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Assessment of a novel stapler performance for laparoscopic sleeve gastrectomy

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Abstract

Background Optimal stapler selection during laparoscopic sleeve gastrectomy requires careful balance between tissue compression, hemostasis, and mechanical integrity. Junctions along a staple line can further increase the risks of technical or mechanical staple line failures. The aim of this study was to compare two commonly utilized laparoscopic linear gastrointestinal staplers (Ethicon, Medtronic) with a novel linear stapler (Titan) designed to perform a sleeve gastrectomy with a single stapler firing.

Methods Excised gastric remnants from laparoscopic sleeve gastrectomy were utilized and tissue thickness was measured from fundus to antrum. An optimized experimental staple line was then created. The greater curve remnant was insufflated to determine the staple line burst pressure and location. The doubly stapled (clinical and experimental) gastric specimen underwent staple analysis for junctional location, malformation, and height.

Results The Titan stapler withstood a significantly higher burst pressure than both Ethicon and Medtronic linear cutting staplers. While the Medtronic and Ethicon staplers had a similar percentage of staples in junctions, the Titan stapler has no junctions. In considering the formation of all staples outside of junctions, the Medtronic and Titan staplers had no difference in percentage of malformed staples, while the Ethicon stapler had a significantly higher percentage. Additionally, there were no differences in mismatch between staple height and tissue thickness between experimental groups.

Conclusions The Titan stapler conveys the mechanical benefits of higher burst pressure with the advantage of single load functionality. This single staple load eliminates staple line junctions without sacrificing the integrity of staple formation.

Keywords Bariatrics · Sleeve gastrectomy · Surgical staples · Novel stapler

Laparoscopic sleeve gastrectomy is the most common bariatric procedure performed worldwide, with an average excess weight loss of 55%, short operative time, relatively low rate of complications, and simplicity of technique [1–3]. The use of linear stapling devices to resect the lateral portion of the stomach is the established standard of care; being considered safe and straightforward to use, while minimizing tissue manipulation and reducing surgical procedure time [4]. Optimal stapler selection during laparoscopic sleeve gastrectomy requires a careful judgment of tissue thickness for adequate compression and hemostasis as well as appropriate technique to maximize mechanical integrity of the staple line, given the overlap and reorientation that can occur with multiple staple fires [5, 6]. Undercompression of tissue can lead to lower mechanical integrity as measured by burst pressure [7]. Conversely, overcompression of tissue can lead to serosal tearing and decreased mechanical integrity conferred by the incidence of malformed staples within the staple line [8]. Stapler junctions and increased number of staple firings along the gastrectomy staple line have been shown to further increase the risks of technical or mechanical staple line failures [9].

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A novel linear stapler was developed to perform a sleeve gastrectomy with a single stapler firing. The ultimate rationale for this stapler is to decrease technical and mechanical failure by eliminating junctions along the staple line, decreasing tissue manipulation and operative time, while optimizing gastric tissue compression. The aim of this study was to compare the performance of two commercially available and commonly utilized laparoscopic linear gastrointestinal staplers (Ethicon, Medtronic) with the novel linear stapler.

Methods

The study was designed to analyze the excised gastric tissue following standard laparoscopic sleeve gastrectomy following informed consent by all enrolled patients, with the goal was to enroll 15 patients in each stapler arm as a pilot study. The study was approved by the University of Cincinnati Institutional Review Board (IRB#2019-0010.)

Titan stapler

Standard Bariatrics, Inc. has developed a stapler specifically designed for longitudinal gastric resection (Fig. 1A). The specific design features of the Standard Titan device that enable a longer staple line are: (1) the stapler is movably coupled at both ends with alignment features that constrain the anvil laterally when closed; (2) the knife blade advances from the end of the device proximally along with a robust I-beam knife; (3) the stapler has more rigid jaws compared to current commercial gastrointestinal staplers, enabling the alignment of the device during staple formation. The stapler was also designed based an anatomic map of the human stomach obtained at 15 g/mm^2 of tissue compression [10]. The anvil face is slanted relative to cartridge face, which was derived from the linear human stomach tissue thickness decrease from the antrum to the fundus. The device produces staple heights from 2.2 mm at the proximal end of the device to 1.2 mm at the distal end. All staples formed decrease linearly in height from the proximal to the distal end of the device.

As with current commercial staplers, the Titan stapler is not individually adjustable to patient anatomy. The Titan stapler can be be inserted through a 19 mm trocar and was designed to staple an average human stomach based on freshly excised tissue data. Instructions for use recommend inking the intended staple line at three anatomical landmarks to map the ideal location prior to placement of the stapler; 1 cm from the GE junction, 3 cm from the incisura angularis and 6 cm from the pylorus. After clamping, tissue adjustments can be made to move the correct amount of stomach into the stapler if deemed necessary. Surgeons can position the stomach in a taller or shorter zone according to patient anatomy and perceived gastric thickness. Standard methods of reinforcement, such as clips, sealants, or oversewing may be used with the device based on surgeon preference. The intended placement of the Titan stapler around the stomach during laparoscopic sleeve gastrectomy is shown in Fig. 1B.

Tissue acquisition and measurements

The laparoscopic sleeve gastrectomies were performed per standard surgical practice using 60 mm Echelon Flex™

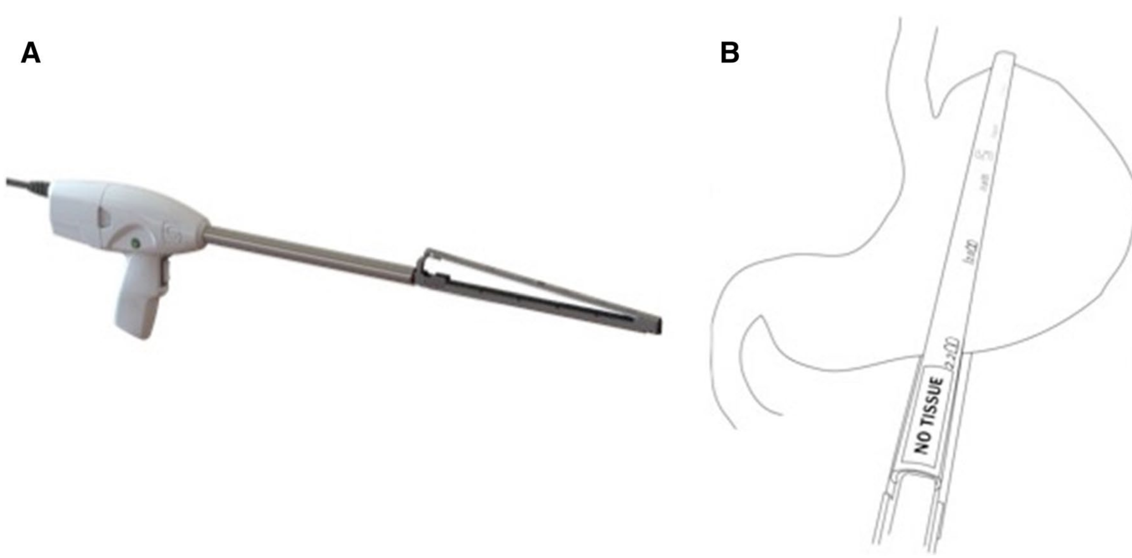

Fig. 1 **A** Titan stapler from Standard Bariatrics, Inc. The stapler has a 220 mm staple line from tissue stop to tissue stop. **B** Intended placement of Titan stapler around stomach

Powered Plus Stapler with GST staple reloads (Ethicon, Inc., Cincinnati, OH) Excised clinical gastric remnants were acquired at the time of laparoscopic sleeve gastrectomy and inspected for damage. A novel device was utilized to assess gastric tissue thickness (Standard Bariatrics, Blue Ash, Ohio) (Fig. 2A). The tissue thickness was then measured along 13 probes at 2 cm intervals from fundus to antrum using pressures of 8 g/mm^2 and 15 g/mm^2 [11]. Using a set algorithm to select staple cartridge load, an experimental staple line was created 2 cm lateral and parallel to the clinical staple line, using either the single load Standard Titan stapler, the predicate Ethicon Echelon Flex Powered Plus stapler with a series of 60 mm reloads, or the predicate Medtronic Signia Stapling System with EndoGIA Tri-Staple Technology with a series of 60 mm reloads. This algorithm is displayed in Table 1. The Titan stapler was able to traverse each gastric specimen in one fire, while the Ethicon and Medtronic staplers each used 4–5 cartridges to form a full staple line. Creation of this experimental staple line allowed for the division of the original clinical specimen into two pieces: the greater curve remnant that was used for burst pressure analysis, and the double-stapled sliver (clinical and experimental staple lines) for malformed staple measurement.

Burst pressure analysis

After experimental optimized staple firing, the greater curve remnant was insufflated under water to determine the staple line burst pressure. A needle was placed in the fundus of the stomach and the specimen was submerged under a plexiglass viewing window. Air was insufflated into the stomach at a rate of 300 mL/min. An intra-gastric pressure monitor and external cameras were used to determine the location and pressure at which the staple line failed, as indicated in real time by bubble detection in the water outside of the insufflated gastric remnant.

Staple analysis

The doubly stapled (clinical and experimental) gastric sliver underwent computed tomography (Fig. 2B). Using digital subtraction of tissue from the CT data, a 3D representation of the staple line was created (Fig. 2C). This was used to assess staple form (well-formed vs malformed staples) and staple height. Commercially available solid modeling software (GOM Inspect https://www.gom.com/3d-software/gom-inspect.html) was used to analyze each staple for junctional location, malformation, and height. The ratio of tissue thickness measured with 15 g/mm^2 pressure to experimental

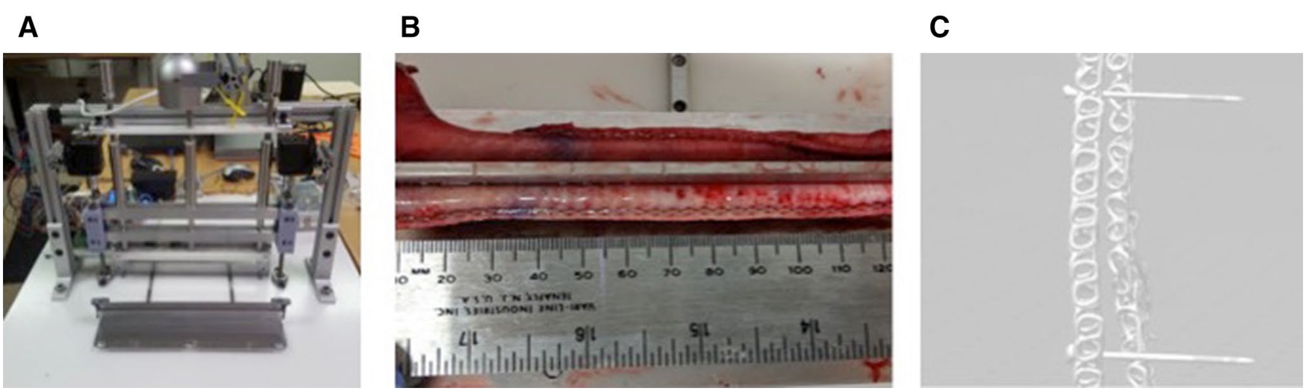

Fig. 2 **A** Standard Bariatrics Tissue Measuring Device used to measure gastric tissue thickness. **B** Experimental staple line pictured adjacent to the ruler on the "sliver" of tissue sent for CT scanning. The clinical staple line is the top staple line. **C** CT screenshot of sliver staple lines with pins stabilizing the tissue sliver to the foam board

Table 1 Standardized staple cartridge selection algorithm based on tissue thickness measured by the probe with 15 g/mm^2 pressure applied

Medtronic EndoGIA with tri-staple technology (60 mm)		Ethicon echelon powered plus 60 mm with GST	
Staple cartridge	Staple height (mm)	Staple cartridge	Staple height (mm)
Tan	Probe < 1.25	White	Probe < 1.5
Purple	1.25 ≤ Probe < 1.75	Blue	1.5 ≤ Probe < 1.8
Black	Probe ≥ 1.75	Gold	1.8 ≤ Probe < 2.0
		Green	2.0 ≤ Probe < 2.3
		Black	Probe ≥ 2.3

Table 2 Relationship of surgeon-selected clinical staple loads as compared to ideal load optimized for gastric thickness, by height of staple load selected

	Ethicon			Medtronic		
	% Taller than ideal	% Ideal	% Shorter than ideal	% Taller than ideal	% Ideal	% Shorter than ideal
1st load	31	19	50	16	61	22
2nd load	25	25	50	11	55	33
3rd load	25	56	19	5	22	72
4th load	19	63	19	0	11	83

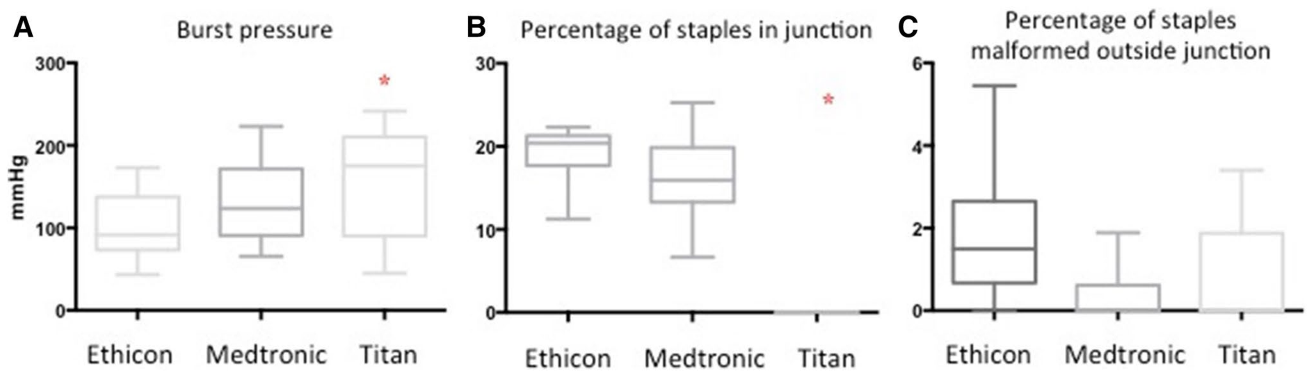

Fig. 3 **A** The gastric remnants created using a Titan stapler withstood a significantly higher average burst pressure at 159.8 mmHg than Ethicon (102.1 mmHg) and Medtronic (128.0 mmHg) linear cutting staplers ($p=0.01$). **B** Medtronic and Ethicon staplers had a similar percentage of staples measured within junctions of the specimen (19.0 vs 16.8; $p=0.16$), while the Titan stapler has no junctions. **C** The Medtronic and Titan staplers had no difference in percentage of malformed staples (0.37 vs 0.65%), while the Ethicon stapler had a significantly higher percentage (1.82%) of malformed staples ($p=0.05$)

staple height was calculated at each pressure probe site. Two way ANOVA was used for statistical comparison, and *p*-values ≤ 0.05 were considered statistically significant. Prism comprehensive statistics software (GraphPad Software, San Diego, CA) was used to perform all statistical analysis.

Results

Resected gastric sleeves were randomized to experimental groups for analysis, 18 in the Ethicon group, 18 in the Medtronic group, and 15 in the Titan group. Seventeen resected sleeve gastrectomy specimens were used with a preliminary prototype of the Titan stapler, and the results are not included in this analysis. Overall, the patient population was 22% male and 78% female; and 70.5% white and 29.5% non-white with a mean age 38.6 years and mean BMI 46.4 kg/m^2. There were no significant demographic differences between experimental groups. Comparison of clinical Ethicon and Medtronic stapler loads to the optimized gastric thickness driven experimental stapler loads is demonstrated in Table 2.

The gastric remnants created using a Titan stapler withstood a significantly higher average burst pressure than both Ethicon and Medtronic linear cutting staplers, shown in Fig. 3A. The location of the staple line failure and number of failures that occurred at a staple junction is displayed in Table 3.

Table 3 Location of burst and number of bursts occurring at a stapler junction, by stapler type

	Ethicon $N=17$	Medtronic $N=18$	Titan $N=15$
Burst location			
Remote to staple line	4	2	2
Staple line- top third	4	8	8
Staple line- middle third	7	3	5
Staple line- bottom third	2	5	0
Number of burst at stapler junction	6	6	0

There was no significant difference between groups by burst location ($p=0.45$)

The Medtronic and Ethicon staplers had a similar percentage of staples measured within junctions of the specimen (Fig. 3B), while the Titan stapler had no junctions, as it is a single fire stapler. In considering the formation of all staples outside of junctions, the Medtronic and Titan staplers had no difference in percentage of malformed staples, while the Ethicon stapler had a significantly higher percentage of malformed staples (Fig. 3C).

Further, a linear regression was completed comparing the average tissue thickness of gastric tissue with average staple height at each probe. Importantly, there were no significant differences in mismatch between optimally selected experimental staple height and tissue thickness between Ethicon (0.20 mm), Medtronic (0.14 mm), and Titan staplers (0.18 mm; $p=0.75$) (Fig. 4).

Discussion

These experiments demonstrate that the novel Titan stapler withstands higher burst pressure than clinically utilized Ethicon and Medtronic staplers. This is suggestive of higher mechanical integrity of the Titan staple line. This novel stapler has equal incidence of malformed staples as the industry standard staplers, without the technical disadvantage conferred by junctions in the staple line. In matching staple height to tissue thickness, the Titan stapler was not significantly different than Ethicon or Medtronic, but trended towards better matching in a linear regression.

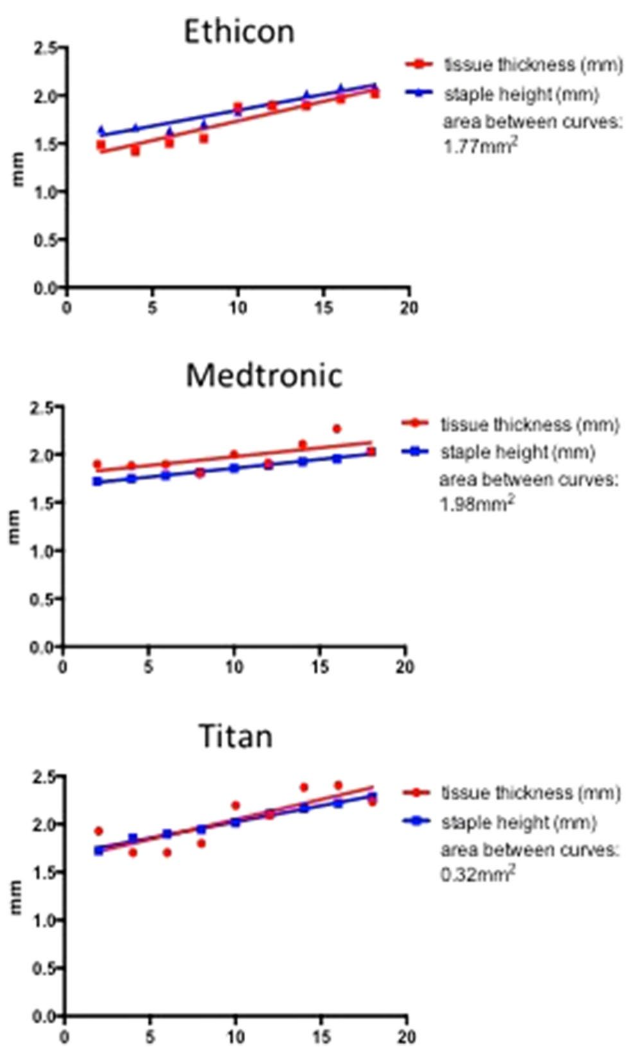

Fig. 4 A linear regression was performed using the average staple height and tissue thickness from each stapler type, and the area between the curves was determined. Titan stapler had the smallest average difference between the two curves

Improvements in staple technology play a pivotal role in bettering both clinical outcomes and operative technique in laparoscopic sleeve gastrectomy. While this procedure is popular in part due to low rates of major complications (less than 1% reported nationally) [1], the incidence of a gastric leak can have devastating consequences. Much of the operative technical success relies on the creation of a perfect linear staple line. A spiral or non-cylindrical gastric tube puts the patient at increased risk for gastric volvulus or functional gastric obstruction, resulting in high intraluminal pressures, and predisposing to leak [12]. In this study, the novel single-fire Titan stapler was shown to produce a stapled gastric specimen able to withstand higher burst pressures than the current industry standard, with a more uniform staple line, which may allow for a more cylindrical gastric sleeve. Additionally, our experimental cartridge selection algorithm was validated by our results. Both the Ethicon and Medtronic staplers conveyed higher burst pressures than was previously published [13].

Junctions in a staple line may cause points of staple mechanical failure or increased tissue ischemia, prompting development of a subacute leak. In our study, the Ethicon and Medtronic staplers had 35% and 33% of their burst locations occur at the junction between stapler fires, respectively. The Titan single-load linear stapler eliminates junctions along the staple line, removing potential points of weakness from each sleeve created. In each arm of the industry-standard staplers, six burst locations occurred at the staple load junction. With the single load, it could be argued that the lack of ability to change staple load colors across different thicknesses of gastric tissue could affect surgical outcomes. However, we analyzed the differences between tissue thickness and staple height from each specimen across the three different stapler types. The Titan stapler uses a single standard tapering staple height that showed no difference in match between staple height to tissue thickness, with both the industry standard staplers, and nonsignificantly trended towards having a smaller average difference between the two measurements.

Additionally, given the novelty of the Titan stapler, we compared the integrity of staple formation with the current industry standard. It has been demonstrated that increased incidence of staple malformation can compromise the staple line integrity, leading to higher rates of leak and hemorrhage [14]. The Titan stapler performed on par with the Medtronic stapler, with equivalent proportions of malformed staples outside of junctions. Both Titan and Medtronic outperformed the Ethicon stapler, which proved to have a significantly greater proportion of malformed staples outside of the junctions. The rate of optimal staple formation is thought to predict staple line failure [15], but further data to correlate is still needed [16].

Limitations of this study include the novelty of the tissue thickness analysis strategy, although the methods used were consistent across all specimens and stapler groups, While this study validates stapler performance in an *ex-vivo* model, this was an experimental pilot study of stapler performance and does not address clinical outcomes. Experiments were carried out using a late model prototype that is very similar but not identical to the final clinical product. A subsequent study of clinical performance of the Titan stapler production model is being designed for recruitment and will contain clinical outcomes including staple line leaks, staple line placement confirmation, and surgeon impression of appropriate staple line creation. Additionally, this study was sponsored by Standard Bariatrics, the inventor and manufacturer of the novel Titan stapler.

Conclusions

The novel single-fire tapered staple height Titan stapler conveys the mechanical benefits of withstanding higher burst pressure with the notable advantage of single load functionality. This single staple load eliminates staple line junctions without sacrificing the integrity of staple formation along the staple line. This new stapler may provide optimized stapling capability for the performance of laparoscopic gastric resections.

Compliance with ethical standards

Disclosures Dr. Jon Thompson is the founder and CMO of Standard Bariatrics, Inc. Dr. Salyer, Dr. Goodman, Mr. Spuzzillo, Mr. Wakefield, and Ms. Gomaa have no conflicts of interest or financial ties to disclose.

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