



# Outcomes after per-oral endoscopic myotomy for Zenker's diverticula (Z-POEM) and correlation with impedance planimetry (FLIP)

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## Abstract

**Introduction** Zenker's diverticulum (ZD) is a false pulsion diverticulum of the cervical esophagus. It is typically found in older adults and manifests with dysphagia. The purpose of this study is to describe our experience with Per-oral endoscopic myotomy for Zenker's (Z-POEM) and intraoperative impedance planimetry (FLIP).

**Methods** We performed a single institution retrospective review of patients undergoing Z-POEM in a prospective database between 2014 and 2022. Upper esophageal sphincter (UES) distensibility index (DI, mm<sup>2</sup>/mmHg) was measured by FLIP before and after myotomy. The primary outcome was clinical success. Secondary outcomes included technical failure, adverse events, and quality of life as assessed by the gastroesophageal health-related quality of life (GERD-HRQL), reflux severity index (RSI), and dysphagia score. A statistical analysis of DI was done with the paired *t*-test ( $p < 0.05$ ).

**Results** Fifty-four patients underwent Z-POEM, with FLIP measurements available in 30 cases. We achieved technical success and clinical success in 54/54 (100%) patients and 46/54 patients (85%), respectively. Three patients (6%) experienced contained leaks. Three patients were readmitted: one for aforementioned contained leak, one for dysphagia, and one post-operative pneumonia. Three patients with residual dysphagia underwent additional endoscopic procedures, all of whom had diverticula > 4 cm. Following myotomy, mean DI increased by  $2.0 \pm 1.7$  mm<sup>2</sup>/mmHg ( $p < 0.001$ ). In those with good clinical success, change in DI averaged  $+1.6 \pm 1.1$  mm<sup>2</sup>/mmHg. Significant improvement was found in RSI and GERD-HRQL scores, but not dysphagia score.

**Conclusion** Z-POEM is a safe and feasible for treatment of ZD. We saw zero cases of intraoperative abandonment. We propose that large diverticula (> 4 cm) are a risk factor for poor outcomes and may require additional endoscopic procedures. An improvement in DI is expected after myotomy, however, the ideal range is still not known.

**Keywords** Zenker's diverticulum · Z-POEM · EndoFLIP · Impedance planimetry · Distensibility index

Zenker's diverticulum (ZD) is a false, pulsion diverticulum of the cervical esophagus. ZD has a prevalence of 0.01–0.11% and is most common in elderly men in their

7th and 8th decades of life [1]. The most common symptom of ZD is dysphagia (80–90%). Halitosis, regurgitation, and aspiration also occur. As a ZD enlarges, it can become impacted leading to extraluminal compression of the esophagus and subsequent dysphagia. Over time, this can give rise to weight loss and malnutrition.

The underlying etiology of ZD unknown. It is proposed that the cricopharyngeus muscle becomes increasingly fibrotic with age and decreases the compliance of the upper esophageal sphincter. Intraluminal pressure increases causing an outpouching of the mucosa and submucosa through a weak point in the posterior esophageal wall bounded by the transverse fibers of the cricopharyngeus muscle and the oblique fibers of the inferior constrictor muscles [2].

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The management of ZD is centered around dividing the cricopharyngeal muscle. The Zenker's per-oral endoscopic myotomy (Z-POEM) is a flexible endoscopic technique that adopts the use of submucosal tunneling to safely and effectively perform cricopharyngeal myotomy. Compared to rigid endoscopic techniques, it is not bound by the anatomic constraint of requiring neck hyperextension. Z-POEM also allows for complete visualization and division of the entire cricopharyngeus muscle.

Complete division of the cricopharyngeus is important in preventing primary failure and recurrence. Completion of myotomy leads to an objective increase in distensibility of the upper esophageal sphincter (UES) [3]. Changes in UES distensibility can be measured with the functional lumen imaging probe (FLIP), also known as impedance planimetry, a catheter-based method to measure endoluminal distensibility. This device is well known in its application to measuring lower esophageal sphincter distensibility and has been used to assess adequate myotomy in patients with achalasia. Several groups have looked into measuring the UES with FLIP [4]. In review of the literature, there are two small series, with 13 and 11 patients, measuring changes in distensibility after Z-POEM [5, 6].

This study describes our clinical outcomes in Z-POEM patients. We also aim to add to the current literature of UES distensibility following cricopharyngeal myotomy and to determine if changes in distensibility can predict clinical success.

## Methods

### Data collection

This study is a single-center, retrospective review of a prospectively kept database. ZD was diagnosed on esophagram or endoscopy. All patients undergoing Z-POEM from 2014 to 2022 were included. Our database records patient demographics, pre-operative symptoms, prior intervention, operative time, length of hospital stay, clinical success (defined as > 85% resolution of dysphagia), intraoperative complications, adverse events, and recurrent symptoms.

Patients undergo routine follow-up to assess percent improvement in dysphagia two weeks after Z-POEM. Additional follow-up was provided for persistent or recurrent symptoms. Patients also receive electronic surveys provided before surgery and at 3 weeks, 6 months, 1 year, and 2 years after Z-POEM. Surveys assess quality of life based on the Reflux Severity Index (RSI), Gastroesophageal reflux disease health-related quality of life (GERD-HRQL), and Dysphagia scores. The RSI consisting of nine questions on a 0–5 severity scoring system and GERD-HRQL consisting of twelve questions on a 0–5 scale were designed to

assess gastroesophageal reflux disease. We use these scores as adjuncts for measuring symptoms of ZD as many of the questions are relevant.

This retrospective review was approved by an institutional review board.

### Diagnostic testing: upper endoscopy, FLIP system, and impedance planimetry protocol

All procedures were performed by a single surgeon. Z-POEM was completed under general anesthesia due to high aspiration risk. Patients undergo diagnostic upper endoscopy to identify the ZD and measure the distance of the ZD from the incisors as well as the depth of the ZD pouch.

We then perform impedance planimetry to measure UES distensibility. The FLIP (EndoFLIP™, Medtronic Inc.) is a balloon catheter consisting of sixteen axially oriented impedance planimetry electrodes spaced 0.5 cm apart with a pressure sensor that measures intraballoon pressure. Distensibility is a function of endoluminal diameter and intraballoon pressure. For Z-POEM, an 8 cm catheter (EF-325) is utilized.

Under endoscopic visualization, the EndoFLIP™ catheter is guided into the true lumen of the esophagus. The balloon is filled to 30 mL and centered across the UES. This fill volume corresponds with our laboratories' historical protocols [7]. We record the balloon pressure (P, mmHg), minimum diameter (D<sub>min</sub>, mm), cross-sectional area (CSA, mm<sup>2</sup>), and distensibility index (DI, mm<sup>2</sup>/mmHg). These measurements are repeated after myotomy and prior to mucosotomy closure with endoscopic clips.

### Z-POEM technique and post-operative care

Following diagnostic endoscopy, the diverticulum is cleared of any impacted contents. A clear endoscopic cap is placed and the HybridKnife I-type (Erbe USA, Inc.) is used for dissection. A longitudinal mucosotomy is created directly on the cricopharyngeal septum. A 0.8% indigo carmine mixture is used to lift the mucosa on either side. We then proceed with myotomy with completion determined by visualization of the circular muscles of the esophagus. The mucosotomy is then closed with endoscopic clips.

In our initial experience, patients were observed overnight in the hospital with routine barium esophagram. Currently, patients are typically discharged from the post-operative care unit after a period of observation. Imaging is not routine and only performed when clinically indicated. In the first two weeks after Z-POEM, patients maintain a pureed diet and advance to a regular diet in the outpatient setting.

## Statistical analysis

Descriptive statistics were reported as a mean with standard deviation, median with interquartile range (IQR) or frequency rate and percentage. Comparison of pre-operative and post-operative RSI, GERD-HRQL, and dysphagia scores as well as distensibility index were done with a paired *t*-tests. Identifying ideal DI following myotomy was completed using a Fisher's exact tests. All statistical analysis was performed using SAS 9.4 (SAS instate, Cary, NC) with a two-tailed test with a significant level of  $p < 0.05$ .

## Results

### Patient demographics

In our study period, 54 patients (mean age of  $72 \pm 12$  years) underwent Z-POEM (Table 1). All procedures were completed by a single surgical endoscopist. The most common pre-operative symptoms were dysphagia (94%) and regurgitation (78%). Median diverticulum size was 2.3 cm (IQR 2.0–3.0 cm) with seven patients having large ZD (> 4 cm). Median follow-up was 2 months (IQR 1–19 months).

### Operative and clinical outcomes

Z-POEM was completed in all patients (54/54, 100%). Mean operative time was  $35 \pm 14$  min. There were no intraoperative complications. Median hospital length of stay was 5 h (IQR 2–7). 30-day mortality rate was 0% (see Table 2).

**Table 1** Patient characteristics for Z-POEM patients

	All patients
Total patients ( <i>N</i> )	54
Demographics	
Age, years (mean $\pm$ SD)	$72 \pm 12$
BMI (mean $\pm$ SD)	$26.9 \pm 5.4$
Female [ <i>N</i> (%)]	22 (43.1)
Pre-op symptoms [ <i>N</i> (%)]	
Regurgitation	40 (78.4)
Dysphagia	49 (94.2)
Cough	14 (28.0)
Nocturnal symptoms	6 (12.0)
Gurgling	25 (50.0)
Halitosis	19 (37.3)
Anorexia	1 (2.0)
Pre-op PPI use [ <i>N</i> (%)]	20 (40.0)

Z-POEM per-oral endoscopic myotomy for Zenker's, SD standard deviation, BMI body mass index, PPI proton pump inhibitor

**Table 2** Z-POEM outcomes

	All patients
Total patients ( <i>N</i> )	54
Surgical characteristics	
Operative time, min (mean $\pm$ SD)	$35 \pm 14$
EBL (mL) [median (Q1–Q3)]	0 (0–0)
ASA classification [ <i>N</i> (%)]	
2	28 (52.8)
3	22 (41.5)
4	3 (5.7)
Diverticulum size (cm) [median (Q1–Q3)]	2.3 (2.0–3.0)
Diverticulum location (cm) [median (Q1–Q3)]	17 (16–18)
Intraoperative complications [ <i>N</i> (%)]	0 (0.0)
Technical success [ <i>N</i> (%)]	54 (100%)
Clinical success [ <i>N</i> (%)]	46 (85%)
Postoperative outcomes	
LOS (hours) [median (Q1–Q3)]	5 (2–7)
30-day mortality [ <i>N</i> (%)]	0 (0.0)
30-day complication [ <i>N</i> (%)]	3 (5.6)
30-day ED visit [ <i>N</i> (%)]	0 (0.0)
30-day readmission [ <i>N</i> (%)]	3 (5.6)
Follow-up duration (months) [median (Q1–Q3)]	2 (1–19)

Z-POEM per-oral endoscopic myotomy for Zenker's, EBL estimated blood loss, ASA American Society of Anesthesiologists, LOS length of stay

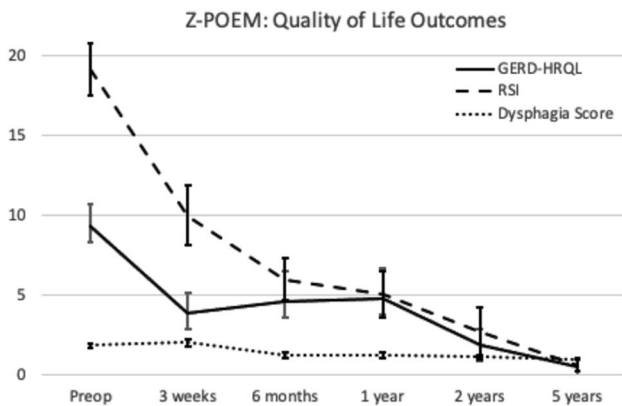
Clinical success was obtained in 46 of 54 patients (85.2%) at 1 month follow-up. Three of the eight non-responders (38%) had large ZD and three of seven patients with large ZD (43%) were poor responders. Pre-operative quality of life scoring was obtained in 32 patients. At 3 weeks, with a 66% response rate (21 of 32 patients), we found statistically significant improvement in RSI ( $19.2 \pm 9.2$  vs  $10.0 \pm 8.6$ ,  $p < 0.05$ ) and GERD-HRQL ( $9.3 \pm 7.8$  vs  $3.9 \pm 5.9$ ,  $p < 0.05$ ), but not in dysphagia score ( $1.9 \pm 0.8$  vs  $2.0 \pm 1.1$ ,  $p = 0.429$ ). Improvements in RSI and GERD-HRQL were seen up to 5 years post-op with a 19% (6 of 32 patients) response rate (Table 3, Fig. 1).

In 49 of 54 patients (91.8%), Z-POEM was completed without complication. Of the five patients (9.2%) with perioperative adverse events, three patients had contained leaks. Two of these leaks were found early in our experience when we performed routine post-operative imaging. Both patients were clinically asymptomatic. The third patient was readmitted on post-operative day 2 with fevers and neck pain which resolved with conservative management. In none of these instances, additional endoscopic or operative management was required with all leaks resolving following supportive care. There were also three readmissions (5.6%). In addition to the aforementioned patient readmitted with a contained leak, one patient was

**Table 3** Quality of life for Z-POEM patients

	Pre-op	3 Weeks	6 Months	1 Year	2 Years	5 Years
	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD
	N=32	N=21	N=15	N=11	N=8	N=6
RSI	19.2 ± 9.2	10.0 ± 8.6	6.0 ± 5.1	5.1 ± 4.8	2.7 ± 4.1	0.7 ± 1.0
<i>p</i> -value from pre-op	–	≤ 0.001	≤ 0.001	≤ 0.001	≤ 0.001	≤ 0.001
GERD-HRQL	9.3 ± 7.8	3.9 ± 5.9	4.6 ± 6.7	4.8 ± 6.3	1.9 ± 2.8	0.5 ± 1.2
<i>p</i> -value from pre-op	–	0.008	0.018	≤ 0.001	0.029	0.012
Dysphagia score	1.9 ± 0.8	2.0 ± 1.1	1.3 ± 0.6	1.3 ± 0.6	1.1 ± 0.4	1.0 ± 0.0
<i>p</i> -value from pre-op	–	0.429	0.096	0.081	0.175	0.208

Z-POEM Per-oral endoscopic myotomy for Zenker’s, RSI reflux severity index, GERD-HRQL Gastroesophageal Reflux Disease Health-related Quality of Life



**Fig. 1** Quality of life in patients undergoing Z-POEM RSI (reflux severity index), GERD-HRQL (gastroesophageal health-related quality of life)

readmitted for severe dysphagia and another for aspiration pneumonia.

Three patients (5.6%) underwent repeat endoscopic interventions. One patient, with an 8 cm ZD, underwent repeat Z-POEM with good outcome. Two patients, both with 5 cm ZD, underwent subsequent endoscopic diverticulopexy resulting in resolution of symptoms.

**Table 4** Pre and post Z-POEM impedance planimetry measurements

Measurement	Pre Z-POEM Mean ± SD	Post Z-POEM Mean ± SD	Change pre to post Mean ± SD	<i>p</i> -value* Pre vs. post
	N=30	N=30	N=30	–
Dmin (mm)	11.4 ± 2.1	13.1 ± 1.1	1.8 ± 2.0	≤ 0.001
Pressure (mmHg)	33 ± 10	28 ± 9	– 5 ± 11	0.015
CSA (mm <sup>2</sup> )	105 ± 33	137 ± 23	32 ± 29	≤ 0.001
DI (mm <sup>2</sup> /mmHg)	3.5 ± 1.2	5.5 ± 2.3	2.0 ± 1.7	≤ 0.001

Z-POEM per-oral endoscopic myotomy for Zenker’s, SD standard deviation, Dmin minimum diameter, CSA cross-sectional area, DI distensibility index

\*Paired *t*-test

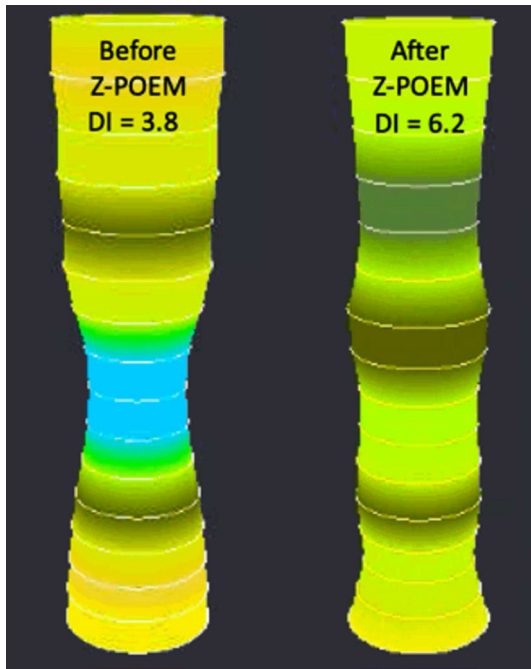
### Impedance planimetry results

UES distensibility was measured in 30 patients. Six patients were omitted due to incomplete data and 18 patients early in our experience did not undergo impedance planimetry. Prior to myotomy, average DI was 3.5 ± 1.2 mm<sup>2</sup>/mmHg. Following myotomy, there was a mean increase in DI by 2.0 ± 1.7 mm<sup>2</sup>/mmHg (*p* < 0.005). Improvements in Dmin and CSA were also identified (Table 4). Furthermore, graphical changes in morphology were visualized on the EndoFLIP system (Fig. 2).

When stratifying between patients with good clinical response to those without, there were 23 patients with good clinical response and 7 patients with poor clinical response. Mean increase in DI was 1.6 ± 1.1 vs 3.3 ± 2.9 mm<sup>2</sup>/mmHg (*p* = 0.037), respectively (Table 5). There were no differences in increases of Dmin or CSA between these two groups with varying clinical response.

### Discussion

We performed Z-POEM in 54 patients. This is one of the largest single-center experiences published to date. Our rate of clinical success was slightly lower than those published in three systemic reviews (85% vs 91.0–93.0%), but rates



**Fig. 2** Graphical representation of UES morphology before and after Z-POEM. DI (distensibility index,  $\text{mm}^2/\text{mmHg}$ )

**Table 5** Pre and post Z-POEM impedance planimetry measurements—clinical responders

Measurement	Not responder Mean $\pm$ SD	Clinical responder Mean $\pm$ SD	<i>p</i> -value*
Pre Z-POEM	<i>N</i> =7	<i>N</i> =23	
Dmin (mm)	10.7 $\pm$ 2.8	11.6 $\pm$ 1.9	0.470
Pressure (mmHg)	37 $\pm$ 14	32 $\pm$ 9	0.271
CSA ( $\text{mm}^2$ )	95 $\pm$ 41	108 $\pm$ 30	0.515
DI ( $\text{mm}^2/\text{mmHg}$ )	3.1 $\pm$ 1.7	3.6 $\pm$ 1.1	0.445
Post Z-POEM	<i>N</i> =7	<i>N</i> =23	
Dmin (mm)	13.2 $\pm$ 1.0	13.1 $\pm$ 1.2	0.332
Pressure (mmHg)	29 $\pm$ 16	28 $\pm$ 7	0.770
CSA ( $\text{mm}^2$ )	138 $\pm$ 20	136 $\pm$ 25	0.354
DI ( $\text{mm}^2/\text{mmHg}$ )	6.4 $\pm$ 3.9	5.2 $\pm$ 1.5	0.234
Change pre to post	<i>N</i> =7	<i>N</i> =23	
Dmin (mm)	2.5 $\pm$ 2.9	1.6 $\pm$ 1.6	0.301
Pressure (mmHg)	- 8 $\pm$ 15	- 4 $\pm$ 10	0.297
CSA ( $\text{mm}^2$ )	43 $\pm$ 41	29 $\pm$ 25	0.442
DI ( $\text{mm}^2/\text{mmHg}$ )	3.3 $\pm$ 2.9	1.6 $\pm$ 1.1	0.037

Z-POEM per-oral endoscopic myotomy for Zenker's, *SD* standard deviation, *Dmin* minimum diameter, *CSA* cross-sectional area, *DI* distensibility index

\*Unpaired *t*-test

of technical success were higher (100% vs 91.0–93.0%). Our adverse event rate was comparable (6% vs 10.6–12.4%) [8–10].

Our higher rate of clinical failure may not necessarily be the result of a technical failure of Z-POEM, as patients in this aging population often have many other underlying etiologies for dysphagia such as ineffective esophageal motility, poor initiation of swallows, or even ineffective UES barrier function [4]. For patients with persistent dysphagia, we often perform either a repeat imaging study or endoscopy. If there is no appreciable defect, we refer them for evaluation with speech therapy.

In our series, we were able to successfully complete the Z-POEM in all patients. A recently published meta-analysis reports an abandonment rate of 10% (95% CI 3–19%) mainly due to difficulty in identifying or completely visualizing the cricopharyngeus muscles [11]. We believe our technique of creating the mucosotomy directly on the cricopharyngeal bar allows us to complete the Z-POEM with lower rates of abandonment without increasing the risk of full thickness perforation.

We do note a low adverse event rate without any need for endoscopic or surgical management due to complications of Z-POEM. We did not have any complications of bleeding, which were often noted in other studies [11]. All three contained leaks were not severe adverse events as they were able to be managed conservatively. Furthermore, two of the patients with contained leaks were from Z-POEM performed within our first five experiences and both patients were completely asymptomatic. Adverse events were uncommon after the initial learning curve.

We also report long-term durability of Z-POEM and durable improved quality of life. Quality of life scores, RSI and GERD-HRQL, were used as adjunctive measures of dysphagia and showed persistent improvement on quality of life. At 1 year and 5 years, quality of life surveys were completed by 35% and 19% of our patients, respectively. However, there may be some bias regarding the patient population responding to our surveys. Contrary to RSI and GERD-HRQL, there was no statistical improvement in dysphagia score at any time point. This may be due to most patients having low dysphagia scores pre-operatively with little room for statistical improvement.

Measurement of UES distensibility following Z-POEM has been reported in two smaller series. A retrospective study with thirteen patients found an average increase in DI of 1.0  $\text{mm}^2/\text{mmHg}$  and 1.8  $\text{mm}^2/\text{mmHg}$  at balloon fill volumes of 40 mL and 50 mL [6]. A prospective study with 11 patients found a mean DI change of 2.2  $\text{mm}^2/\text{mmHg}$  at 40 mL fill volume [5]. We used a 30 mL fill volume based on our own historical laboratory methodology. As expected, there is an increase in distensibility following cricopharyngeal myotomy. Despite using a 30 mL fill volume, our improvement in DI was comparable. Based on a study by Sondhi et al., it may be surmised that increasing the fill volume results in higher DI.

When comparing DI changes based on clinical response, we found that poor responders actually had a clinically significantly larger increase in DI than good responders. We therefore could not conclude that poor responders did not have adequate myotomy. Higher changes in DI after myotomy in poor responders may be the result larger endoluminal diameter following myotomy in patients with large ZD. Furthermore, large ZD ( $\geq 4$  cm) may be a predictor of poor outcomes.

We found that large ZD ( $> 4$  cm) are particularly challenging to manage. Unlike rigid endoscopic and open techniques for treating ZD, Z-POEM does not directly address the redundant mucosa and submucosa of ZD. Performing cricopharyngeal myotomy allows the diverticular pouch to converge with the esophageal lumen. Occasionally, after Z-POEM, patients do undergo repeat esophagram or endoscopy and we note either complete resolution of the diverticular pouch or lack of contrast retention. When the ZD is large, despite adequate cricopharyngeal myotomy, the esophageal wall itself can act as a septum between the ZD and the diverticulum persists. We found large ZD to be a risk factor for poor clinical outcome following Z-POEM with a clinical failure rate of 43% (three of seven patients with large ZD). In two patients, we performed a subsequent diverticulopexy to address the redundant mucosa with symptomatic resolution. It may, therefore, be reasonable to counsel patients who have a large ZD that they may require additional procedures if they continue to have symptoms following Z-POEM.

Abnormally high distensibility may also lead to poor outcomes. One study of UES DI in patients without ZD found that individuals with higher DI (mean  $2.8 \text{ mm}^2/\text{mmHg}$ ) were more prone to supra-esophageal symptoms such as globus sensation, aspiration and chronic cough. A higher DI was felt to reflect a loss of barrier function of the UES. It is possible that our patients with poor clinical response with more significant increases in their UES DI developed supra-esophageal symptoms following Z-POEM.

Measurement of the UES distensibility provides additional variability. Unlike the LES, the UES distensibility has contributions from the inferior pharyngeal constrictors and elevation of the hypopharynx during initiation of a swallow. The cricopharyngeus muscle only plays a small part in UES distensibility [12]. Notably, while the cricopharyngeus muscle is only 1–2 cm in width, the high-pressure zone of the UES actually spans 2–4 cm [13]. High-resolution manometry measurement of the UES shows wide variability in UES pressure. This may indicate that the change in DI is more important than the final DI value.

## Limitations

The limitations of this study include the retrospective nature of the analysis and may result in lower quality of evidence,

selection bias, and confounding. Furthermore, despite having a relatively large sample size, the sample size of those undergoing FLIP is still small. This cohort represents a significant learning curve which may lead to higher rates of recurrent dysphagia and adverse events. The long-term follow-up of this cohort is also limited. Finally, all Z-POEM procedures were completed by a single surgeon and results may not be congruent in all instances.

We defined our clinical success as a subjective improvement in dysphagia of more than 85%. Across the literature, there exists a heterogeneity in the definition of clinical success. The use of a validated tool, like the Kothari Haber Scoring System, would be helpful in standardizing our definition of clinical success [14].

Generalizability of our impedance planimetry results is difficult as measurements of the UES are not standardized. Studies published to date measure UES distensibility with balloon volumes of 20 mL to 70 mL [4, 6]. Two studies looking at UES distensibility after Z-POEM use the 40 mL and 50 mL FLIP fill volumes [5, 6].

## Conclusions

Z-POEM is a safe and effective management of ZD. We did note that individuals with large ZD may be best treated with subsequent diverticulopexy. Impedance planimetry shows an improvement of DI following Z-POEM with a mean DI change of  $2.0 \pm 1.7 \text{ mm}^2/\text{mmHg}$  ( $p < 0.005$ ). However, there is no ideal final DI or change in DI that correlates to clinical success. Interestingly, our patients with poor clinical outcomes had an average post-Z-POEM DI higher than that of our good clinical responders, which may reflect anatomic differences of large diverticula.

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## Declarations

**Disclosures** Michael B. Ujiki is a scientific advisory board member for Boston Scientific and Apollo, a consultant and speaker for WL Gore and Associates, and a speaker for Medtronic. Simon YW Che, Stephanie Joseph, Kristine Kuchta, Julia R. Amundson, Vanessa N. VanDruff, Shun Ishii, Christopher J. Zimmermann, Herbert M. Hedberg, Michael B. Ujiki have no conflicts of interest or financial ties to disclose.

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