Research Article
Volume 19:02, 2023

Journal of Surgery [Jurnalul de chirurgie]

ISSN: 1584-9341 Open Access

Safety and Usability of the Echelon Endopath Staple Line Reinforcement in Gastric Resections

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Abstract

Background: Staple line integrity is of upmost importance to surgeons in gastric surgery. Staple line reinforcement is utilized to improve strength and stability of the staple line. The Echelon Endopath™ SLR (Staple Line Reinforcement, ESLR) was developed for staple line reinforcement. Our goal is to present results from a real-world study using the ESLR in gastric procedures.

Methods: A prospective, single-arm, multi-center, post-market study was performed to determine the incidence of device-related adverse events (AEs) through 70 days post-procedure in gastric procedures. AEs were defined as staple line bleeding, intra- or post-operative leak and radiographically documented stricture. Secondary outcomes were number of devices replaced intraoperatively due to bunching or slippage. Eligibility included subjects who underwent elective gastric resections in which ESLR was used.

Results: Of the 109 subjects enrolled, 98 completed the study with a mean age of 45.5 ± 11.3 years and a majority female (83.5%). All procedures were performed laparoscopically, with sleeve gastrectomy being the most commonly performed (77.1%), followed by Roux-en-Y gastric by-pass (22.9%) and other (0.9%). There were no reported cases of leak, bleeding, or strictures deemed device related though there was one intraoperative leak (anastomotic leak), which was deemed not related. Ten device replacements (out of 637 firings) occurred none of which was a result of slippage or bunching. Surgeons reported less frustration with set-up and ease-of-use of the device (100%), with the majority expressing strong or slight agreement that there was less buttress manipulation and movement during the procedure (75%).

Conclusion: In this study, the ESLR was shown to be effective and safe for buttressing staple lines during certain bariatric procedures.

Keywords: Buttress • Stapler • Surgery • Gastric • Bariatric • Staple line reinforcement

Introduction

Surgeons have commonly utilized stapling devices for the rapid and efficient cutting and securing of tissue [1]. Bariatric surgery is one specialty that heavily relies on the creation of robust staple lines for the creation of intestinal anastomoses, gastric pouches during bypass procedures, or transecting the stomach during a gastric sleeve operation [2]. Although stapling devices are frequently used in bariatric procedures resulting in low rates of bleeding and leakage at the staple line, such complications can still occur post-operatively and lead to increased healthcare costs and patient morbidity and mortality [2,3]. these staple line complications have been found to be ameliorated with a variety of techniques including buttressing, over-sewing the staple line, or reinforcement with fibrin, synthetic glue, or synthetic material. This study presents a buttressing technique using staple line reinforcements (SLRs), which are designed as an adjunct to staples to support soft tissue at the staple line in order to redistribute stress, minimize space between staples and improve peri-operative hemostasis [2-6].

Frequently used buttressing reinforcement materials include bovine pericardium and biocompatible glycolide copolymers [7,8]. Historically these SLRs have required manual attachment of flat reinforcement strips to the stapler's anvil and cartridge immediately prior to use with an adhesive agent like gel or shoelace-like strings which need to be removed prior to firing. However, these methods of reinforcing the staple line can increase operative time and issues with twisting, slippage and bunching can occur with any unintentional movement of the buttress [9].

Smaller studies have shown that buttressing with bovine pericardium is well tolerated and has resulted in decreased staple leak rates and shorter length of hospital stay for patients, while other reports have demonstrated a statistically significant reduction in bleeding rates and leak rates at the staple line in comparison to non-reinforced, suture reinforced, or biological material reinforced staple lines [2]. Despite this, some surgeons opt not to reinforce their staple lines due to lack of consensus on efficacy of staple line reinforcement, concern of cost and difficulty in usage of buttressing techniques [2-10]. A novel SLR, the Echelon Endopath Staple Line Reinforcement (ESLR, Ethicon, Inc., Cincinnati, OH), which was approved for commercial distribution in October 2019, was developed for ease-of-use in surgical procedures where soft tissue transection or resection is occurring. This unique buttress is comprised of a high tensile synthetic and rapidly absorbable material which attaches to the anvil and cartridge of the stapler with a simple click-and-go

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Received: 02 March, 2023; Manuscript No. JOS-23-90595; **Editor Assigned:** 04 March, 2023; PreQC No. P-90595; **Reviewed:** 21 March, 2023; QC No. Q-90595; **Revised:** 27 March, 2023, Manuscript No. R-90595; **Published:** 04 April, 2023, DOI: 10.37421/1584-9341.2023.19.85

applicator thus eliminating multiple steps for attachment which other SLR's require [6]. While the ESLR has been utilized for reinforcement of staple lines during lung resection, bariatric, gastric, small bowel and colorectal procedures, real-world data is sparse [11]. Thus, the study presented here was performed to prospectively assess safety and efficacy data from a subset of patients undergoing gastric procedures in which the ESLR was utilized.

Methods

This prospective, single-arm, multi-center study was conducted in a post-market setting to evaluate the safety of the Echelon Endopath SLR (Staple Line Reinforcement, i.e., ESLR, [ECH60R, Ethicon Inc., Cincinnati, OH]) in subjects undergoing clinically indicated gastric surgical resections. The device was used in compliance with the Echelon Endopath SLR Instructions for Use (IFU). All subjects provided informed consent and were screened for eligibility anytime during the 8 weeks prior to surgery. A subject was considered "treated" when at least one ESLR was placed during a procedure. All treated subjects were followed for approximately 19 weeks post-operatively (day 28, 70 and 135 [± 14 days]). Individual sites sought IRB (Institutional Review Board) approval prior to study onset and the study was conducted in accordance with ICH (International Conference on Harmonization) Harmonised Tripartite Good Clinical Practices (1996), the Helsinki Declaration (2008) and any pertinent local and federal regulations.

Inclusion/Exclusion

Criteria for inclusion included surgical candidates ≥ 18 years of age who were willing and able to provide informed consent and who were scheduled to undergo any of the following gastric primary procedure in which the use of the ESLR was being planned for reinforcement of staple line: laparoscopic gastric resection, robot assisted laparoscopic gastric resection, partial gastrectomy, gastric wedge resection, subtotal gastrectomy, laparoscopic Roux-en-Y gastric bypass and robotic laparoscopic gastric bypass. Potential subjects were excluded if any of the following were true: 1) physical or psychological condition which could impair their ability for participation; 2) BMI ≥ 50.0 kg/m^2, 3) procedure was a reoperation or revision in the same anatomical location, 4) procedure in which an extended wound or organ support was mandated, 5) medical condition which could impact inflammatory or immune response, 6) concurrent medication usage which could influence wound healing, 7) history of hypersensitivity to polyglactin (Vicryl®), polydioxanone (PDO or PDS), or related products, or 8) enrollment in a simultaneous interventional clinical trial which could impact study endpoints. Intraoperative exclusion included presence of adhesions that could, in the opinion of the surgeon, lead to an increased risk of leak at a different location (other than the staple line) and a change in the surgical plan where the ESLR was not utilized.

Study endpoints

The primary study endpoint was the incidence of specific device-related adverse events (AEs) through 70-day post-procedure follow-up. Specific primary endpoint AEs were defined as: 1) bleeding (occurrence of post-operative blood transfusion deemed related to staple line bleeding and/or return to the operating room before the 70-day follow-up due to staple line bleeding), 2) leak (incidence of intra- or post-operative gastrointestinal leak related to staple line as documented intra-operatively, by clinical exam, or radiographically) and 3) stricture (number documented radiographically or endoscopically at the staple line). Secondary performance endpoints were the number of devices replaced during surgery due to slipping or bunching or not properly loaded onto the stapler cartridge. Additionally, a 9-item questionnaire was completed by each site after completion of gastric procedures number 1, 3 and 5 to assess usability of device. A scale of 1 to 5 was used and mean scores calculated for each response

Data variables collected

As part of screening, demographic and subject baseline characteristics were collected which included age, gender, race, ethnicity, height, weight, medical and surgical history, ASA classification, tumor incidence/location/staging and use of pre-surgical radiation or chemotherapy (90 days prior to surgery). Surgical variables were collected pre-, intra- and post-operatively which included the: number of devices used during procedure; number of devices replaced during surgery due to slippage, bunching, or misfiring; interventions for intra-operatively for staple line bleeding; blood loss and transfusions; potential chest tube placement; conversion to open; bleeding, leak or stricture related to staple line bleeding; concurrent surgical procedures or medication use; length of stay (LOS) and procedure-related readmission. A complete schedule of events is outlined in (Table 1).

Statistical plan

No formal statistical hypothesis was defined a priori given the single-arm nature of this study. Summary statistics were performed for subject demographic data. Number and percentage of subjects experiencing an occurrence of the primary endpoint were summarized and a 95% confidence interval estimated. Similarly, the number and percentage of subjects experiencing each component of the composite endpoint were summarized. AEs and Serious AEs (SAE) summaries were calculated for those deemed device-related and procedure-related. A post-hoc analysis was later performed to assess all adverse events and their relatedness to the study device. The questionnaire results are presented in a summary fashion as well. All statistics were performed *via* SAS software (version 9.4: SAS Institute, Cary, NC, USA).

Table 1. Schedule of events.

Activity	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Unscheduled Visit, if applicablea
	Screening (-56 to -1 Days)	Procedure (Day 0-discharge)	Post-Procedure Follow Up (28 ± 14 days)	Post-Procedure Follow Up (70 ± 14 days)	Post-Procedure Follow Up (135 ± 14 days)	
Informed consent	X					
Demographics	X					
Height and weight	X					
Medical and surgical history	X	X				
Review of inclusion/exclusion criteria	X	X				
Surgical data collected for evaluation		X				
Device usability questionnaire*		X				
Concomitant procedures conducted		X	X	X	X	X
Concomitant medications	X	X	X	X	X	X
Device-related and procedure-related Adverse Events		X	X	X	X	X
Video Assessment (as applicable)		X				
Unscheduled visits (if applicable)						X
Subject completion/discontinuation		X	X	X	X	X

*The device questionnaire was completed after an investigator's 1st, 3rd, and 5th procedure

Results

This study was performed at 4 individual sites. Of the 115 subjects who provided informed consent, 109 were enrolled in the study of which 104 (95.4%) contributed to the primary endpoint. Screen failures were due to completion of anticipated enrollment prior to the subject's scheduled gastric procedure. A total of 98 subjects completed the study. The mean age at consent was 45.5 ± 11.3 years with a predominance of females (83.5%) (Table 2).

Provides a complete overview of baseline subject demographics. The most performed procedure was sleeve gastrectomy (77.1%) followed by Roux-en-Y (22.9%) and other (0.9%). Indications for surgery included weight loss (92.7%), weight loss/metabolic (5.5%), metabolic (0.9%) and multiple factors (0.9%). The American Society of Anesthesiologists (ASA) scores assessing physical status ranged from ASA II (9.2%), ASA III (89.9%), to ASA IV (0.9%). Most subjects (50.5%) were reported to have never smoked, while 48.6% were former smokers and 0.9% were current smokers. All procedures were laparoscopic with the mean procedure duration being 1.2 ± 0.6 hours and an estimated blood loss of 24.1 ± 14.5 mL there were no conversions to open procedures. There was one intraoperative anastomotic leak which required oversewing at the leak point after which an additional leak test was performed and no further leak detected. This leak was deemed not to be related to the device. There were no reported cases of bleeding or strictures deemed possibly, probably, or causally related to the device. In a post-hoc review of all specific AEs, there were none that were determined to be possibly, probably, or causally related to the device.

Of 109 subjects in whom the ESLR was used at least once, 89 did not require intervention for intraoperative bleeding (81.7% of the time no intervention was required). Interventions used included hemoclips (n=14, 12.8%), sutures (n=4, 3.7%), fibrin sealants (n=1, 0.9%) and a combination of hemoclips with a monopolar energy product (n=1, 0.9%) (Table 3).

There were 239 AEs reported during the study in 74 (67.9%) of subjects and were not deemed related to the device. Most of the AEs were gastrointestinal (GI) related (n=146, 52.3%) with nausea being the most common (n=39, 31.2%). Eighteen AEs related to injury and procedural complications were reported of which incision site pain was the most frequently reported (n=8, 7.3%). Other AEs included metabolic/nutrition (n=9), nervous system (n=16), respiratory, thoracic and mediastinal (n=18), GI and administration site (n=10) and skin and subcutaneous tissue (n=9) disorders.

Of the total 637 device firings which occurred during the study period, 10 device replacements occurred: 7 were due to being improperly loaded, one was due to a wrong color reload, one instance where the technician did not have the reload in prior to the buttress being added and one buttress dropped on the floor. No reloads were replaced due to slippage or bunching.

In a questionnaire, device usability was rated by surgeons most of whom reported experiencing less buttress manipulation and movement during the procedure with the ESLR than other commercially available SLRs (strongly agree 25%, slightly agree 50%, neutral 25%). All expressed that the ESLR simplified setup and that their OR staff was less frustrated with its use. One surgeon "slightly disagreed" when queried about having greater confidence that the ESLR buttress material would deliver the best outcomes when compared to previous reinforcement material. Complete usability responses are provided in Table 4 and Intraoperative interventions required are provided in (Table 5).

Discussion

This observational study demonstrates an acceptable safety profile and generally positive surgeon usability responses for the ESLR in gastric procedures in the study population. Feared complications in GI surgery include bleeding and leaks at the staple line along with its attendant risks [12,13]. Soft tissue reinforcement is thus utilized by GI surgeons. Downey DM, et al [14] and Zafar SN, et al [15] report that 75% of GI surgeons perform some form of reinforcement of which 57% use a buttressing material and 43% oversew the staple line. A meta-analysis performed by Shikora SA, et al. evaluated 253 gastric surgery studies found that bleeding and leak rates were improved with any kind of SLR [3,12].

Key safety parameters for this study included bleeding, leak, or stricture deemed related to the study device. All AEs were surgeon-assessed. The rates as determined by both the primary endpoint analysis and eventual post hoc analysis are lower than the event rates previously identified in literature. A comprehensive literature search was undertaken to ascertain reported select safety and usability outcomes over the past 5 years for permanent, semi-absorbable and absorbable SLRs. Based upon a meta-analysis performed by Aiolfi A, et al., which included 796 patients and a registry study with 107,726 patients, the reported bleeding rate was determined to be between 0.20-1.87% [16,17]. Staple line leak rates after the use of semi-absorbable SLR during gastric surgery were reported to be between 0.87-3.74% in two meta-analyses which included 2,932 patients [17,18]. Stricture rates were reported to be 1.56% [18]. Results from our study were well within these ranges with one device-related AE of anastomotic leak (0.96%) being identified. It is important

Table 2. Baseline subject demographics.

Variable	Category/Statistic	Gastric (N=109)
Age at consent (years)	Mean (SD)	45.5 (11.3)
	Median (Min, Max)	45.0 (21.0, 79.0)
Gender n (%)	Male	18 (16.5%)
	Female	91 (83.5%)
Ethnicity n (%)	Hispanic or Latino	6 (5.5%)
	Not Hispanic or Latino	99 (90.8%)
	Not Reported	4 (3.7%)
Race n (%)	American Indian or Alaska Native	1 (0.9%)
	Asian	1 (0.9%)
	Black or African American	15 (13.8%)
	White	85 (78.0%)
	Not Reported	4 (3.7%)
	Multiple	0 (0.0%)
	Other	3 (2.8%)
Height (cm)	Mean (SD)	167.0 (9.6)
	Median (Min, Max)	166.0 (144.2, 195.6)
Weight (kg)	Mean (SD)	118.2 (15.5)
	Median (Min, Max)	115.6 (83.9, 158.2)
Body Mass Index (kg/m^2)	Mean (SD)	42.3 (3.4)
	Median (Min, Max)	42.1 (34.0, 49.5)

Table 3. Intraoperative and discharge characteristics.

Characteristic	Category/ Statistic	Gastric (N=109)
Procedure Duration (hours)	Mean (SD)	1.2 (0.6)
	Median (Min, Max)	0.9 (0.5,3.1)
Surgical Approach	VATS	0 (0.0%)
	Open	0 (0.0%)
	Laparoscopic	109 (100.0%)
	Robotic	0 (0.0%)
Conversion to Open Procedure	Yes	0 (0.0%)
	No	109 (100.0%)
Volume of Estimated Blood Loss (mL)	Mean (SD)	24.1 (14.5)
	Median (range)	20.0 (5.0,50.0)
Subjects with at Least 1 Intervention for Intraoperative Bleeding[1]	Yes	20 (18.3%)
	No	89 (81.7%)
Type of Hemostatic Intervention Used[1]	None	89 (81.7%)
	Hemoclips	14 (12.8%)
	Sutures	4 (3.7%)
	Fibrin sealants	1 (0.9%)
	Multiple	1 (0.9%)
Presence of Intraoperative Leak	Yes	1 (0.9%)
	No	108 (99.1%)
Discharge Location	Home	109 (100.0%)
	Skilled nursing facility	0 (0.0%)
	Long-term care	0 (0.0%)
	Hospice care	0 (0.0%)
	Other	0 (0.0%)

[1]Percentages were calculated using the total number of cases in the analysis set

Table 4. Usability questionnaire responses.

Variable	Characteristic	Gastric (N=12)
Previous Buttress Device Used	GORE® SEAMGUARD®	8 (66.7%)
	Baxter Peri-Strips Dry	3 (25.0%)
	Endo GIA™ Reinforced Reload	1 (8.3%)
	Other	0 (0.0%)
I experienced less buttress manipulation and movement (during procedure) using the ECHELON SLR device compared to previous buttress product use	1 - Strongly disagree	0 (0.0%)
	2 - Slightly disagree	0 (0.0%)
	3 - Neutral	3 (25.0%)
	4 - Slightly agree	6 (50.0%)
	5 - Strongly agree	3 (25.0%)
I experienced greater confidence that the buttress I used, which is designed from materials found in Vicryl and PDS Sutures, will deliver the best outcome I expect from a staple line reinforcement product like the ECHELON SLR device compared to previous buttress product use	1 - Strongly disagree	0 (0.0%)
	2 - Slightly disagree	3 (25.0%)
	3 - Neutral	6 (50.0%)
	4 - Slightly agree	2 (16.7%)
	5 - Strongly agree	1 (8.3%)
The ECHELON SLR device setup simplifies concerns I have when my OR staff is preparing my surgical instruments for stapling and transection compared to previous buttress product use	1 - Strongly disagree	0 (0.0%)
	2 - Slightly disagree	0 (0.0%)
	3 - Neutral	0 (0.0%)
	4 - Slightly agree	0 (0.0%)
	5 - Strongly agree	12 (100.0%
My surgical staff experienced less frustration with the ECHELON SLR device compared to previous buttress product use	1 - Strongly disagree	0 (0.0%)
	2 - Slightly disagree	0 (0.0%)
	3 - Neutral	0 (0.0%)
	4 - Slightly agree	0 (0.0%)
	5 - Strongly agree	12 (100.0%)
I foresee less waste of the ECHELON SLR device compared to the previous buttress product use due to the simplicity and ease of loading and preparing my surgical stapler	1 - Strongly disagree	0 (0.0%)
	2 - Slightly disagree	1 (8.3%)
	3 - Neutral	1 (8.3%)
	4 - Slightly agree	4 (33.3%)
	5 - Strongly agree	6 (50.0%)

How satisfied are you with the operative flow while using the ECHELON SLR device?	1 - Very dissatisfied	0 (0.0%)
	2 - Dissatisfied	0 (0.0%)
	3 - Neither dissatisfied nor satisfied	0 (0.0%)
	4 - Satisfied	3 (25.0%)
	5 - Very satisfied	9 (75.0%)
How satisfied are you with the ability to manipulate and reposition the ECHELON SLR device on tissue before firing the stapler?	1 - Very dissatisfied	0 (0.0%)
	2 - Dissatisfied	0 (0.0%)
	3 - Neither dissatisfied nor satisfied	0 (0.0%)
	4 - Satisfied	1 (8.3%)
	5 - Very satisfied	11 (91.7%)
I would recommend the ECHELON SLR device to a colleague	1 - Strongly disagree	0 (0.0%)
	2 - Slightly disagree	0 (0.0%)
	3 - Neutral	0 (0.0%)
	4 - Slightly agree	5 (41.7%)
	5 - Strongly agree	7 (58.3%)

* Questionnaires completed by surgeons after 1st, 3rd, and 5th procedures

Table 5. Intraoperative interventions required.

Characteristic	Category / Statistic	Gastric (N=109)
Subjects with at least 1 Intervention for Intraoperative Bleeding on Staple Line	Yes	20 (18.3%)
	No	89 (81.7%)
Number of Intervention Used for Intraoperative Bleeding on Staple Line	Total	21
Hemostatic Intervention Used to Obtain Hemostasis [2]	Hemoclips	15 (71.4%)
	Sutures	4 (19.0%)
	Monopolar energy product	1 (4.8%)
	Fibrin sealants	1 (4.8%)
	Other	0 (0.0%)

to note that the ESLR is not indicated for use in an anastomosis. No device-related bleeding or stricture was reported. While there were ten devices replaced during the course of the study, it is important to note that none of which were due to slippage or bunching.

The ESLR is a simple click-and-go stapler attachment in which all study surgeons reported satisfaction regarding the ease of set-up and subsequent use. Specially, steps historically required to attach buttressing material to the anvil of the stapler are obviated by the design of the study device. Study design allowed for each site's surgeon to be queried after 3 specific procedures, yielding four surgeons completing 12 questionnaires. All investigators reported satisfaction by their OR teams with the simplicity of the device set-up especially when compared with other devices which often require multiple steps prior to use. Importantly, the majority surgeons were either satisfied or very satisfied with the manipulation and repositioning capabilities of the device. In only three questionnaires (25%) did respondents report that they slightly disagreed that they had greater confidence in the device delivering the best results when compared to previous device suggesting improved usability with the ESLR. There was less consensus by clinicians when queried regarding whether the ESLR resulted in less waste, or if the material provided "the best outcome" when compared to previous devices. These nuanced responses potentially resulted from divergent surgical procedures performed during the study period. Ricketts C and Pollack E reported that the Echelon Endopath SLR took significantly less time to load compared to competitor products and surgical scrub nurses reported increased ease of set up, usage of device and less wastage compared to the competitor products [6].

Limitations and Recommendations for Future Studies

During analysis, a study design flaw involving data collection was identified which may have impacted the analysis of the primary endpoint. An overlap in case report forms was noted: one for the primary endpoint and one for adverse events. Investigators were queried on the AE form to determine relatedness of any potential event to the procedure or device leading to several issues:

- The primary endpoint form did not specifically state "device-related" which was the requirement for the primary endpoint,
- The primary endpoint was evaluated through day 70 (visit 4) (meaning the primary endpoint form was not part of visit 5). Several patients missed visit 4 but completed visit 5. Thus, from a programming standpoint, the primary endpoint form was missing for that patient.,
- The case report form listed an option of "unlikely related" to the device (MDCG guidelines changed during the study and this option was not current at the time of analysis).
- To address this, a two-step post hoc analysis was performed: Step 1 identified all adverse events that met the definition of the primary endpoint and Step 2 reviewed the relatedness. This analysis yielded a 1.9% (2/104) rate of AEs related to bleeding, leak, or stricture. This event was an anastomotic leak reported from a staple line in a patient who underwent Roux-en-Y (RYGB) gastric bypass. An additional AE was listed as a gastro-gastric fistula and was reported after a gastric sleeve resection. This AE was presumably a result of staple line failure with secondary healing as a fistula without presentation as a clinical leak. Neither of these events were deemed possibly, probably, or causally related to the device.
- In addition to the data collection issues referenced above, this study had several limitations including the fact that no explicit comparison was made to other SLRS, the relatively small sample size, a limited number of surgeons answering questionnaires and adverse events being surgeon-determined. Additional clinical data will be valuable to further assess safety and usability in real world practice.

Conclusion

This study demonstrated that the Echelon Endopath SLR has an acceptable safety profile with selected use to buttress staple lines during gastric procedures in this study. Complications following the use of the Echelon Endopath SLR were generally low as expected. Though several patients required a hemostatic intervention for intra-operative bleeding, these were deemed unrelated to the device. In addition, there were favorable results reported by the surgeons on the usability questionnaire. The results showed that the click-and-go applicator was simple to use, leading to improved ease of device set up, maneuverability and less wastage for surgeons and operating room staff. To confirm these results further evaluation is recommended.

Conflict of Interest

JB, PV, SM are employees of Ethicon, Inc. DM receives research support from Beckton Dickinson, Johnson & Johnson and Intuitive Surgical. JS teaches and attends advisory board meetings at Johnson & Johnson. AW is a consultant for Ethicon, Inc and also receives education funding for his general residency program. KS is a speaker for WL Gore.

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How to cite this article: Andrew, Wheeler, Jon Schram, Keith Gersin and Dmitri Stefanidis, et al. "Safety and Usability of the Echelon Endopath Staple Line Reinforcement in Gastric Resections." *J Surg* 19 (2023): 85.