Original Article

Safety and usability of an endo staple line reinforcement device for pulmonary resections

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Background: Pulmonary resection can present technical challenges for surgeons due to the dissection and closure of tissues, which vary in thickness and elastic properties, occasionally leading to prolonged air leaks. Staple line reinforcements (SLRs) are widely utilized tools for fortifying the stability and integrity of closures in thoracic surgery, however, materials available and ease of use for both surgeon and scrub nurse have been suboptimal. A novel "click-and-go" device pre-loaded with bioabsorbable buttress material was recently developed, the Echelon Endopath SLR (ESLR, Ethicon, Inc., Cincinnati, OH, USA). This prospective study examines the safety and efficacy of this novel device in lung resections.

Methods: Adult surgical candidates undergoing primary pulmonary resection (both open and thoracoscopic) where the ESLR would be used were enrolled. Exclusion included reoperation/revision in same anatomical location, hypersensitivity to polyglactin or related products, and body mass index (BMI) ≥46.0 kg/m^2. The primary endpoint assessed the incidence of specific device-related adverse events (AEs): prolonged air leak and empyema. Additional endpoints included number of devices replaced during surgery due to slippage or bunching, and surgeon-reported usability responses. Data was summarized for AEs deemed device-related and usability questionnaire responses.

Results: A total of 131 subjects were included in the primary endpoint analysis data set with 120 subjects completing the study (91.6%). The mean age at consent was 62.8±12.0 years and 55.7% were female. The most common primary indication for the procedure was malignancy 61.1%, and primary non-malignant lung disease (non-chronic obstructive pulmonary disease) 12.2%. Common procedures performed were wedge resection (58.0%) and lobectomy (34.4%). There were zero reported device-specific/-related AEs which counted toward the primary endpoint. Responses from a usability questionnaire found all surgeons (100.0%) reported the ease of setup was superior to previous devices utilized. Surgeons expressed greater confidence in the buttress material of the ESLR than that of previous SLR devices (strongly agree 88.9%; slightly agree 11.1%). Most also felt that there was less wastage with the click-and-go ESLR (strongly agree 77.8%, slightly agree 11.1%, neutral 11.1%).

Conclusions: The ESLR device demonstrates safe and effective performance in this post-market study of specific thoracic procedures. Furthermore, surgeons found this was easier to use.

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Keywords: Pulmonary surgery; staple line reinforcement (SLR); stapler; buttress; pulmonary air leak

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Introduction

Lung resection can present technical challenges due to the dissection and closure of tissues of varying degrees of thickness and elasticity including blood vessels, lung parenchyma, and bronchi. Surgical stapling devices are commonly used in lung resections, often transecting these three tissue components in a single staple firing. The thoracic cavity is a dynamic environment where the site of lung transection is subjected to significant forces during the respiratory cycle. Therefore it is crucial to ensure that transection staple lines are strong enough to withstand these forces (1). The primary potential complication from failure at the staple line is a postoperative air leak, one of the most common complications reported after lung resections (2). A prolonged air leak is typically defined as one that persists more than 5–7 days (3), and is most often caused by an alveolopleural fistula. This necessitates further intervention or prolonged tube thoracostomy drainage, thereby lengthening hospital stay and increasing the risk for pleural infections, pain, and overall patient morbidity.

While there has been a dramatic increase in the number of thoracic procedures performed annually and a decrease in overall complications observed, the rate of air leaks has not decreased (4). There is literature to suggest that buttressing of the staple line may reduce air leaks following sub-lobar or anatomic resections for lung cancer or chronic obstructive pulmonary disease (5-7).

As a result, staple line reinforcements (SLRs) and sealants have become widely utilized tools for fortifying the stability and integrity of lung resection sites in thoracic surgery (8-10). Methods of SLR, which aim to provide temporary support until the tissue healing, include the use of buttresses, adhesives, and absorbable materials. Buttresses, such as biologic or synthetic materials, are used to provide additional tensile strength to the staple line. Adhesives, such as fibrin glue and cyanoacrylate, have been used to help seal the staple line and reduce the risk of air leaks (11,12). Absorbable materials, such as polyglycolic acid or polyglactin, provide temporary reinforcement and are eventually absorbed by the body (13,14). Overall, buttressing distributes tension evenly across the staple line and provides a broad pressure profile around the individual staples, reducing staple line dehiscence and improving hemostasis (15).

One type of stapler buttress material is bovine pericardium, which may pose a risk of severe allergic reaction in certain patients with alpha-gal syndrome (16). There may also be concerns about long term issues including material migration, expulsion, and infection risk with a non-absorbable buttress such as bovine pericardium (13,17). The risk of postoperative pleural space infection with purulent fluid collection, or empyema, occurs in a small percentage of patients undergoing thoracic surgery but has significant associated morbidity and mortality (18,19). Any adjunctive buttress, adhesive, or absorbable materials should not increase the risk of post-operative empyema. Furthermore, surgical devices must not compromise patient safety by increasing the risk of other complications such as bleeding or death.

An easy-to-use SLR would have the potential to reduce post-operative complications for patients while streamlining operating room workflow. A novel "click-and-go" device with pre-loaded bioabsorbable buttress material, the Echelon Endopath SLR (ESLR, Ethicon, Inc., Cincinnati, OH, USA), was recently developed for procedures where soft tissue resection or transection is indicated. The study presented here examines the safety and efficacy of this novel preloaded SLR in lung resections. We present this article in accordance with the TREND reporting checklist (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1019/rc).

Methods

This study was conducted as a single-arm, multicenter, prospective trial to assess the safety and efficacy of the ESLR (ECH60R, Ethicon, Inc.; *Figure 1*) in a study population undergoing clinically indicated pulmonary resections. Surgeons utilized the device in compliance with the device's instruction for use (IFU). Specifically, stapler firings with SLR were only used on lung parenchyma and not on bronchi or vascular structures. The study was conducted at six US sites. Consecutive surgical subjects

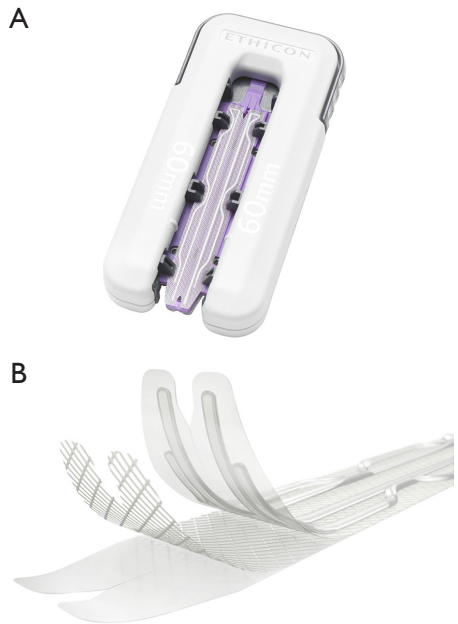

Figure 1 Echelon Endopath Staple Line Reinforcement device with bioabsorbable buttressing material.

who met eligibility were approached in the clinic pre-operatively for potential participation. All subjects were screened for eligibility prior to any study procedures being performed. Subjects who had at least one ESLR placed during a procedure were viewed as "treated". The follow-up period of treated subjects was approximately 19 weeks post-operatively [day 28, 70, and 135 (±14 days)]. The study was conducted in accordance with ICH Harmonised Tripartite Good Clinical Practices (1996), the Declaration of Helsinki (as revised in 2013), ISO 14155, MDR Annex XV, and any pertinent local and federal regulations, and was approved by individual study sites' institutional review boards (IRBs). Specific review boards included Henry Ford Health System IRB, Northwell Health IRB, Missouri University Subject Research Protection Program IRB, University of Virginia IRB for Health Sciences Research, Human Research Protection Program (HRPP) Indiana University, and WCG IRB. Specific registration numbers are available from the journal editorial office. Written informed consent was obtained from all study subjects prior to study inclusion.

Inclusion/exclusion

Key inclusion criteria included adult surgical candidates undergoing a lung resection procedure where the ESLR would be appropriately used on lung parenchyma, who were willing to provide informed consent and comply with study-related evaluations and follow-up schedules. Specifically, procedures included lobectomy, segmentectomy or wedge resection, and lung volume reduction surgery. This included video-assisted thoracic surgery (both thoracoscopic and robotic-assisted thoracoscopic procedures using laparoscopic staplers as compliant with the study device IFU) and open procedures.

Exclusion criteria included: (I) a physical or psychological condition which could hinder a subject's ability to participate in the study; (II) body mass index (BMI) ≥46.0 kg/m^2; (III) a reoperation or revision procedure in the same anatomical location; (IV) procedures in which an extended wound or organ support was mandated; (V) medical conditions which could impact inflammatory or immune response; (VI) concurrent medication usage that could influence wound healing; (VII) a history of hypersensitivity to polyglactin (Vicryl®, Ethicon Inc.), polydioxanone (PDO or PDS), or related products; or (VIII) enrollment in a simultaneous interventional clinical trial which could impact study endpoints. Based upon the surgeon's discretion, intraoperative exclusion included presence of adhesions that could lead to an increased risk of leak at a location other than the staple line, and a procedure where the ESLR was not utilized.

Study endpoints

The primary endpoint was the incidence of specific device-related adverse events (AEs, assessed by the surgical team) through the post-procedure follow-up defined as follows: (I) prolonged air leak (greater than day 7 postoperatively) from the staple line; and (II) empyema, defined as purulent fluid collection in the pleural space seen radiographically (excluding chronic empyema). Secondary endpoints included (I) number of devices replaced during surgery deemed due to slipping or bunching or improperly loaded ESLR onto the stapler cartridge; and (II) a nine-item questionnaire completed by one surgeon at each site after the completion of their 1st, 3rd, and 5th procedures, with mean scores calculated for each response.

Data variables collected

Baseline demographic data were collected and included age, gender, race, ethnicity, height, weight, medical and surgical history, American Society of Anesthesiologists

Table 1 Baseline subject demographics

Variables	Category	Results (n=131)
Age at consent (years)	Mean [SD]	62.8 [12.0]
	Median (range)	65.0 (21.0, 84.0)
Gender	Male, n (%)	58 (44.3)
	Female, n (%)	73 (55.7)
Ethnicity	Hispanic or Latino, n (%)	2 (1.5)
	Not Hispanic or Latino, n (%)	122 (93.1)
	Not reported, n (%)	7 (5.3)
Race	American Indian or Alaska Native, n (%)	1 (0.8)
	Asian, n (%)	1 (0.8)
	Black or African American, n (%)	12 (9.2)
	White, n (%)	108 (82.4)
	Not reported, n (%)	8 (6.1)
	Multiple, n (%)	1 (0.8)
	Other, n	0
Height (cm)	Mean [SD]	170.4 [9.4]
	Median (range)	170.2 (152.4, 193.0)
Weight (kg)	Mean [SD]	79.3 [19.2]
	Median (range)	77.9 (38.1, 150.8)
Body mass index (kg/m^2)	Mean [SD]	27.2 [5.7]
	Median (range)	27.0 (16.4, 46.2)

SD, standard deviation.

(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 and included the number of devices used during procedure; number of devices replaced during surgery due to slippage, bunching, or misfiring; any required intra-operative interventions for staple line bleeding; blood loss and transfusions; chest tube placement, if any; air leak; concurrent surgical procedures; length of stay (LOS); and procedure-related readmissions.

Statistical analysis plan

No formal statistical hypothesis was defined *a priori* for this single-arm study. Summary statistics were performed for subject demographic data. Number and percentage of subjects experiencing an occurrence of the primary endpoint were summarized. 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 AEs and their relatedness to the study device. Summary statistics were used for the usability questionnaire responses. Statistical analyses were performed via Statistical Analysis System software (version 9.4: SAS Institute, Cary, NC, USA).

Results

A total of 131 subjects were enrolled at six study sites, with 120 completing the study (91.6%). Eleven subjects did not complete the study for reasons unrelated to the device including being lost to follow-up (N=7), death (N=2), withdrawal by subject (N=1), and other (N=1). The mean age at enrollment was 62.8±12.0 years, with the majority of subjects female (55.7%). A full description of baseline demographics is shown in *Table 1*. Specific indications for the procedure performed and subject ASA scores are presented in *Table 2*. Note that multiple primary indications/procedures could be selected by the sites. The most common primary indication for the procedure was malignancy (61.1%), followed by primary non-malignant, non-chronic obstructive pulmonary disease (12.2%). The most common procedure performed was wedge resection (58.0%), followed by lobectomy (34.4%). Most subjects had an ASA III score (87.0%). Collected intraoperative data are displayed in *Table 3*. The majority of cases were performed thoracoscopically without robotic assistance (63.4%), followed by open thoracotomy (28.2%). The mean procedure time was 102±60 minutes.

Out of the 131 subjects, five experienced prolonged air leak (3.8%). However, in each case, the surgeons reported these AEs as not related or unlikely related to the study device. No patient experienced an empyema postoperatively.

There were 730 stapler firings over the course of the trial, of which 598 (81.9%) used the ESLR. Of those, four ESLR devices had to be replaced due to slipping (N=3) or bunching (N=1). Additionally, three ESLR devices were loaded improperly by operating room staff and therefore not used. The vast majority of subjects did not require any ESLR device replacements (125/131, 95.4%).

Table 2 Specifics relating to procedure, indication, and health scores

Variables	Category	Results (n=131)
Primary indication for the procedure performed†	Malignancy	80 (61.1%)
	COPD	1 (0.8%)
	Primary non-malignant lung disease (non-COPD)	16 (12.2%)
	Persistent pneumothorax (including blebs)	5 (3.8%)
	Other‡	36 (27.5%)
Procedure performed†	Lobectomy	45 (34.4%)
	Segmentectomy	19 (14.5%)
	Wedge resection	76 (58.0%)
	Lung volume reduction surgery	0
	Other‡	29 (22.1%)
ASA score§	ASA I	1 (0.8%)
	ASA II	13 (9.9%)
	ASA III	114 (87.0%)
	ASA IV	3 (2.3%)
Current smoking status	Current smoker	32 (24.4%)
	Former smoker	64 (48.9%)
	Never smoked	35 (26.7%)

†, multiple responses were permitted for primary indication and procedure performed. Thus, it was possible to have more than 100% in these categories. ‡, this category was provided on case report forms for surgeon to select for procedures which did not fall in other major categories. §, ASA I: a normal healthy patient; ASA II: a patient with mild systemic disease; ASA III: a patient with severe systemic disease; ASA IV: a patient with severe systemic disease that is a constant threat to life; ASA V: a moribund patient who is not expected to survive without the operation. COPD, chronic obstructive pulmonary disease; ASA, American Society of Anesthesiologists.

Table 3 Intra-operative and discharge variables

Characteristics	Category	Results (n=131)*
Procedure duration (hours)	Mean [SD]	1.7 [1.0]
	Median (range)	1.6 (0.3, 4.5)
Surgical approach	VATS, n (%)	83 (63.4)
	Open, n (%)	37 (28.2)
	Robot-assisted, n (%)	3 (2.3)
	Other, n (%)	1 (0.8)
	Multiple surgical approach, n (%)	7 (5.3)
Conversion to open procedure	Yes, n (%)	2 (1.5)
	No, n (%)	129 (98.5)
Volume of estimated blood loss (mL)	Mean [SD]	51.0 [83.8]
	Median (range)	25.0 (0.0, 600.0)
Discharge location	Home, n (%)	128 (97.7)
	Skilled nursing facility, n (%)	1 (0.8)
	Other, n (%)	2 (1.5)

*, percentages calculated using total number of subjects in each group. SD, standard deviation; VATS, video-assisted thoracoscopic surgery.

Responses from the usability questionnaire demonstrated that all surgeons found the ease of setup to be superior to previous devices they had utilized (n=18, 100.0%), which included Baxter Peri-Strips Dry (44.4%), GORE® SEAMGUARD® (22.2%), Endo GIA™ Reinforced Reload (11.1%), and other (22.2%). Surgeons expressed greater confidence in the buttress material of the ESLR than that of previous devices (strongly agree 88.9%; slightly agree 11.1%). Most surgeons also reported feeling that there was less wastage with the click-and-go ESLR (strongly agree 77.8%, slightly agree 11.1%, neutral 11.1%). A complete overview of questions and responses is presented in *Table 4*.

Aside from primary and secondary endpoints, other study findings included a mean LOS of 3.6±3.2 days (range, 0.0–19.0 days), with no reported procedure-related re-admissions. The majority of subjects did not require any intraoperative intervention for bleeding after use of ESLR (122/131, 93.1%). The nine subjects who required intraoperative intervention for bleeding at the staple line were successfully treated with sutures or fibrin sealants. *Table 5* summarizes intraoperative interventions required throughout the study.

Discussion

Prolonged air leak remains a complication that is difficult to prevent and causes significant morbidity and associated costs (20). It has also been inconsistently reported in the literature as air leaks occurring after 5, 7, or even 10 days postoperatively (21-23). This, in addition to variable

Table 4 Usability questionnaire responses

Variables	Category	Results
Number of questionnaires completed by surgeons[†]	–	18
Previous buttress device used[†]	GORE® SEAMGUARD®	4 (22.2%)
	Baxter Peri-Strips Dry	8 (44.4%)
	Endo GIA™ Reinforced Reload	2 (11.1%)
	Other	4 (22.2%)
I experienced less buttress manipulation and movement (during procedure) using the ECHELON SLR device compared to previous buttress product use[‡]	1 Strongly disagree	1 (5.6%)
	2 Slightly disagree	1 (5.6%)
	3 Neutral	1 (5.6%)
	4 Slightly agree	2 (11.1%)
	5 Strongly agree	13 (72.2%)
I experienced greater confidence that the buttress I used, which is designed from materials found in Vicryl and polydioxanone 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
	2 Slightly disagree	0
	3 Neutral	0
	4 Slightly agree	2 (11.1%)
	5 Strongly agree	16 (88.9%)
The ECHELON SLR device setup simplifies concerns I have when my operating room staff is preparing my surgical instruments for stapling and transection compared to previous buttress product use[‡]	1 Strongly disagree	0
	2 Slightly disagree	0
	3 Neutral	0
	4 Slightly agree	0
	5 Strongly agree	18 (100.0%)
My surgical staff experienced less frustration with the ECHELON SLR device compared to previous buttress product use[‡]	1 Strongly disagree	0
	2 Slightly disagree	0
	3 Neutral	0
	4 Slightly agree	0
	5 Strongly agree	18 (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
	2 Slightly disagree	0
	3 Neutral	2 (11.1%)
	4 Slightly agree	2 (11.1%)
	5 Strongly agree	14 (77.8%)
How satisfied are you with the operative flow while using the ECHELON SLR device?[†]	1 Very dissatisfied	0
	2 Dissatisfied	0
	3 Neither dissatisfied nor satisfied	0
	4 Satisfied	2 (11.1%)
	5 Very satisfied	16 (88.9%)

Table 4 (*continued*)

Table 4 (*continued*)

Variables	Category	Results
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
	2 Dissatisfied	0
	3 Neither dissatisfied nor satisfied	0
	4 Satisfied	3 (16.7%)
	5 Very satisfied	15 (83.3%)
I would recommend the ECHELON SLR device to a colleague	1 Strongly disagree	0
	2 Slightly disagree	0
	3 Neutral	0
	4 Slightly agree	2 (11.1%)
	5 Strongly agree	16 (88.9%)

†, all subjects in the analysis set were included. One surgeon per site completed the questionnaire after the surgeon's 1st, 3rd, and 5th procedure. The number of completed questionnaires was the denominator. ‡, denominator and percentages based on the total number of devices used previously. SLR, staple line reinforcement.

Table 5 Interventions required intraoperatively

Characteristics	Category	Results (n=131)
Subjects with at least 1 intervention for intraoperative bleeding on staple line	Yes	9 (6.9%)
	No	122 (93.1%)
Number of intervention used for intraoperative bleeding on staple line	Total	9
Hemostatic intervention used to obtain hemostasis	Hemoclips	0
	Sutures	3 (33.3%)
	Monopolar energy product	0
	Fibrin sealants	4 (44.4%)
	Other	2 (22.2%)

surgical techniques and patient pathology, contributes to widely ranging published rates of occurrence from 5.6% to 26% in lung cancer resections to upwards of 50% in lung volume reduction surgery for chronic obstructive pulmonary disease (24-27).

Despite this heterogeneity in PAL definition and expected occurrence rate, the present study demonstrates efficacy of a novel SLR device with only 3.8% of patients experiencing prolonged air leak, within the range of other published series to date. There is some belief that wedge resections, which were included in this study, may be even more prone to air leak than lobectomies due to increased pressure at the staple line (28). This may suggest the potential for the ESLR to contribute to even lower PAL rates than 3.8% in specific patient population subsets. Importantly, safety of the ESLR device was also demonstrated as zero patients experienced a device-related AE of empyema.

In addition to demonstrating safety and efficacy, this study shows that surgeon users reported positive feedback related to use of the novel SLR. All surgeons reported improved ease of use, and the results showed minimal rates of slipping or bunching. Other key feedback measures included confidence in the material and less waste anticipated relative to other SLR products used by the surgeons. This is consistent with data from a separate study of nursing experience with the Echelon Endopath SLR where device setup time was shorter than for other products and led to less nursing frustration (29). Limitations of this study include the single arm nature of this non-randomized observational trial.

Conclusions

The ESLR device demonstrates safe and effective performance in this post-market study of specific pulmonary procedures without any reported events of post-operative empyema, and with acceptable usability.

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Footnote

Reporting Checklist: The authors have completed the TREND reporting checklist. Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1019/rc

Data Sharing Statement: Available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1019/dss

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Conflicts of Interest: All authors have completed the ICMJE uniform disclosure form (available at https://jtd.amegroups.com/article/view/10.21037/jtd-23-1019/coif). K.A.K., D.Z., L.W.M., E.C., A.W., Z.H., and A.P. (or their institutions) received study sponsorship from Ethicon, Inc. Additionally, L.W.M. has been a consultant and speaker for Ethicon, Inc. and Z.H. has been a speaker for Ethicon, Inc. J.E.B., P.P.V., and M.G.S. are employees of Ethicon, Inc. The authors have no other conflicts of interest to declare.

Ethical Statement: The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with ICH Harmonised Tripartite Good Clinical Practices (1996), the Declaration of Helsinki (as revised in 2013), ISO 14155, MDR Annex XV, and any pertinent local and federal regulations, and was approved by individual study sites' institutional review boards (IRBs). Specific review boards included Henry Ford Health System IRB, Northwell Health IRB, Missouri University Subject Research Protection Program IRB, University of Virginia IRB for Health Sciences Research, Human Research Protection Program (HRPP) Indiana University, and WCG IRB. Specific registration numbers are available from the journal editorial office. Written informed consent was obtained from all study subjects prior to study inclusion.

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