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Advances in Usability and Performance of a Linear Stapler-Cutter

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ABSTRACT

Background: *Linear staplers are widely utilized in a variety of surgical procedures to cut, remove, and connect tissue with technology that is constantly evolving and improving. The Echelon Linear Cutter was recently launched with improved tissue handling via Gripping Surface Technology (GST), advanced 3D staple formation, and an ergonomic design with locking halves for one-handed operation. This study was performed to compare the new stapler to the previous version, the Proximate Linear Cutter.*

Methods: *Comparisons between the two staplers were performed in porcine models to evaluate staple formation, compression uniformity, leakage at the staple line, and tissue grasping force. Surgeons evaluated the usability and performance of the Echelon stapler in a simulated procedure.*

Results: *Compared to the Proximate stapler, the Echelon Linear Cutter had significantly lower rates of malformed staples in thin (colon) and thick (stomach) tissue. In addition, results showed the new stapler had more uniform compression, higher tissue grasping force, and higher leak pressure at the staple line. Surgeons found the new stapler easy to assemble, control, place with one-hand without assistance, and capable of capturing thick tissue.*

Conclusion: *In preclinical testing, the new Echelon Linear Cutter with GST, 3D staples, and locking halves allowing for one-handed device placement offers improved tissue manipulation, stapling and ergonomics compared to the previous stapler. Clinical testing is necessary to determine whether these benefits extend to patient outcomes.*

Keywords

Linear stapling, Linear cutter, Staple line leaks, Tissue grasping, Tissue manipulation, Staple line pressure, Usability.

Introduction

Linear surgical staplers are commonly utilized in general and thoracic surgical operations to perform tissue transection, resection, and establish anastomoses. Technical features, correct selection of staplers and cartridges, and appropriate tissue handling are essential factors that contribute to achieving optimal interaction between the stapler and tissue [1].

The Ethicon linear cutter platform has provided dependable and uniform staple lines for over 25 years. In a study by Edholm [2], linear staplers had shorter operative time, less wound infections, and shorter length of stay in laparoscopic Roux-en-Y gastric bypass. Linear staplers have also been successfully used for securing the distal rectum during low anterior resection in mid to low rectal cancers [3], in esophagojejunostomy surgery [4], and stapled anastomosis of gastro/duodenojejunostomy in pancreaticoduodenectomy [5].

The new Echelon Linear Cutter (Figure 1) features several improvements over the previous version, the Proximate Linear Cutter. Key enhancements include Gripping Surface Technology (GST), 3D staples, and the ability to lock the halves together for one-handed operation. When using stapling devices, surgeons are interested in managing the risk of leaks and improving outcomes.

Gripping Surface Technology and 3D stapling design has been incorporated into the Echelon Linear Cutter to improve device tissue interaction by providing lower tissue slippage via GST and more evenly distributed compression with 3D stapling technology [6].

Figure 1: The Ethicon Echelon Linear Cutter.

Prior research has associated GST with a decrease in intraoperative staple line interventions, such as endoclip placement, oversewing, and targeted cautery compared to standard reloads [7]. Retrospective studies in thoracoscopic lobectomy and radical nephrectomy showed that the GST technology was associated with fewer hemostasis-related complications and reduced hospital costs [8,9]. 3D stapling technology was designed to equally distribute the compression throughout the staple line. A review by Rojatkar et al., showed that 3D staples had lower variability in compression pressure, and higher onset leak pressures than 2D staples in both linear cutters and circular staplers [10].

Recent studies have shown the impact of surgeon ergonomic strain during minimally invasive surgery. A recent meta-analysis found that more than 80% of gynecologic surgeons who engage in laparoscopy reported experiencing musculoskeletal symptoms. Of this group, 30% sought treatment for their symptoms, while 3% required modifications to their work hours [11]. The assembly and firing of a linear stapler during a procedure can be challenging and may require two individuals to assemble in place. The new linear cutter stapler provides surgeons with the option to keep the device halves locked, or to separate them, which offers better control of the device placement when navigating a patient's anatomy.

The aim of this study was to compare the performance of the Echelon stapler with GST reloads and 3D staples to the previous Proximate Linear Cutter using porcine tissue and evaluating key elements of device performance, such as staple formation, compression uniformity, leakage at the staple line and grasping force. Usability and performance was also evaluated by a survey of surgeons who used the Echelon Linear Cutter in a simulated surgical procedure.

Methods

Staplers evaluated were the ECHELON LINEAR™ Cutter (GLC80 with GLCR80B/G reloads, Ethicon, Inc., Cincinnati OH) and the Ethicon PROXIMATE® Linear Cutter (TLC75 with TCR75/TRT75 reloads, Ethicon, Inc. Cincinnati OH) [12].

All *in vivo* procedures were reviewed, and animals approved for use by an Institutional Animal Care and Use Committee in compliance with the US Animal Welfare Act Regulations (9CFR, Parts 1, 2 & 3) and the Guide for the Care and Use of Laboratory Animals of the Association for Assessment and Accreditation of Laboratory Animal Care, International (AAALAC).

Malformed staples

Stapling performance was compared in excised porcine colon and stomach under thin and thick tissue environments for GLC80 and TLC75 using Blue or Green reloads. Blue reloads were evaluated on porcine colon of average thickness 2.5mm, and green reloads on porcine stomach of average thickness 3.3mm. Firings on stomach tissue were across the large curvature, while firings on colon tissue were along or at an angle to the colon to allow the tissue to cover the whole cartridge deck. Staple lines were scanned using computer tomography and analyzed using Kinetic Vision software 1.6.0.0 (Kinetic Vision, Cincinnati OH). Staple form was categorized on a 5-point Staple Form Quality (SQF) scale [13]. Malformed staples were considered to be those with an SFQ category of 3-5. The rate of malformed staple legs was compared using a normal approximation or Fisher's exact test if the number of samples in any cell was 5 or below. All tests used an alpha of significance of 0.05.

Compression uniformity

Staple line compression was measured by assessing the deformation of 3-mm ethylene-vinyl acetate foam (Shanghai Moyuan Industrial Co., Shanghai, China). After stapling, the foam was glued on flat plastic tongue depressors and scanned using Laser Keyence VR-5000 (Keyence Corporation of America, Itasca, IL) for surface topology determination. The surface topology contained the compressed foam (in the Z-axis) in the staple line zone. The compression strain from the staple to the foam was calculated using the strain formula ($\varepsilon = \Delta l/l$) through the deformed Z-axis value in the thickness direction. The coefficient of variation of compression pressure (i.e., strain) was compared via Student's t-test with an alpha of significance of 0.05.

Leaking

Staple lines were created on 1.5 ± 0.2mm harvested porcine colon tissue using Blue reloads for both GLC80 and TLC75. The pressure at the onset of leak was evaluated by filling the lumen of stapled tissue with aqueous blue dye indicator while the sample was submerged in a visualization tank. The test fluid was injected at a rate corresponding to an increase in pressure of 30 mmHg per minute. Pressure was recorded at the observed onset of leaking of the blue dye. Comparisons were made for average onset of leak pressure via Student's t-test, and for the proportion of

leaking samples at or below 25, 30, and 35 mmHg using a normal approximation unless the number of samples in any cell was 5 or below, in which case Fisher's exact test was used. All tests used an alpha of significance of 0.05.

Cutting and Grasping

A comparison between the tissue cutting force and tissue grasping force at the cutting location was performed to evaluate the likelihood of tissue movement during firing of the stapler. Prior to testing the grasping and cutting forces, staples were removed from the reloads. While the formed staple can help to hold the tissue, staples cause the tissue to be stretched between the knife and the staple leg, which could affect the leak performance (fluid leak and bleeding) of the staple line. Tissue was selected for appropriate thickness for porcine centrifuged stomach (2.0-2.5 mm) and colon tissue (1.5-2.0 mm). A dry run without tissue was performed to measure baseline friction. Precompression time before knife movement was 15 seconds after closure of the device. Using a new stapler with a sharp knife the tissue cutting force was measured while grasping tissue. The cutting force was measured at the middle of the cut, where the force was highest. The knife was then mechanically dulled, and grasping force was measured with the same stapler while grasping tissue and pushing the dulled knife. The force-displacement curves were analyzed to measure the cutting and grasping forces. Tissue slippage potential was defined as the grasping force being lower than the tissue cutting force.

Usability

In the usability evaluation, participants were asked to complete use scenarios in which they performed simulated procedures relevant to their surgical specialty (colorectal, general, gastric, thoracic) using GLC80. Colorectal and general surgeons performed a porcine jejunojejunostomy, gastric surgeons performed a gastrectomy and a gastroenterostomy, and thoracic surgeons performed a wedge resection. Following the simulated procedures participants responded to seven predesigned assessment statements using a 5-point Likert scale of "Strongly Agree", "Agree", "Neither Agree nor Disagree", "Disagree" or "Disagree Strongly." Participants were asked what brand stapler they normally use. Statements were centered around one-handed positioning of the device during creation of anastomosis or transection. Statistical analysis was performed on the proportion of "Strongly Agree" and "Agree" responses out of total responses via a one-sample proportion test with a hypothesized value of 0.5.

Results

Malformed Staples

In 2.5mm colon tissue, GLC80 had 62% fewer malformed staple legs than TLC75, whereas in 3.3mm stomach tissue, GLC80, with no malformed staples of over 5000, had 100% fewer than TLC75 (Table 1, Figure 2).

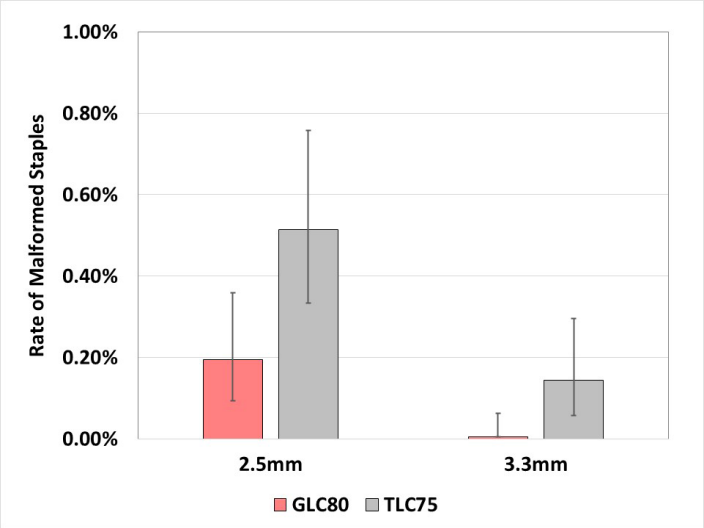

Figure 2: Rate of malformed staples for GLC80 and TLC75 in 2.5mm and 3.3mm tissue. Error bars represent 95% confidence intervals.

Compression Distribution

GLC80 staplers with blue reloads had a 3.1% lower coefficient of variation of compression pressure than TLC75.

Leak Pressure

GLC80 had 34% higher average onset leak pressure than TLC75, and 90% fewer leaks occurring below or at a pressure of 25 mmHg, 47% fewer leaks occurring below or at a pressure of 30 mmHg, and 44% fewer leaks occurring below or at a pressure of 35 mmHg (Figure 3).

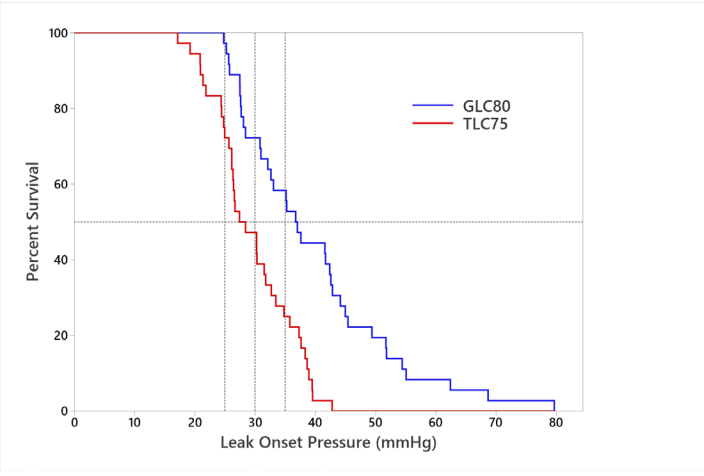

Figure 3: Survival plot of leak onset pressure for GLC80 and TLC75, with pressure criteria reference lines for 25, 30 and 35 mmHg and median percent survival.

Cutting and Grasping Force

GLC80 had an 87% higher grasping force than TLC75 in stomach tissue and 94% higher force in colon tissue (Figure 4). Additionally, the difference between grasping force and cutting force was 122% greater for GLC80 than for TLC75 in stomach tissue and 197% higher in colon tissue.

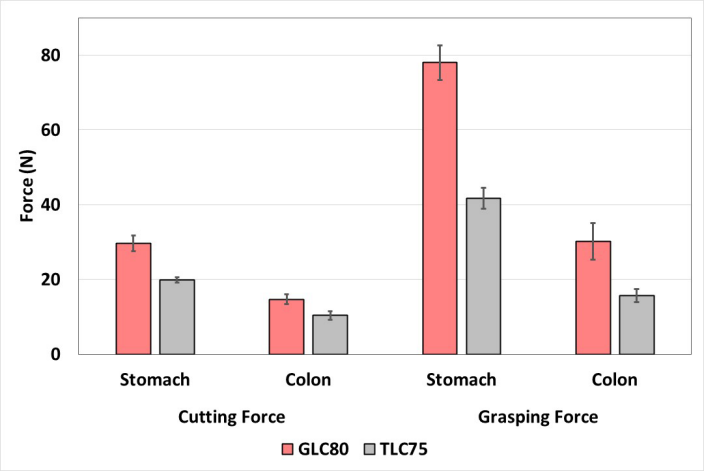

Figure 4: Cutting and grasping force for GLC80 and TLC75 in stomach and colon tissue. Error bars represent 95% confidence intervals.

Table 1: Summary of Comparisons of GLC80 and TLC75.

Measure	GLC80	TLC75	p-value
Malformed Staples			
2.5mm tissue	0.20% (10/5118)	0.51% (25/4864)	0.008
3.3mm tissue	0.0% (0/5120)	0.14% (7/4864)	0.006*
Compression pressure			
Coefficient of variation	7.20%	7.44%	0.012
Leak Onset Pressure			
Average	39.7 ± 13.0 mmHg	29.5 ± 6.7 mmHg	<0.001
Median	36.7 mmHg	27.4 mmHg	
Leaks			
≤25 mmHg	2.8% (1/36)	27.8% (10/36)	0.006*
≤30 mmHg	27.8% (10/36)	52.8% (19/36)	0.025
≤35 mmHg	41.7% (15/36)	75.0% (27/36)	0.002
Cutting Force			
Stomach (n=30)	29.62 ± 5.67 N	19.86 ± 1.97 N	<0.001
Colon (n=18)	14.62 ± 2.76 N	10.34 ± 2.30 N	<0.001
Grasping Force			
Stomach (n=30)	78.00 ± 12.62 N	41.68 ± 7.50 N	<0.001
Colon (n=18)	30.23 ± 10.36 N	15.60 ± 3.71 N	<0.001
Δ(Grasping:Cutting Force)			
Stomach			
Difference	48.38 ± 13.84 N	21.82 ± 5.26 N	<0.001
Ratio	2.63	2.10	
Colon			
Difference	15.61 ± 10.72 N	5.26 ± 4.37 N	0.001
Ratio	2.07	1.51	

* Using Fisher's exact test.

Usability

After using the GLC80 in simulated procedures, surgeons significantly appreciated the stapler for one-handed use, ability to capture thick tissue in the wide jaws, less need for assistance, ease of connecting the device together, and control of the device (Table 2). Although surgeons were favorably disposed, the dual firing knobs and placement precision were not significantly superior.

Table 2: Usability Survey.

No.	Topic	Post-use Statement	% Agree or Strongly Agree	p-value (> 50%)
1	Ease of connecting	Compared to my usual device, the test device's halves were easier to connect at the proximal end.	70% (26/37)	0.010
2	Control of device	I have greater control of device placement on tissue when the halves are locked.	65% (24/37)	0.049
3	Placement precision	I can more precisely place the test device on tissue compared to my usual device.	51% (19/37)	0.500
4	One-handed use	The test device enabled simple, one-handed positioning and placement when the halves are locked.	86% (32/37)	<0.001
5	Need for assistance	I require less assistance during placement on tissue when the halves are locked.	73% (27/37)	0.004
6	Thick tissue capture	When the device's halves are locked, the wide jaw aperture allowed for easier engagement on thick tissue compared to my usual device.	81% (30/37)	<0.001
7	Dual firing knobs	The test device's dual firing knobs allowed for more versatile firing positions compared to my usual device.	57% (21/37)	0.256

Discussion

Surgical devices are continually evolving with the goal of providing clinical value to surgeons and improving patient outcomes. The advancements in surgical device technology have played a significant role in achieving these improved outcomes. One such device is the GLC80 that in this study has been compared to its predicate, the TLC75. The GLC80 contains the newest innovations in linear staplers including Gripping Surface Technology (GST), 3D stapling, and the ability to connect the proximal portion of the jaws to create a single piece for easier manipulation and one-handed use.

Gripping Surface Technology provides elevations in the cartridge deck surrounding the staple legs that reduces tissue slippage between the jaws, as well as guides staples into a correct trajectory into the tissue [14,15]. Kimura et al. used porcine small bowel in an ex-vivo study to evaluate the number of malformed staples and degree of malformation and found significantly less malformation of staples with GST versus a traditional flat-deck stapler [16]. Real-world studies have shown clinical effectiveness in reducing postoperative complications, such as anastomotic leaks, hemorrhage, and stenosis [7,8,17-19]. In our study, we evaluated the effectiveness of GST and the creation of malformed staples in the new GLC80 linear stapler compared to the TLC75. A 62% reduction in staple malformation occurred with use of the GLC80. We utilized grasping force as a proxy for tissue slippage, and observed up to 94% higher grasping force and almost double the difference in grasping and cutting force, enabling far less tissue slippage.

Introduction of a 3D stapling technology is a newer innovation that creates a 3-dimensional formation of a fired staple as opposed to

the flat "B" formation in standard staples. The 3D formation was developed to produce a uniform path of compression with a larger surface area that would ideally reduce leak paths and require less force from application of the device to reduce tissue injury [10]. Rojatkar, et al. compared pressure distribution forces of 2D and 3D staples and found less variability in compressive forces near and within the staple line. The authors also used excised porcine tissue to test pressure leak rate and found a 61% higher leak onset pressure and 47% lower leak rate below 30 mmHg when compared to 2D staples. In clinical studies when 3D staples have been used, reduced anastomotic leakage, shorter hospital stays, lower rate of anastomotic bleeding, and re-operation have been reported [20-22]. In our study, the GLC80 with 3D staples had significantly less pressure variation in the staple line compared to the TLC75. Additionally, the average onset leak pressure was 35% higher for GLC80 than for TLC75 and the leak rate at 30 mmHg or below was 47% lower.

Ergonomics is receiving more attention in surgery to ensure that difficulty in device usage does not hinder surgical tasks. Wells, et al. surveyed 569 endoscopic and gastrointestinal surgeons and found that 50% were experiencing musculoskeletal pain during their surgeries [23]. This physical discomfort gave rise to fear for career longevity, created lower satisfaction, higher burnout, and more callousness toward colleagues. Multiple specialties that involve minimally invasive procedures have expressed similar sentiments [11,24,25]. Given the strain of surgery, improved ergonomics in devices is needed on a system-wide level. GLC80 provides improved ergonomics and usability via the one-piece proximal connection that allows for one-handed operation of this linear stapler. In a survey after use in a porcine model simulating actual usage, 70% of surgeons agreed that the two halves of the GLC80 were easy to connect, and 86% of surgeons agreed that the device was simple to manipulate and place in the desired location. In addition, 73% of surgeons agreed that they needed less assistance while using the GLC80, and 81% of surgeons agreed that when the proximal end was locked, the wider jaw aperture allowed for thicker tissue capture.

Conclusion

The technical characteristics of surgical staplers may play a role in preventing complications. This study has demonstrated that Echelon Linear Cutter provides even compression, low leakage rates, better tissue grasping, low rates of malformed staples and improved ease-of-use compared to the Proximate stapler. The results have the potential to provide valuable guidance to surgeons when they are choosing a linear stapler in benefiting patients and advancing the field of surgery.

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