USA.

Methods Matched small bowel anastomoses were created in four pigs, one with each stapler (a total of two per animal). After 14 days, investigators blinded to stapler type evaluated the anastomoses grossly and microscopically. Each anastomosis was scored on multiple measures of healing. Individual parameters were added for a global "healing score."

Results Clinical stapler function and gross quality of anastomoses were similar between stapler groups. Individual scores for anastomotic ulceration, reepithelialization, granulation tissue, mural healing, eosinophilic infiltration, serosal inflammation, and microscopic adherences were also statistically similar. The mean "healing scores" were equal. While this study was underpowered for subtle differences, safe and reliable performance in large animals still supports the feasibility of introducing new devices into human use.

Conclusions The new stapler system delivers a similar technical performance and is cross-compatible with currently marketed stapling devices. An equivalent quality device at a lower price point should enable case cost reduction, helping to maintain hospital case margin and procedure value in the face of potentially declining reimbursement. This device may provide a safe and functional alternative to currently used laparoscopic surgical staplers.

Keywords Bariatric surgery · Surgical devices · Value · New technology

Kurt E. Roberts and L. Renee Hilton contributed equally to this work.

Kurt E. Roberts and L. Renee Hilton are co-first authors.

✉ Danielle T. Friedman
danielle.t.friedman@yale.edu

Kurt E. Roberts
kurt.roberts@yale.edu

L. Renee Hilton
lhilton@augusta.edu

Joel S. Frieder
joelfrieder13@gmail.com

Xuchen Zhang
xuchen.zhang@yale.edu

Andrew J. Duffy
andrew.duffy@yale.edu

1 Department of Surgery, Gastrointestinal Section, Yale University, 40 Temple Street, Suite 7B, New Haven, CT 06510, USA

2 Department of Surgery, Minimally Invasive and Digestive Diseases, Augusta University, Augusta, GA, USA

3 Universidad Central de Venezuela, Caracas, Venezuela

4 Department of Surgical Pathology, Yale University, New Haven, CT 06520, USA

Introduction

Staplers have greatly impacted gastrointestinal surgery since introduction in the 1960s. They allow the surgeon to perform anastomoses more quickly, with equal or better outcomes [1, 2]. They have been well adapted for use in laparoscopic surgery, particularly bariatric surgery [3]. While laparoscopy provides quicker postoperative recovery with fewer complications compared to open surgery, it also faces higher procedural costs [4, 5].

The value of stapling devices in bariatric procedures is bolstered by high reliability. The characteristics of the stapler reload chosen may influence critical outcomes [6]. Meanwhile, the cost of handles and reloads contributes significantly to the overall cost of the procedure. A device that preserves functional characteristics at a lower cost could increase surgical value, especially in high-volume procedures.

There are currently two primary stapler manufacturers, Medtronic (Medtronic, Minneapolis, MN, USA) and Ethicon (Ethicon Inc., Somerville, NJ, USA). This duopoly limits opportunities for significant cost reduction by limiting the bargaining position of health care systems. Lexington Medical, an independent device company (Lexington Medical Inc., Billerica, MA, USA), has designed the manual AEON™ Endoscopic Stapler Handle and single-use Reloads; both have been cleared by the U.S. Food and Drug Administration (USFDA) [7]. These devices incorporate Medtronic technology no longer under patent protection. The endoscopic stapler is designed to be at least equivalent in performance and cost-competitive with existing devices on the market. It is also designed to be cross-compatible with the existing Medtronic Endo GIA™ Universal line [8].

We undertook this study to demonstrate equivalent function and ensure cross-compatibility of the AEON™ Endoscopic Stapler Handle and Reloads to Medtronic's Endo GIA™ Reloads with Tri-staple™ Technology in a large animal survival study.

Materials and Methods

Four female swine weighing 24–26 kg were purchased from an approved vendor. They were received and acclimated according to the facility's standard procedures, accredited by the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC). Their pre-operative and postoperative care complied with the Guide for the Care and Use of Laboratory Animals (National Research Council, current edition). The study was performed under an appropriate Institutional Review Board (IRB) protocol with the approval from the Animal Care and Use Committee. Pre-operatively, the animals fasted overnight. Experienced facility staff prepared the animals for surgery and monitored them throughout the performance of the surgical procedures.

All staple firings were performed by three bariatric surgeons (AJD, KER, LRH). Two proximal small intestinal anastomoses were created in each animal: side-to-side and functional end-to-end. These anastomoses were carried out using the manual AEON™ Endoscopic Stapler Handle with AEON™ Endoscopic Stapler Reloads (Lexington Medical) and Endo GIA™ Reloads with Tri-Staple™ Technology (Medtronic). All anastomoses were performed laparoscopically with no complications.

Each animal underwent one anastomosis using the AEON™ Reloads and the other anastomosis using Endo GIA™ Reloads, alternating the location (proximal versus more distal) between the animals. These devices incorporate Medtronic technology no longer under patent protection and as such have analogous components. The manual AEON™ endoscopic stapler handle replicates its Medtronic counterpart in appearance and function. AEON™ reloads are available in gray (a 2.0-mm open staple height), tan (2.25 mm), orange (3.25 mm), purple (4.0 mm), and black (5.0 mm) thicknesses. Gray and tan loads are 45 mm in length, orange loads 45 mm or 60 mm, and purple and black loads 60 mm only. The AEON™ reloads are similar to the Endo GIA™ Tri-Staple Technology in that the cartridges deploy three parallel rows of staples on each side of a central bladed channel. The Endo GIA™ features graduated heights of the three staple rows while the AEON™ utilizes equal heights. We selected Endo GIA™ 45 mm Tan Reloads with Tri-Staple™ Technology (our typical choice when creating a jejunojejunal anastomosis) or AEON™ Endoscopic Stapler 60-mm Tan Reloads for each anastomosis. All loads were non-reinforced. All staple loads were fired using the AEON™ stapler handle.

Operative Technique

Pneumoperitoneum was established to 12 mmHg after a Veress needle entry. A 10-mm laparoscope was used. A 12-mm laparoscopic trocar was inserted in the right upper quadrant, a 5-mm trocar in the midclavicular line just lateral to the umbilicus, and a 12-mm trocar in the right lower quadrant. The ligament of Treitz was identified and the jejunum run distally for approximately 20 cm. This site was chosen for the proximal anastomosis.

A loop of proximal jejunum was elevated and shears were used to create a 1-cm enterotomy on the anti-mesenteric wall. A side-to-side entero-enteric anastomosis was then created. The staplers' jaws were directed through the enterotomy, one jaw into each limb with the help of a Maryland dissector. The stapler was fired and the common enterotomy borders were everted to review the correct placement of the staple lines and exclude bleeding or leakage. The stapler was then reloaded and positioned perpendicularly to the first staple lines, just below the margin of the enterotomy on the antimesenteric border of the bowel [9–13]. The stapler was fired again and the second staple line was carefully inspected for bleeding or leakage. The excised tissue specimen was also grossly examined. For the more distal anastomosis, the bowel was run approximately 40 cm from the first enterotomy and performed in the same fashion, using the alternate stapling device.

Following surgery, the animals were fed per institution protocol and assessed by facility staff for 2 weeks. Daily weights were obtained. Observations included examining incisions for signs of wound infection, food intake, and assessment of bowel movements. Two of the pigs did experience postoperative vomiting, but were still able to be advanced per protocol. The feeding protocol included a liquid diet for the first 24 postoperative hours then progressed to soaked pig food, followed by a regular diet at 72–96 postoperative hours. The pigs were weighed on the day prior to the procedure, postoperative day 7, and postoperative day 14.

Pathology

On postoperative day 14, the animals were euthanized by intravenous administration of pentobarbital sodium, and laparotomy was performed. Gross evaluations of the anastomoses were done by the same three surgeons (AJD, KER, LRH). The surgeons were blinded to which pig they were examining and which stapler corresponded to each anastomosis. The evaluations included assessment for the presence of adhesions, anastomotic leaks, patency, and other gross abnormality. Following this, the anastomoses were resected and sent for pathological examination. The tissue was embedded in paraffin blocks representing mesenteric and antimesenteric border orientation. The histological sections were stained with hematoxylin and eosin. The slides were then evaluated by a pathologist (XZ) who was blinded and did not know which stapler reload was used on each specimen. The anastomotic healing evaluation was based on eight microscopic parameters including inflammatory markers, fibrous healing, and cellular infiltrates as previously described by Ntourakis et al. with slight modification [14]. A score was assigned for each listed parameter. As in Ntourakis's study, a global "healing score" for the anastomosis was calculated as the sum of individual parameter scores (Table 1).

Statistical Analysis

Quantitative data for the healing parameters scored are given as medians with their interquartile range (IQR). One-way analysis of variance (ANOVA) was used to compare single healing parameter and global healing mean scores between staplers. The P value was set at 0.05. Graphical data are presented as box-and-whisker plots (mean, quartiles, and range). The statistical analysis was performed with StatPlus:mac LE (AnalystSoft, Inc., Walnut, CA, USA).

Results

The AEON™ Endoscopic Stapler Handle functioned with both types of stapler reloads. The reloads were loaded, fired, and unloaded without technical issues.

All firings were successful regardless of device. There was no intraoperative hemorrhage. In one case, the enterotomy closure was not completed with one firing of the stapler and required the use of a third reload. There, four or five firings occurred per animal (total of 17 firings, 9 Endo GIA™ Tan Reloads with Tri-Staple™ Technology, 8 AEON™ Endoscopic Stapler Tan Reloads). All animals recovered uneventfully from the anesthetic. Operative times ranged from 30 to 42 min [15–22].

All animals survived 14 days post-operatively. The pigs gained 5.6–8.6 kg of weight (mean 6.95 kg). No life-threatening complications were evident during this period. No clinical signs of postoperative hemorrhage, bowel obstruction, leaks, or strictures were noted.

On necropsy, no gross differences were seen between specimens. There were no leaks or strictures [23]. Adhesions to staple lines were present in six of the eight anastomoses, but were not specific to the stapler used [14]. All anastomoses were widely patent with no proximal dilatation of small bowel or signs of obstruction. On microscopic evaluation, focal ulceration with granulation tissue, reepithelization, and inflammatory cell infiltrate were seen in the anastomotic site mucosa. The muscularis mucosa, submucosa, and muscularis proria all showed fibrous healing process with connective tissue. No changes suggestive of perforation or leak were seen at the anastomotic sites. The serosa of the anastomoses showed differing degrees of serositis and fibrous adhesion. However, the histological healing parameters and the mean anastomotic healing score did not differ between the two groups (Table 2, Fig. 1). The pathologist attempted to group specimens according to staple load, but was unable to distinguish between the two manufacturers.

Discussion

In a large animal survival study, the AEON™ Endoscopic Stapler Reloads appear equivalent in function and also technically compatible with Endo GIA™ Reloads with Tri-Staple™ Technology. There was no difference observed between the two brands of stapler in technical function, gross anastomotic parameters, and 14-day outcomes. Both staple loads were successfully fired from the AEON™ handle without difficulty, demonstrating cross-compatibility. All four

Table 1 Histological evaluation of anastomotic healing as established by Ntourakis et al., 2016

Parameter	Description	Grading
Anastomotic ulcer	Mucosal ulceration at the anastomotic site	0 = none; 1 = small; 2 = medium; 3 = extended
Reepithelialization	Reepithelialization at the anastomosis	0 = complete; 1 = partial; 2 = no
Granulation tissue	Presence of granulation tissue versus connective tissue at the anastomosis	0 = connective tissue; 1 = granulation tissue
Mural healing	The degree of muscularis mucosa, submucosa and muscularis propria fibrous healing	0 = complete healing; 1 = incomplete healing
Inflammation	Presence of inflammatory cells at the anastomosis	0 = no; 1 = yes
Eosinophilic infiltration	Eosinophilic infiltration at the anastomosis	0 = no; 1 = yes
Serosal inflammation	Presence of inflammatory cells in the intestinal serosa and the peritoneum	0 = no; 1 = yes
Microscopic adherences	Microscopic adherences at the anastomosis	0 = no; 1 = minor; 2 = extended

Lower scores represent better healing

The anastomotic healing score was calculated as the sum of scores of all parameters except microscopic adherences

animals survived the trial without major complications. All four gained weight during the study period. There was no evidence of anastomotic leaks or strictures, and adhesions were independent of the type of stapler reload used.

Pathologic analysis confirmed only minor variations in histology of the anastomoses. The pathologist was unable to differentiate the staple load brands among the eight specimens. Individual healing parameters as well as mean global "healing score" did not differ between staplers, further supporting similar rate and quality of healing regardless of device. Interestingly, global healing scores were more widely variable in anastomoses performed by the more established stapler brand, perhaps suggesting a more consistent performance in the newer device. However, given the technical similarities between devices, it is not intuitively clear why this pattern emerged. Such a trend would need to be validated and investigated in a larger study.

A stapled small bowel anastomosis was chosen to simulate a critical technique in Roux-en-Y gastric bypass and duodenal switch procedures, while using a minimal and predictable number of reloads. It also allowed paired anastomoses to be created within the same animal for head to head comparison, which would not be possible with a simulated sleeve gastrectomy. However, we anticipate that the findings of this initial safety and feasibility study will be applicable to multiple bariatric procedures, given the central role surgical staplers play in all common primary and many revisional bariatric surgeries. Their impact may be magnified in procedures requiring multiple staple firings.

Hospitals are reimbursed for many laparoscopic bariatric surgical procedures and associated hospital stays in diagnosis-related groups (DRG). Reimbursement is fixed, regardless of the number, type, or contractual cost of staplers used. Specialty items like staplers and reloads can add significant cost to a surgical case. In our institution, over a sample of representative sleeve procedure stapler costs represented 17–34% (mean 25%) of total direct costs per case. Standardizing surgical technique within a practice (ensuring efficient use of reloads) may help stabilize operative cost variability for common procedures. However, as the cost of stapler products is fixed under existing purchase contracts, further reduction in the cost of equipment would require a reduction in the unit cost of the stapler handle and reloads. Adding an equivalent quality device at a lower price point should enable case cost reduction and generate significant value for the institution.

Table 2 Histological evaluation of anastomotic healing by group

Parameter	Stapler A	Stapler B	*p* value
Anastomotic ulcer	1 (0.75–1)	0.5 (0–1)	$p = 0.54$
Reepithelialization	1 (1–1)	1 (1–1)	–
Granulation tissue	0 (0–0.25)	0.5 (0–1)	$p = 0.54$
Mural healing	0.5 (0–1)	0.5 (0–1)	$p = 1.0$
Inflammation	1 (1–1)	1 (1–1)	–
Eosinophilic infiltration	1 (1–1)	1 (1–1)	–
Serosal inflammation	1 (1–1)	1 (1–1)	–
Microscopic adherences	1.5 (1–2)	1 (1–1.25)	$p = 0.54$

Median scores (interquartile range) are given for each group

p value by one-way ANOVA

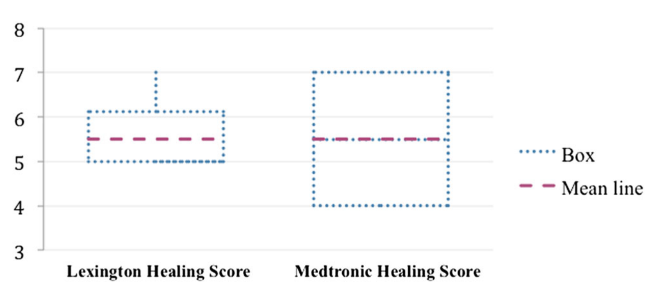

Fig. 1 Healing score by stapler type. Boxplot shows mean values (dashed horizontal line), interquartile range (box), and minimum and maximum values (whiskers). The mean healing score was 5.5 for each group ($p = 1$, one-way ANOVA)

Large animal models, while valuable for pilot demonstrations, are inherently limited by species as well as small sample size. Broader human studies are needed to robustly prove equivalent performance, as this study was underpowered to detect subtle differences. Such studies might benefit from multiple arms utilizing different combinations of handles and staple loads to further clarify the performance of individual components. This would require a comprehensive informed consent process balancing the subtle risks of parallel but not yet standard technology against the expectation of non-inferior results. In addition, industry-sponsored studies are vulnerable to investigator bias. However, safe and reliable performance in large animals may still support the cautious feasibility of introducing new devices into more common human use.

Conclusions

Findings suggest that the AEON™ Endoscopic Stapler Handle and Reloads are ready for human use. This is supported by recent FDA approval of the device and reloads [7]. The device is cross-compatible with existing Medtronic handles and reloads and may lead to the commoditization of what had previously been a specialty product. This may provide novel competition in a market locked on two vendors, with the potential to disrupt existing pricing patterns. This device may provide a safe and functional alternative to currently used laparoscopic surgical staplers.

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Compliance with Ethical Standards

All applicable institutional and national guidelines for the care and use of animals were followed.

Conflict of Interest Kurt E. Roberts M.D. is a consultant for Lexington Medical, Inc. receiving consultation fee and stock options for services, and was paid only for the time of the trial. L. Renee Hilton M.D. was paid by Lexington Medical, Inc. for the time of the trial.

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