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Esophagogastric junction compliance on impedance planimetry (EndoFLIP™) following peroral endoscopic myotomy (POEM) predicts improvement in postoperative eckardt score

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Abstract

Background Peroral endoscopic myotomy (POEM) is a mainstay of treatment for achalasia. Tailored myotomy based on compliance, as measured with impedance planimetry (FLIP), has yet to be described. In this study we describe the associations between Eckardt score, postoperative GERD, and compliance.

Methods A retrospective review of a prospectively maintained database was performed, evaluating patients who underwent POEM and intraoperative FLIP between January 2019 and November 2021. Group comparisons were made using two-tailed Wilcoxon rank-sum and Fisher's exact tests. Spearman's correlation coefficients (r) were used to assess the relationship between compliance and outcomes, all with two-tailed statistical significance of $p < 0.05$.

Results Thirty five patients underwent POEM with intraoperative FLIP. At a 30 mL and 40 mL fill, respectively, compliance increased by 80% (180 ± 152%) and 77% (177 ± 131%) from pre to post myotomy. Mean Eckardt score improved from 5.5 ± 2.6 preoperatively to 1.3 ± 1.6 and 1.8 ± 1.9 at first and second follow up, respectively. Median times to first and second follow up were 22 days (IQR 16–23) and 65 days (IQR 58–142). A higher compliance at 40 mL fill was moderately associated with lower Eckardt score at first ($r = -0.49$, $p = 0.012$) and second ($r = -0.64$, $p = 0.014$) follow up. Post myotomy compliance ≥ 125 mm^3/mmHg at 40 mL fill was associated with lower Eckardt scores, < 3, at first (0.4 ± 0.5 vs 1.8 ± 1.3, $p = 0.008$) and second (0.4 ± 0.5, vs 2.0 ± 1.4, $p = 0.027$) follow up. Compliance ≥ 125 mm^3/mmHg performed better than previously defined ideal ranges of DI and CSA in predicting postoperative Eckardt scores. Compliance was not significantly associated with development of postoperative GERD.

Conclusions A target post myotomy compliance of ≥ 125 mm^3/mmHg at a 40 mL fill is associated with normal Eckardt scores at first and second postoperative visits, and performs better than previously defined ideal ranges of DI and CSA in predicting post-operative Eckardt scores. Compliance is a poor predictor of developing GERD after POEM.

Keywords Achalasia · Impedance planimetry · EndoFLIP · Eckardt Score · Compliance

Peroral endoscopic myotomy (POEM) is a mainstay of treatment for achalasia and other esophageal motility disorders. POEM was first described as an alternative to Heller myotomy in 2010 [1]. Benefits to an endoscopic over a laparoscopic or open approach include a less invasive, scar-less procedure requiring decreased levels of sedation, shorter operative times, less narcotic use, and shorter hospital stays [2]. One drawback to POEM has been the high rates of postoperative gastroesophageal reflux disease (GERD), up to 57% [3].

A standard myotomy is defined as extending 6 cm onto the esophagus, across the gastroesophageal junction (GEJ), and an additional 3 cm onto the stomach [4]. Multiple studies have looked at a tailored myotomy for achalasia. For type 3 achalasia, improved postoperative Eckardt scores have been demonstrated if the proximal extent of myotomy begins

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at the most proximal site of diseased esophagus identified on preoperative high-resolution manometry [5].

With the availability of impedance planimetry, as measured with a functional lumen imaging probe (FLIP), real-time intraoperative feedback to determine the adequacy of myotomy is now available. However, the FLIP metric that best guides surgeons to an appropriate length myotomy that both resolves achalasia symptoms and minimizes postoperative GERD is not yet known. Several studies have reported on the cross-sectional area (CSA) or distensibility index (DI) of the gastroesophageal junction (GEJ) after POEM and correlation with postoperative Eckardt and GERD scores [6–9].

While CSA and DI evaluate the geometry of the GEJ in a single plane, compliance (C), another metric calculated by the FLIP system, is defined as the change in volume divided by the change in intra-bag pressure. This evaluates a 2 cm segment along the FLIP catheter, centered around the narrowest cross-sectional plane of the GEJ. Tailored myotomy based on intra-operative compliance has yet to be described. The authors hypothesize that compliance more accurately represents the function of the GEJ than either CSA or DI and therefore will better predict postoperative Eckardt score and GERD. In this study, we describe the associations between post myotomy compliance and both improvement in Eckardt score and development of post-operative GERD.

Materials and methods

An Institutional Review Board approved retrospective review of a prospectively maintained gastroesophageal database was performed. Data is abstracted from patients' electronic medical records in a prospective manner by dedicated research fellows. Demographic and perioperative data of patients who underwent POEM and intraoperative FLIP evaluation between January 2019 and August 2021 at a single institution were analyzed. All procedures were performed by a single surgeon.

Demographic data included age, body mass index (BMI), sex, smoking status, Chicago Classification v3.0 for achalasia, preoperative Eckardt score, history of prior intervention including dilation or Botox injection, preoperative acid suppression, and American Society of Anesthesiology performance classification (ASA). Eckardt score, a cumulative score of 1–3 across four categories: dysphagia, retrosternal chest pain, regurgitation, and weight loss, with a maximum score of 12, is a commonly used metric to define treatment response following interventions for achalasia. A score of ≥ 3 represents poor symptomatic control while a score < 3 defines treatment success.

Intraoperative variables included length of myotomy in centimeters, operative time in minutes, intraoperative complications, perforation, length of stay in days, pain at discharge measured by visual analog scale (VAS), and days to cessation of narcotic use. FLIP measurements included minimum diameter (Dmin), intra-bag pressure (P), CSA, DI, and C using the below described protocol. Early postoperative data included 30-day mortality, 30-day emergency department visit, 30-day readmission, any other complication, Eckardt score at first and second postoperative visit, the need for postoperative intervention including esophagogastroduodenoscopy (EGD) or dilation, the presence and grade of postoperative esophagitis seen at time of EGD, and postoperative BRAVO data. All patients are sent quality of life surveys at one and two-year postoperative timepoints, including reflux symptom index (RSI) and GERD health related quality of life (GERD-HRQL) questionnaires.

POEM procedure

Prior to undergoing POEM, all patients completed a comprehensive esophageal work-up including upper endoscopy, high-resolution manometry and esophogram.

All POEM procedures were performed in the operating room with the patient positioned flat under general endotracheal anesthesia. A single dose of cefazolin for prophylaxis is routinely administered prior to procedure start. An upper endoscope is passed into the esophagus, through the cricopharyngeus, into the stomach and the duodenum. The scope is withdrawn, loaded with an EMR cap, and passed into an overtube prior to reinsertion into the esophagus. The submucosa is injected with a mixture of saline and indigo carmine proximal to the z-line, at a location tailored to the patient's specific pathology. The same mixture is used throughout the procedure to infiltrate the submucosal space. A mucosotomy is made at the level of proximal saline and indigo carmine injection with a Hybrid T knife (EndoCutQ 3-1-1) in the 3 o'clock position. The endoscope is then tunneled into the submucosal space using copious injection to lift the mucosa away from the underlying muscle. The Hybrid T knife is used to develop the submucosal plane in a proximal to distal direction, ending 1-3 cm distal to the GEJ. A myotomy is then performed in a proximal to distal direction, starting 2 cm distal to the mucosotomy and ending 1-3 cm distal to the GEJ, cauterizing the circular fibers of the esophagus with the Hybrid T knife. The scope is then withdrawn from the submucosal tunnel and inserted back into the stomach, evaluating for incidental mucosal injuries and distal extent of myotomy. Any incidental mucosal injuries are repaired using endoscopic clips. The mucosotomy is then closed with endoscopic clips and the procedure is complete.

FLIP protocol

An 8 cm (EF-325) catheter was used for all FLIP measurements. During the first half of the study period, measurements were only recorded at a 30 mL fill. Halfway through the study period, our institutions FLIP protocol was updated to include an additional set of measurements taken at a 40 mL fill. After FLIP system set up and immediately prior to catheter insertion, the balloon is zeroed to atmospheric pressure.

Initial measurements are taken after intubation, prior to mucosotomy, with the patient in a flat position. If there is any difficulty in blindly passing the FLIP catheter via a transoral approach, endoscopic guidance is utilized. The catheter is advanced into the stomach, roughly 45–50 cm, then inflated and slowly withdrawn until an hourglass shape is seen on the FLIP monitor. The readings are taken with a high-weighted filter and allowed 30 s to stabilize prior to documentation. The live image is paused at peak intra-bag pressure; the Dmin, P, CSA, DI, and C are all recorded. A 30 mL fill may not adequately fill the balloon and allow for apposition of the catheter to the walls of the esophagus, resulting in a final intra-bag pressure of < 20 mmHg. After recognizing several cases of low intra-bag pressure with a 30 mL fill, our FLIP protocol was updated to collecting data at both a 30 mL and 40 mL fill. The authors recommend that a 40 mL fill be utilized to improve the accuracy of FLIP measurements, in concordance with expert consensus recommendations [10]. The catheter is then deflated and fully removed while the myotomy is performed. Additional measurements are taken after completion of myotomy, prior to closure of the mucosotomy. Of note, the FLIP catheter is ***always*** placed under direct endoscopic visualization after the mucosotomy has been performed to minimize the risk of esophageal perforation.

GEJ compliance calculation

The EndoFLIP™ 2.0 system automatically calculates five metrics, including compliance. Compliance is defined as the change in volume over a 2 cm long segment spanning 5 electrodes, centered around the GEJ, divided by the intra-bag pressure. This calculation is based on the volume of a cylinder, $V = \pi r^2 h$ (r = radius, h = height). Each sensor is spaced 5 mm apart, with the mean diameter at each electrode measured by the FLIP system. The mean diameter of each 5 mm long segment is calculated by averaging the diameter at the two sensors bounding each segment. The volume of the two segments above and two segments below the narrowest cross-sectional plane, representing 1 cm above and 1 cm below the GEJ, is calculated using the formula $V = \pi r_{mean}^2 h_{segment}$. The sum of the calculated volumes for each of the four segments centered around the GEJ equals total volume in mm^3, and is subsequently divided by the intra-bag pressure in mmHg to yield a compliance in mm^3/mmHg.

In cases where compliance was not calculated by the FLIP system, due to low intra-bag pressure (< 20 mmHg) or more frequently due to the GEJ being poorly centered on the monitor, compliance was calculated manually in a post-hoc review of intraoperative FLIP data. This was done using the above described methodology, which has been previously published and was developed in conjunction with industry professionals [11]. To confirm the accuracy of the calculation, several patients with FLIP generated compliance were reviewed, and compliance recalculated using the above described methodology, with 100% concordance.

Statistical methods

Descriptive statistics, such as frequency with percentage, mean with standard deviation, or median with interquartile range were used to summarize results. The paired t-test was used to assess change in FLIP measurements from pre to post myotomy. Spearman's correlation coefficients (r) were used to assess the relationships between compliance, distensibility index, and outcomes. A compliance cutoff value of 125mm^3/mmHg was determined by receiver operating characteristic curves for Eckardt score resolution at both first and second follow up for the 24 patients with a compliance at a 40 mL fill available for review. Group comparisons were made using Wilcoxon rank-sum and Fisher's exact tests. All statistical analysis was performed using SAS 9.4 (SAS Institute, Cary, NC) with two-tailed tests and statistical significance set at $p < 0.05$.

Results

Demographics

During the study period, 35 patients underwent POEM and intraoperative evaluation with FLIP. Classification of esophageal motility disorders included type 1 achalasia ($n = 7$, 20.0%), type 2 achalasia ($n = 17$, 48.6%), type 3 achalasia ($n = 8$, 22.9%), and esophagogastric junction outflow obstruction (EGJOO) ($n = 3$, 8.6%). One patient who underwent POEM for diffuse esophageal spasm and two for Jackhammer Esophagus during the study period were excluded from analysis due to normal lower esophageal sphincters. Further demographic information is available in Table 1.

Perioperative data

Mean operative time was 58 min (SD 18 min) and 71.4% of patients were discharged the day of surgery. Two intraoperative complications were noted, both inadvertent gastric mucosotomies, identified and repaired at the time of surgery

Table 1 Patient demographics

Total patients, *N*	35
Age, years [Mean ± SD]	61 ± 19
BMI [Mean ± SD]	26.1 ± 7.0
Male [N (%)]	17 (48.6)
Current or Former Smoker [N (%)]	11 (31.4)
Achalasia Type [N (%)]	
1	7 (20.0)
2	17 (48.6)
3	8 (22.9)
EGJOO	3 (8.6)
Preop Eckardt Score [Mean ± SD]	5.5 ± 2.6
Previous Dilation [N (%)]	9 (25.7)
Previous Botox [N (%)]	3 (8.6)
Preop PPI Use [N (%)]	17 (48.6)
ASA Class 3 or 4 [N (%)]	18 (51.4)

BMI body mass index, *EGJOO* esophagogastric junction outflow obstruction, *PPI* proton pump inhibitor, *ASA* american society of anesthesiology performance class

Table 2 Perioperative Data and Short-Term Outcomes

Length of myotomy, cm [Mean ± SD]	11.0 ± 5.4
OR Time, minutes [Mean ± SD]	58 ± 18
Intraoperative Complication [N (%)]	2 (5.7)
LOS, days [Median (Q1-Q3)]	0 (0–1)
Pain at Discharge, VAS [Median (Q1-Q3)]	2 (0–3)
Medication Stopped, days [Median (Q1-Q3)]	0 (0–2)
Return to ADL, days [Median (Q1-Q3)]	2 (1–4)
Perforation [N (%)]	0 (0.0)
30 Day Mortality [N (%)]	0 (0.0)
30 Day ED Visit [N (%)]	4 (11.4)
30 Day Readmission [N (%)]	4 (11.4)
Follow-up, months [Median (Q1-Q3)]	5 (2–14)
Postop FU1 Eckardt Score [Mean ± SD]	1.3 ± 1.6
Resolved (Eckardt < 3) [N (%)]	29 (93.5)
Days to FU1 [Median (Q1-Q3)	22 (16–23)
Postop FU2 Eckardt Score [Mean ± SD]	1.8 ± 1.9
Resolved (Eckardt < 3) [N (%)]	14 (82.4)
Days to FU2 [Median (Q1-Q3)	65 (58–142)
Postop EGD [N (%)]	9 (25.7)
Postop Dilation [N (%)]	0 (0.0)
Postop Esophagitis [N (%)]	4 (44.4)
Esophagitis Grade [N (%)]	
A	1 (25.0)
B	2 (50.0)
D	1 (25.0)
Postop BRAVO [N (%)]	6 (17.1)
Highest DeMeester [Median (Q1-Q3)]	35.0 (28.0–71.0)

OR operating room, *LOS* length of stay, *VAS* visual analog scale, *ADL* activities of daily living, *ED* emergency department, *FU*1 first follow up, *FU*2 second follow up, *EGD* esophagogastroduodenoscopy

with endoscopic clips. The first occurred in a patient with prior Nissen fundoplication and subsequent takedown with extensive scar tissue, and the second in a patient with type 2 achalasia. Technical success was achieved in all cases, defined as completion of all steps of the procedure. There were no delayed postoperative complications or deaths within 30 days of POEM. Four patients visited the emergency department and subsequently required readmission within 30 days of surgery.

Postoperative GERD

Starting in 2017, we routinely recommend EGD with BRAVO for all patients at one-year post POEM. Nine patients underwent postoperative EGD, six with BRAVO, and an additional two patients who did not undergo endoscopy filled out postoperative quality of life surveys. Six of the eleven (54.5%) were identified as having GERD. We were unable to identify an upper limit of compliance that placed patients at risk of developing postoperative GERD, defined as grade C/D esophagitis on EGD, DeMeester score ≥ 14.72 on BRAVO, or RSI score > 13 at 1 or 2 years after POEM [Table 2]. We found no association between post myotomy compliance and the development of GERD [Fig. 1].

FLIP changes from pre to post myotomy

There was significant improvement in all FLIP measurements at both 30 mL and 40 mL fill post-myotomy (all $p < 0.001$). With a 30 mL and 40 mL fill, respectively, compliance increased by 80% (180 ± 152%) and 77% (177 ± 131%) from pre to post-myotomy. This was paralleled by a pre to post-myotomy increase in CSA and DI seen at both a 30 mL and a 40 mL fill [Table 3].

Long term compliance measurements

Four patients underwent FLIP at the time of postoperative endoscopy and had compliance measurements at a 40 mL fill available for review. All four patient's compliance measurements increased from post myotomy measurements in the operating room to the time of postoperative EGD. The first patient had an increase in compliance from 94 mm^3/mmHg at time of surgery to 161.3 mm^3/mmHg at EGD 3 months postop, with presence of LA Grade B esophagitis but no BRAVO data. The second patient's EGD compliance increased from 123.4 mm^3/mmHg at time of surgery to 174.4 mm^3/mmHg at EGD 9 months postop, with a positive BRAVO study (DeMeester 18.9). A third patient's

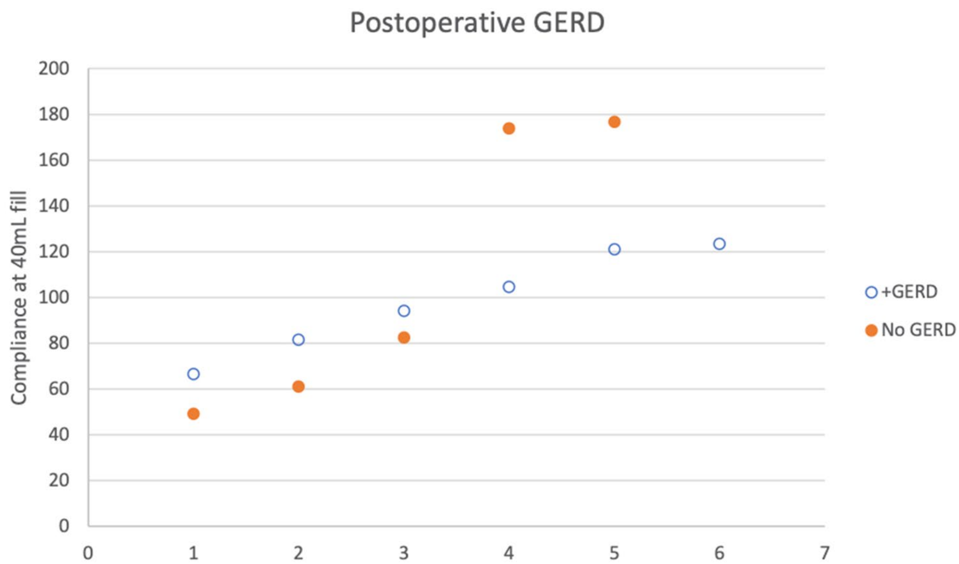

Fig. 1 Postoperative GERD and post-myotomy compliance with a 40 mL fill. GERD (gastroesophageal reflux disease)

Table 3 Intraoperative EndoFLIP™ Measurements

Volume fill	Timepoint	Dmin, mm	Pressure, mmHg	CSA, mm^2	DI, mm^2/mmHg	Compliance, mm^3/mmHg
30 mL	Initial	6.8 ± 2.1	35 ± 17	41 ± 27	1.5 ± 1.6	46 ± 37
	Post Myotomy	10.6 ± 1.9	25 ± 7	91 ± 28	3.9 ± 1.6	93 ± 34
	Change	+ 3.8 ± 2.1	-11 ± 13	+ 50 ± 27	+ 2.5 ± 1.3	+ 48 ± 31
	p-value	< .001	0.001	< .001	< .001	< .001
40 mL	Initial	8.3 ± 2.9	44 ± 21	60 ± 43	1.8 ± 1.7	56 ± 46
	Post Myotomy	13.0 ± 1.8	32 ± 11	130 ± 38	4.7 ± 2.1	115 ± 49
	Change	+ 4.6 ± 2.2	-13 ± 15	+ 69 ± 43	+ 2.8 ± 1.6	+ 60 ± 36
	p-value	< .001	< .001	< .001	< .001	< .001

Dmin minimum diameter, *CSA* cross sectional area, *DI* distensibility index

compliance increased from 81.4 mm^3/mmHg at time of surgery to 99.9 mm^3/mmHg at EGD 1 year postop, with LA Grade B esophagitis and a positive BRAVO (DeMeester 73.5). The fourth patient's compliance increased from 61.09 mm^3/mmHg at time of surgery to 116 mm^3/mmHg at EGD 18 months postop, yet had no findings of esophagitis and a negative BRAVO.

Improvement in Eckardt scores

Mean preoperative Eckardt score was 5.5 ± 2.6, while mean Eckardt scores at first and second follow up were 1.3 ± 1.6 and 1.8 ± 1.9, respectively. Median times to first and second follow up were 22 days (IQR 16–23) and 65 days (IQR 58–142). Post myotomy DI with a 40 mL fill was moderately associated with Eckardt score at first ($r = -0.51$, $p = 0.005$) and second ($r = -0.689$, $p = 0.002$) post-operative visit. A higher compliance at a 40 mL fill was moderately associated with lower Eckardt score at first ($r = -0.49$, $p = 0.012$) and second ($r = -0.64$, $p = 0.014$) follow up [Fig. 2].

Previously defined ideal range CSA (80–95 mm^2 at a 30 mL fill), found to minimize both achalasia and GERD symptoms, was not reliably associated with Eckart score at first (2.7 ± 0.6 vs 1.6 ± 1.8, $p = 0.115$) postoperative visit in our cohort. Only 3 patients, 15% of those with compliance measurements available with a 30 mL fill, fell into the ideal post-myotomy CSA range, and 0/3 completed a second follow up visit. Previously defined ideal range DI (4.5–8.5 mm^2/mmHg at a 40 mL fill), found to minimize both achalasia and GERD symptoms, trended toward association with Eckardt score at first (0.7 ± 1.0 vs 1.8 ± 1.5, $p = 0.071$) and second follow up (1.0 ± 1.5, $p = 0.181$), but did not reach statistical significance. Half of all patients (12/24) who had FLIP measurements taken with a 40 mL fill fell into the ideal DI range. A post myotomy compliance of ≥ 125 mm^3/mmHg at 40 mL fill was associated with a lower Eckardt score at first (0.4 ± 0.5 vs 1.8 ± 1.3, $p = 0.008$) and second (0.4 ± 0.5, vs 2.0 ± 1.4, $p = 0.027$) postoperative visit [Table 4].

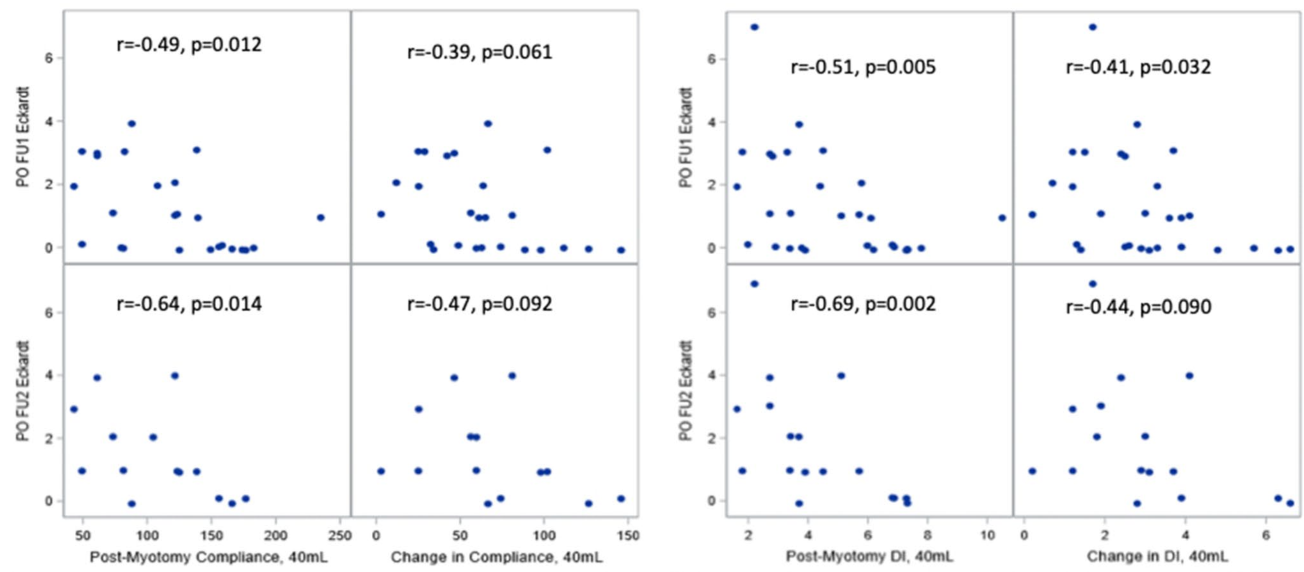

Fig. 2 a. Post-op Eckardt score at first and second follow up based on post-myotomy compliance at 40 mL fill and change in compliance at 40 mL fill. b. Post-op Eckardt score at first and second follow up based on post-myotomy distensibility index at 40 mL fill and change in distensibility at 40 mL fill. *PO* postoperative, *FU*1 first follow up, *FU*2 second follow up

Table 4 Association between Eckardt scores at first and second follow-up and defined ideal ranges for cross-sectional area, distensibility index, and compliance.

	Post-myotomy CSA, 30 mL			Post-myotomy DI, 40 mL			Post-myotomy Compliance, 40 mL		
	< 80 or > 95 mm^2 Mean ± SD	Ideal 80–95 mm^2 Mean ± SD	*p*-value	< 4.5 mm^2/mmHg Mean ± SD	Ideal 4.5–8.5 mm^2/mmHg Mean ± SD	*p*-value	< 125 mm^3/mmHg Mean ± SD	Ideal ≥ 125 mm^3/mmHg Mean ± SD	*p*-value
	N = 17	*N* = 3	–	*N* = 12	*N* = 12	–	*N* = 14	*N* = 10	–
Postop Eckardt Score at FU1	1.6 ± 1.8	2.7 ± 0.6	0.115	1.8 ± 1.5	0.7 ± 1.0	0.071	1.8 ± 1.3	0.4 ± 0.5	0.008
Postop Eckardt Score at FU2	2.4 ± 1.9	–	–	1.8 ± 1.3	1.0 ± 1.5	0.181	2.0 ± 1.4	0.4 ± 0.5	0.027

CSA cross sectional area, *DI* distensibility index, *FU*1 first follow-up, *FU*2 second follow-up

Discussion

POEM has become a widely accepted treatment for achalasia and other esophageal motility disorders, often complicated by the development of postoperative GERD. The goal of a lower esophageal myotomy is to improve symptoms of achalasia, most frequently defined by Eckardt Score. The addition of FLIP technology offers real-time intra-operative feedback regarding adequacy of myotomy and a tailored myotomy can be achieved.

Patients with spastic disorders of the esophagus who underwent POEM were excluded from analysis due to normal LES. Although patients with type 3 achalasia historically have worse response to surgical interventions, lower esophageal myotomy and changes in compliance address the changes seen in their hypertonic LES. The entire cohort saw resolution of Eckardt score following surgical intervention, and results did not differ significantly when excluding type 3 achalasia patients, and thus they were included in analysis.

Although several authors have described optimized outcomes following POEM based on DI or CSA of the GEJ, it is still unclear which metric generated by impedance planimetry best guides a tailored myotomy. Teitelbaum et al. found DI after laparoscopic Heller myotomy or POEM of 4.5–8.5 mm^2/mmHg at a 40 mL fill to optimize both Eckardt score (≤ 1) and GerdQ score (≤ 7) [6]. Ngamruengphong et al. described an ideal CSA of 80–95 mm^2 at a 30 mL fill to achieve Eckardt score < 3 and absence of reflux esophagitis on postoperative EGD and/or normal postoperative pH study [7]. Half of our patients who had measurements taken with a 40 mL fill fell into the ideal DI range described by Teitelbaum et al. However, falling into the ideal DI range was not significantly associated with postoperative Eckardt score, and therefore performed worse than compliance ≥ 125 mm^3/mmHg in predicting postoperative Eckardt score. In our cohort, only 3 patients, 8.57% of the entire cohort, fell into the ideal CSA range described by Ngamruengphong et al., and it did not associate well with postoperative Eckardt score at first follow up. Zero of those three patients completed a second follow up, limiting our ability to assess association with Eckardt score at second follow up. Other authors have described outcomes following POEM related to FLIP measurements taken with a 30 mL fill. Su et al. found worse control of achalasia symptoms defined as Eckardt score ≥ 3 after either laparoscopic Heller myotomy or POEM with final DI ≤ 3.1 mm^2/mmHg ($p = 0.001$) or change in DI ≤ 3.0 mm^2/mmHg ($p = 0.01$) and worse Reflux Symptom Index (RSI) scores at 2 years postop with final CSA > 96 mm^2 ($p = 0.031$) [8]. Attaar et al. found final CSA ≥ 83 mm^2 ($p = 0.008$) or DI ≥ 2.7 mm^2/mmHg ($p = 0.016$) after POEM associated with higher rates of esophagitis seen on postoperative EGD without differences in GERD-HRQL or RSI scores [9].

There are several difficulties in determining which FLIP metric can best guide a tailored myotomy, yielding improved Eckardt scores and minimizing postoperative GERD. To date, wide variations in published FLIP protocols include differences in type of catheter, volume of fill, and metrics reported. All of the above reported studies utilized an 8 cm (EF-325) catheter, as was used in our study. Much of the literature published to date utilizes a 30 mL fill, with recent consensus guidelines recommending a 40 mL fill when evaluating the GEJ to ensure a minimum intra-bag pressure of > 20 mmHg [10]. Both DI and CSA are measures of the single narrowest plane of the GEJ. Compliance, rather than measuring the geometry of a single plane, represents the functional response of a 2 cm long segment, centered around the GEJ, measured as a volumetric distension in response to an increase in pressure. While the authors feel that compliance may be the FLIP metric that best represents the dynamic function of the GEJ, there is minimal literature reporting on compliance as a data point of interest when utilizing impedance planimetry in foregut surgery. Inclusion of compliance as a metric of interest is notably absent from a 2021 consensus statement on use of FLIP technology in foregut surgery from Su et al. [10].

The only paper to date reporting on compliance in foregut surgery was recently published out of our group, evaluating changes in compliance during fundoplication and association with patient-reported quality of life outcomes. Wu et al. noted no significant association between compliance after fundoplication and post-operative RSI or GERD-HRQL scores at 2 years follow up [11]. As we also did not see any strong association between compliance post POEM and development of post-operative GERD, we believe that compliance does not perform well as a predictor of GERD outcomes, and upper limit cutoffs of CSA and DI should continue to guide intraoperative decision making. It remains unclear how compliance changes in the long term, with increase in compliance from post myotomy measurements taken in the operating room to time of postoperative EGD seen in the entire subset of our cohort that underwent post-operative EGD with FLIP evaluation.

Limitations

There are several limitations to this study, most notably the retrospective nature of the data analysis, small sample size, and limited follow-up. Patients for whom the FLIP machine did not calculate a compliance, and who did not have their raw intraoperative FLIP data archived, were unable to undergo a compliance calculation, severely limiting the sample size. Median time to second follow up was approximately 2 months. More data is needed regarding longer term outcomes and any loss of treatment effect or development of GERD over time. Additionally, our groups FLIP protocol for POEM changed during the study period, and patients with data collected early in our groups FLIP experience were evaluated with only a 30 mL fill, and not a 40 mL fill, as recommended by expert consensus [10].

Conclusion

A target post POEM compliance of at least 125 mm^3/mmHg at a 40 mL fill is associated with normal Eckardt scores at first and second post-operative visits. In our cohort, a post myotomy compliance of ≥ 125 mm^3/mmHg performed better than previously defined ideal ranges of DI and CSA in predicting post-operative Eckardt scores. We were unable to define an upper limit of compliance to minimize postoperative GERD, and believe compliance may be a poor predictor of developing GERD.

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Declarations

Disclosures Dr Michael B. Ujiki is a Scientific board member for Boston Scientific, a Consultant for Cook, a Consultant for Olympus, a Consultant and speaker for WL Gore and Associates, and a Speaker for Medtronic. Dr Julia R. Amundson, Dr Hoover Wu, Dr Vanessa VanDruff, Dr Michelle Campbell, Ms Kuchta, and Dr H Mason Hedberg have no conflicts of interest or financial ties to disclose.

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