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Is that 'floppy' fundoplication tight enough?

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Abstract

Background Laparoscopic fundoplication is the treatment of choice for medically refractory gastroesophageal reflux disease (GERD). Surgeons seek to create a competent valve at the gastroesophageal junction (GEJ) but are careful to construct a 'floppy' fundoplication that is not too tight to minimize side effects. The endoscopic functional luminal-imaging probe (EndoFLIP®) uses impedance planimetry to assess the GEJ intraoperatively. We sought to determine if EndoFLIP variables are associated with symptomatic outcomes following fundoplication.

Methods We conducted a retrospective review of prospectively maintained data on subjects who underwent primary laparoscopic fundoplication at a single institution between 2014 and 2018. All patients met standard indications for antireflux surgery. Minimum diameter (Dmin), cross-sectional area (CSA), intra-bag pressure, and distensibility index of the GEJ were obtained at 30 mL volumes. GERD Health Related Quality of Life (GERD-HRQL) surveys were administered pre- and postoperatively. Patients were excluded if they underwent fundoplication without EndoFLIP assessment or if they did not complete a postop GERD-HRQL survey. Receiver operating characteristic curves were used to determine if EndoFLIP measurements were correlated with symptomatic outcomes.

Results Forty-three patients met inclusion criteria. The change in Dmin and CSA measures during fundoplication were associated with daily or more frequent heartburn at 6 or more months postop. A decrease in Dmin of 0.15 mm or less (AUC = 0.718, sensitivity: 71%, specificity: 69%) and a decrease in CSA of 1.5 mm^2 or less (AUC = 0.728, sensitivity: 71%, specificity: 70%) were associated with severe heartburn.

Conclusions GEJ opening dynamics attained by EndoFLIP appear to be associated with symptomatic outcomes. When the Dmin and CSA do not decrease by a defined threshold, heartburn is more likely to be severe at 6 or more months postoperatively. This suggests that the fundoplication may not be tight enough to prevent persistent or recurrent GERD.

Keywords Fundoplication · Gastroesophageal reflux disease · EndoFLIP · Gastroesophageal junction · Distensibility

Laparoscopic fundoplication is the treatment of choice for medically refractory gastroesophageal reflux disease (GERD). Antireflux surgery is indicated when a patient with a confirmed diagnosis of GERD experiences persistent symptoms despite medical therapy [1, 2]. Laparoscopic fundoplication (Nissen or Toupet) has been shown to provide effective and long-lasting relief of GERD-related symptoms [3, 4].

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During surgery, the fundus and distal esophagus are mobilized, and the fundus is wrapped around the esophagus above the gastroesophageal junction (GEJ). The original fundoplication as described by Nissen has evolved since first detailed in 1956 [5]. Most of the modifications were designed to avoid side effects related to the formation of too tight of a wrap including dysphagia and 'gas bloat'. The advantages of a 'floppy' wrap in avoiding gas bloat have been described and adopted as the standard since the 1980's [6].

The endoscopic functional luminal-imaging probe (EndoFLIP®) is a catheter-based probe within a compliant bag that is inflated with saline to a fixed volume. Sensors on the probe use impedance planimetry to assess the diameter, cross-sectional area, and distensibility of the GEJ, all of which have been shown to decrease during fundoplication

[7–9]. This device is both safe and feasible to use during surgery and can provide real-time feedback on GEJ opening dynamics [8]. We sought to determine if GEJ dynamics as assessed by the EndoFLIP device intraoperatively correlate with GERD-related outcomes at 6 or more months following primary laparoscopic fundoplication.

Materials and methods

A retrospective review of prospectively maintained data was conducted to identify subjects who underwent primary laparoscopic fundoplication (Nissen or Toupet) for GERD at one academic medical center by a single surgeon between 2014 and 2018. Patients included in the study met indications for antireflux surgery with symptoms refractory to medical therapy and a diagnosis confirmed based on either upper endoscopy (LA Grade B, C or D erosive esophagitis) or pH/impedance testing. Nuclear medicine gastric emptying studies were conducted in patients with symptoms consistent with gastroparesis or findings of a gastric bezoar on upper endoscopy. Patients with delayed gastric emptying and symptoms sufficient enough to warrant an additional procedure at the time of fundoplication (pyloroplasty) were excluded. Preoperative demographic information including age, sex, and body mass index (BMI) was collected.

All subjects underwent intraoperative distensibility assessment of the GEJ using the EndoFLIP system. The EndoFLIP (Crospon, Galaway, Ireland) is a catheter-based probe with 17 ring electrodes spaced at 5-mm intervals within a bag that can be inflated to fixed volumes. Under sedation, the FLIP was advanced down the patient's esophagus using endoscopic visualization. The probe was inflated with 20 mL of saline and withdrawn until an "hour-glass" visual was displayed on the monitor at a distance from the incisors consistent with where the GEJ has been determined to be located on endoscopy. The balloon was then deflated and the pressure in the bag was 'zeroed' with the center of the bag at the GEJ. EndoFLIP assessments were conducted with 30 mL saline in the bag after zeroing the device. Prior to fundoplication, the GEJ dynamics were assessed with the patient under general anesthesia, in reverse Trendelenburg, and without the abdomen insufflated. Assessment following creation of the fundoplication was attained under identical conditions with the exception that abdomen was insufflated to 15 mmHg. Minimum diameter (Dmin), cross-sectional area (CSA), intra-bag pressure, and distensibility index (DI) of the GEJ were obtained. GEJ DI was calculated by dividing the minimum CSA by the intra-bag pressure. All measurements were the average of a 20-s interval to allow for fluid stabilization within the bag. EndoFLIP data was analyzed using the FLIP Analytics software. We routinely perform EndoFLIP in conjunction with our fundoplication procedures. For the patients in this series, the EndoFLIP data was one of several data points used to intraoperatively determine if a fundoplication had been properly constructed or needed to be revised. Intraoperative endoscopy was routinely performed once the fundoplication was complete to assess the subjective ease of passing the endoscope through the hiatal closure and fundoplication and the endoscopic appearance of the fundoplication. If the GEJ was difficult to pass with an endoscope, if the fundoplication appeared to be tight, and if the EndoFLIP data objectively confirmed these subjective impressions, the fundoplication would be taken down and revised. The threshold at which the fundoplication was considered to potentially be too tight was a DI < 0.5.

GERD Health Related Quality of Life (GERD-HRQL) surveys were administered to assess symptoms pre- and postoperatively. Questions asked patients to rate symptoms on a scale of 0–5, with five indicating the most severe. GERD-HRQL surveys were given preoperatively, and at 6 months, 1 year, and 2 years postoperatively (if applicable) during clinic visits or by phone follow-up. Patients were separated into two groups based on survey results: Those who reported daily or more frequent heartburn at any survey 6 months postoperatively or beyond, and those who did not. Patients were excluded from this study if they did not undergo EndoFLIP assessment in the operating room both prior to and following the construction of the fundoplication or if they did not complete either a preoperative or 6 month or more postoperative GERD-HRQL survey.

Surgical procedures performed were primary laparoscopic Nissen and Toupet fundoplications. Toupet was selected in patients with baseline dysphagia or bloating and/or in patients who had abnormal esophageal motility ($<70\%$ peristaltic contractions, mean amplitude < 30 mmHg). Nissen was selected in all other patients to undergo fundoplication for GERD. The surgical technique was standardized for all procedures. The esophagus was mobilized until there was at least 4 cm of intra-abdominal esophagus as measured from the angle of His to the base of the left crus when there was no axial tension applied to the esophagus. The hiatus was closed posteriorly with interrupted sutures. Hiatal reinforcement with mesh was not necessary for any patient in this series. In patients to undergo Nissen fundoplication, a 56–60 French esophageal bougie was passed prior to crural closure. The hiatus was closed until the crura were snug against the esophagus with the bougie in place. For Toupet, a bougie was not used and the crura were closed until the crural pillars were almost touching the esophagus when not under axial tension (no compression of the esophagus by the crura). The fundus was marked in advance and in a similar fashion for both Toupet and Nissen. A point 3 cm distal to the gastroesophageal junction and 5 cm from the greater curve was marked with a seromuscular suture in a symmetric location on both the anterior and posterior fundoplication.

For a Nissen, this point represented the location of the lower most stitch (out of 4) for a 2.5-cm-long fundoplication. Three of the four sutures incorporated a bite of anterior esophageal muscle. For a Toupet, these sutures represented the lowermost point of the fundoplication on each side. A 2.5-cm-long fundoplication was created by suturing the fundus in the pre-marked location to the esophagus at the 11 o'clock and 1 o'clock positions (as visualized on the monitor, with 12 o'clock representing straight anterior).

Statistical analysis was conducted using SPSS (version 24, IBM Corp.). Pre-insufflation values, postoperative values, and the difference between the two values (denoted as Δ, Δ = pre-insufflation minus post-fundoplication value) were assessed. Measures are reported as mean ± standard deviation. Paired *t* tests were used for intragroup bivariate analysis. For *t* tests, a *p* value of < 0.05 was considered statistically significant. Receiver operating characteristic (ROC) curves were used to assess if EndoFLIP measurements were an accurate predictor of symptomatic outcomes following surgery. The predictive ability of a variable on an outcome can be analyzed using the area under the ROC curve (AUC). An AUC of 0.500 denotes random chance while an AUC of 1.000 represents a perfect predictor of outcome. An AUC of greater than or equal to 0.700 is generally accepted as a good predictor of a given outcome. Following ROC analysis, curves with an AUC ≥ 0.700 were analyzed for an optimal cutoff point by determining a value on the curve that would maximize sensitivity and specificity of that variable. The Medical College of Wisconsin Institutional Review Board approved this study.

Results

A total of 43 patients underwent primary fundoplication and met all inclusion criteria. There were no cases where the intraoperative post-fundoplication DI was less than 0.5, and no cases where we determined that the fundoplication should be revised intraoperatively. Hiatal hernia was present prior to surgery in 50% of the cohort and mean size was 2.5 ± 1.9 cm. Seven patients (16%) reported daily or more frequent heartburn at 6 or more months postoperatively (classified as the severe heartburn cohort), while 36 (84%) reported rare or no heartburn symptoms (classified as the no/mild heartburn cohort). Demographics and surgery details are summarized in Table 1. Those with severe heartburn were significantly younger in age. However, no significant difference was found in BMI, sex, the presence of a hiatal hernia prior to surgery, or the type of fundoplication (Nissen vs. Toupet) performed between cohorts. Of the patients with severe heartburn, three have undergone diagnostic endoscopy and the endoscopic appearance of the fundoplication was normal in all three. None of these patients has had a repeat pH study at the time of this report. All patients with severe heartburn have resumed acid suppression medications.

Table 1 Patient demographics and surgery details

	No/mild heartburn ($n=36$)	Severe heartburn ($n=7$)	*p* value
Age	57.1 ± 11.5	37.3 ± 6.6	< 0.01
BMI (kg/m^2)	31.3 ± 4.5	30.8 ± 5.9	0.89
Female	23 (64%)	6 (86%)	0.21
Nissen	23 (64%)	5 (71%)	0.72
Toupet	13 (36%)	2 (29%)	

Table 2 Intraoperative EndoFLIP measurements for all patients

	No/mild postop heartburn ($n=36$)	Severe postop heartburn ($n=7$)	*p* value
Dmin (mm)			
Pre-insufflation	7.7 ± 2.0	6.7 ± 1.3	0.22
Post-fundoplication	6.3 ± 1.5*	7.3 ± 2.3	0.14
ΔDmin	− 1.4 ± 2.4	0.6 ± 2.5	0.06
CSA (mm^2)			
Pre-insufflation	49.6 ± 25.9	36.7 ± 14.9	0.21
Post-fundoplication	34.0 ± 17.2*	44.6 ± 26.3	0.14
ΔCSA	− 16.6 ± 31.5	7.9 ± 26.3	0.06
Pressure (mmHg)			
Pre-insufflation	15.2 ± 9.4	16.2 ± 5.7	0.79
Post-fundoplication	24.8 ± 6.4*	26.9 ± 8.6*	0.45
ΔPressure	9.6 ± 8.8	10.7 ± 5.3	0.75
DI (mm^2/mmHg)			
Pre-insufflation	4.6 ± 3.9	2.6 ± 1.5	0.20
Post-fundoplication	1.4 ± 0.9*	1.6 ± 1.1	0.57
ΔDI	− 3.2 ± 3.8	− 1.0 ± 1.9	0.15

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

Δ = pre-insufflation minus post-fundoplication values

*$p < 0.05$ for comparison to pre-insufflation value

A comparison of EndoFLIP measurements between cohorts is summarized in Table 2. Using ROC curves, EndoFLIP variables were evaluated for predictive ability of symptomatic outcomes. The ΔDmin (AUC = 0.718) and ΔCSA (AUC = 0.728) during fundoplication were found to be associated with daily or more frequent heartburn at all survey intervals (Fig. 1). These findings are consistent regardless of procedure type (Dmin: Nissen AUC = 0.700, Toupet AUC = 0.846. CSA: Nissen AUC = 0.713, Toupet AUC = 0.885). ROC curves evaluating pre-insufflation values, post-fundoplication values, ΔPressure and ΔDI had an AUC < 0.700 and thus showed no statistically significant correlation with symptomatic outcomes.

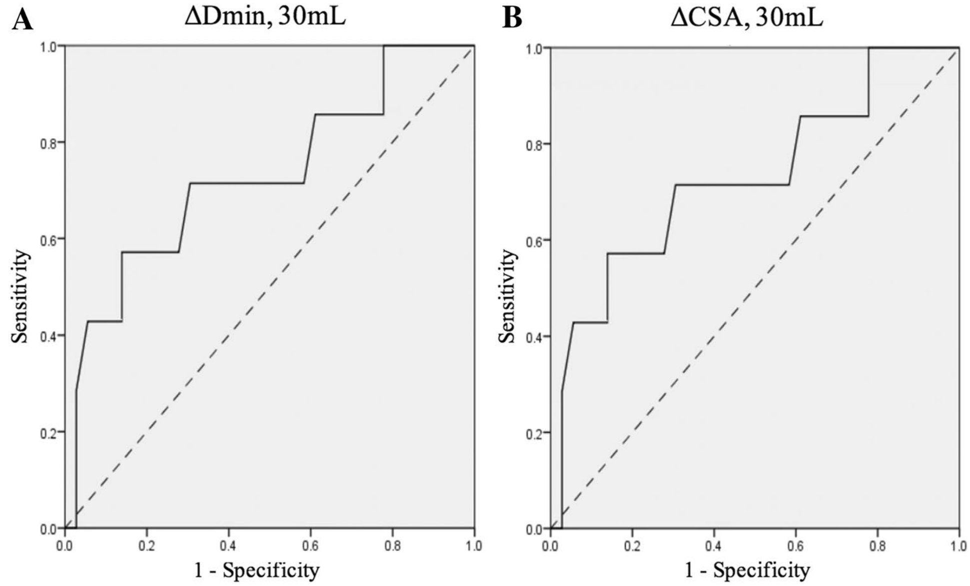

Fig. 1 ROC curves evaluating the change in EndoFLIP values following fundoplication and its association with severe heartburn at 6 or more months following surgery. ROC curves for the change in Dmin (**A**, AUC = 0.718) and CSA (**B**, AUC = 0.728) at 30 mL are shown. The chance diagonal (dotted diagonal line) is a reference line that depicts random chance

After an AUC of > 0.700 was found, ROC curves were used to determine an optimal "cutoff" point to maximize the sensitivity and specificity of the test and serve as a target value during surgery to minimize symptomatic outcomes. A decrease in ΔDmin of 0.15 mm or less (sensitivity: 71%, specificity: 69%) and a decrease in ΔCSA of 1.5 mm^2 or less (sensitivity: 71%, specificity: 70%) were correlated with severe heartburn symptoms at 6 or more months postoperatively.

Discussion

We have demonstrated that GEJ opening dynamics attained by EndoFLIP appear to be associated with postoperative heartburn following fundoplication. If the Dmin and CSA did not decrease by a defined threshold, daily heartburn was more likely to be present at 6 months or more postoperatively. These findings suggest that the EndoFLIP probe can be a useful tool to provide intraoperative feedback during fundoplication and allow the surgeon to tailor wrap geometry to optimize symptomatic outcomes.

During fundoplication surgery, surgeons seek to create a competent antireflux valve that is tight enough to prevent gastric contents from passing back into the esophagus, but not so tight that bolus clearance and esophageal emptying or the ability to vent swallowed air are impaired. Too loose and patients may experience persistent or recurrent GERD symptoms. Too tight and a patient may suffer from dysphagia or bloating as well as difficulty belching.

The original technique as described by Nissen involved approximating the anterior and posterior walls of the gastric fundus around the distal 6 cm of the esophagus. The short gastric arteries were not divided. The fundoplication was performed around a 'large bore intra-esophageal stent' [10]. Modifications have been added over time, mostly to avoid the side effects associated with too tight of a wrap. Standard technical modifications employed by most surgeons include routine division of the short gastric arteries and creation of a shorter wrap to envelop only about 2 cm of distal esophagus as recommended by DeMeester [11]. Various types of partial fundoplications have been proposed including the Dor [12] and Toupet [13] in an effort to reduce the risk of gas bloat syndrome.

Numerous comparative trials have been published contrasting the symptomatic outcomes and side effects of the various types of fundoplications. Several meta-analyses of randomized controlled trials comparing Nissen to Toupet have demonstrated equal effectiveness of Toupet as compared to Nissen fundoplication with fewer side effects related to Toupet including dysphagia, gas bloat, inability to belch, and reoperation due to severe dysphagia [3, 14, 15]. When comparing a 180° anterior fundoplication to other more complete types of wraps, the results are mixed. A recently published meta-analysis comparing anterior 180 degree to posterior 270° fundoplications suggests that heartburn, acid reduction medication use, and reoperations for recurrent GERD are significantly more prevalent following anterior 180° fundoplication [16]. Another meta-analysis comparing 360° to anterior 180° fundoplication reached essentially the same conclusions [17]. These are in contrast to another meta-analysis comparing 360° fundoplications to 180° anterior fundoplication which found similar outcomes with regard to esophageal acid exposure and heartburn with lower rates of dysphagia and gas-related symptoms following anterior partial fundoplication [18]. All of this lends credence to the possibility that a fundoplication can be too tight or too loose depending on a variety of technical factors and the type of procedure that is chosen. The risk of an individual patient developing recurrent symptoms or side effects is complex and depends on a complex interplay of these technical- and procedure-related factors with esophageal and gastric motility, the viscoelastic properties of the GEJ (which includes the distensibility of the fundoplication and the hiatus), eating behaviors, and more.

Lower esophageal sphincter incompetence in GERD patients is associated with increased GEJ distensibility, allowing for greater volumes of reflux to pass into the esophagus [19, 20]. The EndoFLIP and similar probes (i.e., a barostat device) have been used to evaluate the impact of a fundoplication on GEJ opening dynamics. Kwiatek et al. used the EndoFLIP to compare distensibility between 20 GERD patients and 20 asymptomatic controls and found that GERD patients had a significantly greater DI compared to controls [21]. Fundoplication has been demonstrated to decrease GEJ DI to a level similar to, or less than healthy controls [21–23]. In our study, patients with no or mild heartburn 6 months or more following fundoplication experienced a significant decrease in DI when compared to prior to surgery, while those complaining of severe heartburn did not. Pandolfino et al. demonstrated that flow through the GEJ is related to the radius of the opening to the fourth power [19]. Considering that the amount of reflux is proportional to the radius of the GEJ, it is no surprise that patients with a decrease in GEJ opening size reported less heartburn while those who did not see a significant change remained symptomatic.

Intraoperative use of the EndoFLIP for the optimization of procedures has been evaluated in a variety of studies. Kim et al. used the EndoFLIP to tailor the fundoplication to achieve an intraoperative DI > 0.5 [24]. None of the forty fundoplication patients within this study complained of heartburn or dysphagia at 1 month postoperatively. Ilczyszyn and Botha evaluated the EndoFLIP device on 17 patients undergoing Nissen Fundoplication [8]. They identified two cases that highlighted the utility of the EndoFLIP device: One patient with a DI of 0.47 that subsequently required reoperation due to significant dysphagia, and another patient involving intraoperative conversion from a Nissen to a Toupet fundoplication due to a visually tight wrap, increasing the DI from a 0.65 to a 0.89. Finally, a recent case report described the use of the EndoFLIP during a transoral incisionless endoscopic fundoplication following per-oral endoscopic myotomy to assess DI and ensure an adequate fundoplication [25]. These studies offer further support for the feasibility of using the EndoFLIP and derived GEJ dynamics to guide decision-making intraoperatively. We have used EndoFLIP to determine if the fundoplication is too tight and needs to be revised intraoperatively. Based on the current study, we plan to continue to research this issue prospectively to more definitely determine if we should be tightening the fundoplication based on EndoFLIP data as well.

There are several limitations to this study. The number of patients in the severe heartburn cohort was small. Measurements using the EndoFLIP assume radial symmetry and equal pressure throughout the bag of the device, which is not always true, especially at anatomic sphincters. Although all patients had a positive pH or erosive esophagitis on preoperative endoscopy, it is possible that heartburn postoperatively was not related to persistent or recurrent reflux. Objective assessment with repeat pH studies would be required to confirm that heartburn was related to GERD. Finally, the EndoFLIP pre-insufflation measurements were taken prior to establishment of pneumoperitoneum, while the post-fundoplication measurements were taken with the abdomen was insufflated to 15 mmHg. We feel that because our assessment technique was consistent throughout the series and we examined changes in variables as opposed to absolute values that this did not impact our findings. Comparing the specific values attained for distensibility in the current study to values attained in studies where the technique for measurement is different (variations in whether the device is zeroed inside or outside of the esophagus, pneumoperitoneum vs. none) is challenging. A consensus on the standard technique and conditions for using EndoFLIP to assess distensibility at the GEJ in order to allow for meaningful comparisons across studies and pooling of data is needed.

In conclusion, GEJ opening dynamics attained by EndoFLIP intraoperatively at the time of fundoplication for GERD appear to be associated with symptomatic outcomes. When the Dmin and CSA do not decrease by a defined threshold, heartburn is more likely to be severe at 6 or more months postoperatively. This suggests that the fundoplication may not be tight enough to prevent persistent or recurrent GERD. The use of EndoFLIP to provide intraoperative feedback to tailor a fundoplication and optimize outcomes appears to be feasible.

Compliance with ethical standards

Disclosures Dr. Gould is a consultant for Torax/Ethicon. Mr. Turner, Ms. Helm, and Ms. Hetzel have no conflicts of interest or financial ties to disclose.

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