Original Research Article

Tailored Fundoplication for GERD With Impedance Planimetry (EndoFLIP™)

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Abstract

Introduction: Impedance planimetry with the endoluminal functional lumen imaging probe (FLIP) has been used to measure the gastroesophageal junction (GEJ) tightness, the distensibility index (DI), during anti-reflux surgery. We describe our institutional experience of a tailored fundoplication algorithm utilizing FLIP to select whether patients should have Laparoscopic Nissen Fundoplication (LNF) or Toupet Fundoplication (LTF) for treatment of gastroesophageal reflux disease (GERD).

Methods and procedures: A prospectively maintained quality database was queried. Patients who underwent laparoscopic fundoplication for GERD from 2008 to June 2021 were analyzed. Multiple patient factors and intraoperative FLIP measurements were used to guide decision making from 2017 to 2021. Outcomes included quality of life surveys, Reflux Symptom Index, Gastroesophageal Reflux Disease-Health Related Quality of Life (GERDHRQL), and Dysphagia score.

Results: A total of 357 patients were reviewed, 2008-December 2016 (N = 248, 81% LNF) and January 2017 to June 2021 (N = 109, 32% LNF). In the FLIP group, LNF patients had a larger DI compared to LTF patients, $6.5 \pm 2.4\,mm^2$/mmHg at hernia reduction ($P < .01$). Upon 2-year follow-up, FLIP patients reported lower gas-bloat scores, 0.9 ± 1.1 versus 1.8 ± 1.4 in non-FLIP patients ($P < .01$). Patients with normal esophageal motility in the FLIP group had less gas-bloat syndrome than the non-FLIP group (0.9 ± 1.1 vs 1.9 ± 1.4, $P < .01$).

Conclusions: Incorporating FLIP into a tailored fundoplication algorithm led to less gas bloat. Careful selection of which patients can tolerate a Nissen fundoplication may optimize outcomes. Continued exploration with intraoperative impedance planimetry can impact the postoperative quality of life after anti-reflux surgery.

Keywords
EndoFLIP, impedance planimetry, GERD, Nissen fundoplication, Toupet Fundoplication

Introduction

Laparoscopic fundoplication is the surgical management for gastroesophageal reflux disease (GERD).[1-3] Excluding structural dysfunctions from technical errors in the fundoplication, patients may suffer from side effects such as dysphagia and gas-bloat due to a very tight fundoplication.[4] The short and floppy fundoplication was introduced as a solution to a tight complete fundoplication, which included a shorter wrap, different bougie sizes, and fundus mobilization.[1] This surgical dogma continues to evolve through examination of each component. Mickevičius et al[5,6] published a prospective randomized study on the influence of wrap length on the effectiveness of fundoplication and found that wrap length was shown to be more critical in Toupet fundoplication to treat GERD effectively. An early study touted that the Toupet fundoplication had a mechanical advantage over a full wrap due to the ability to restore native anti-reflux barriers supported by better postoperative outcomes.[7] This led

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to numerous studies siding with 1 fundoplication over the other. Meta-analyses at 2 different time points declared Toupet fundoplication as the operation of choice for the surgical management of GERD due to decreased adverse outcomes and equal effectiveness to Nissen fundoplication.[8,9] With that said, there continues to be heterogeneity in practice and technique for the surgical treatment of GERD, possibly due to individual or institutional experience.

Recent innovation incited interest in the investigation of the gastroesophageal junction (GEJ). Impedance planimetry with the functional luminal imaging probe (FLIP) can produce real-time 3-dimensional images of gastrointestinal sphincters of interest, particularly the GEJ. In addition, FLIP has the unique ability to quantify the tightness of a sphincter, known as the distensibility index (DI). In gastroenterology, FLIP was used to describe the GEJ in patients with symptomatic GERD being more distensible than volunteers without GERD.[10] Kwiatek et al[11] showed that patients with mild dysphagia and gas-bloat after a fundoplication had a less distensible hiatus than non-surgical patients without gastrointestinal symptoms. This opened the door for intraoperative impedance planimetry leading to recent studies reporting measurement ranges correlating to patient outcomes such as lower DI leading to worse outcomes.[12,13] Published outcomes are based on the fundoplication distensibility index. Nissen fundoplication ends in an objectively tighter sphincter, so a Toupet may not be as adequate in preventing reflux in a highly distensible GEJ. Therefore, we aim to describe our institutional experience with a comprehensive algorithm that utilizes intraoperative impedance planimetry after hiatal dissection to decide whether a patient will undergo Nissen or Toupet fundoplication.

Methods

Data Collection

This is a retrospective review of a prospectively maintained institutional quality database. Patients who underwent laparoscopic fundoplication between 2008 and June 2021 were included. Research fellows were present during each operation and acquired FLIP measurements. Patient demographic information, diagnostic work-up, symptomatology, perioperative data, and postoperative data are maintained in an institutional quality database. Institutional review board approval was obtained for this study.

FLIP System and Protocol

The EndoFLIP unit 1.0 and 8 cm catheter (EF-325) was used for this study. After set-up, the catheter is placed after each critical operation steps, hiatal dissection, crural closure, fundoplication, and then removed. The catheter is placed transorally and advanced into the esophagus without resistance and is visualized passing through the gastroesophageal junction with laparoscopy. The balloon catheter is inflated while monitoring the FLIP interface to visualize the hourglass shape indicating the location of the GEJ. If needed, the surgeon may pinch the GEJ with a grasper to confirm the location. The minimum diameter (Dmin), cross-sectional area (CSA), intra-balloon pressure, and distensibility index (DI) are recorded at peak balloon pressure after 30 seconds. The DI is calculated by dividing the minimum CSA over balloon pressure. We adhered to the published intraoperative FLIP protocol and analyzed the 40 mL balloon fill values without pneumoperitoneum measurement.[14,15]

Tailored Fundoplication Algorithm With FLIP

Before 2017, most patients had Nissen fundoplication for the treatment of GERD regardless of esophageal motility at our institution. However, some patients did receive Toupet fundoplication for dysmotility. Normal esophageal motility was recognized as peristalsis >70%, with no Ineffective Motility, Diffuse Esophageal Spasm, or Jackhammer Esophagus based on Chicago Classification v3.0. From 2017 on, during the adaptation of the algorithm (Figure 1), the majority of patients with esophageal dysmotility received a Toupet fundoplication. After hiatal dissection, the 40-mL without pneumoperitoneum measurement becomes the crucial point in the algorithm. If the distensibility index was greater than 7, the patient would be considered for a Nissen as long as the patient was less than 70 years old and had adequate fundus for a full wrap after mobilization. Otherwise the patient would receive a Toupet fundoplication.

The DI cut-off is based on multiple studies that showed that patients with GERD had a more distensible GEJ during endoscopic FLIP evaluation and intraoperative FLIP after hiatal dissection during anti-reflux surgery.[10,16] Pandolfino et al[17] stated that the trans GEJ flow is directly proportional to GEJ radius to the fourth power. So a wider GEJ led to more reflux in patients with hiatal hernia and GERD, meaning a more distensible GEJ. Carlson et al[18] examined volunteers who were objectively ruled out for gastrointestinal motility diseases, found the normal DI threshold to be 2.8 mm^2/mmHg, and created a susceptibility graph for GERD with a DI above 6.7 being susceptible for GERD. Therefore, we decided on a theoretical cut-off of greater than 7 in the algorithm since Carlson et al[14] used a 16-cm catheter within a different clinical environment and intraoperative impedance planimetry used an 8-cm catheter. Normal reference ranges with the 8-cm catheter are yet to be discovered. It has been purported that because DI is calculated from a single plane, the different sizes in each catheter should yield similar results,

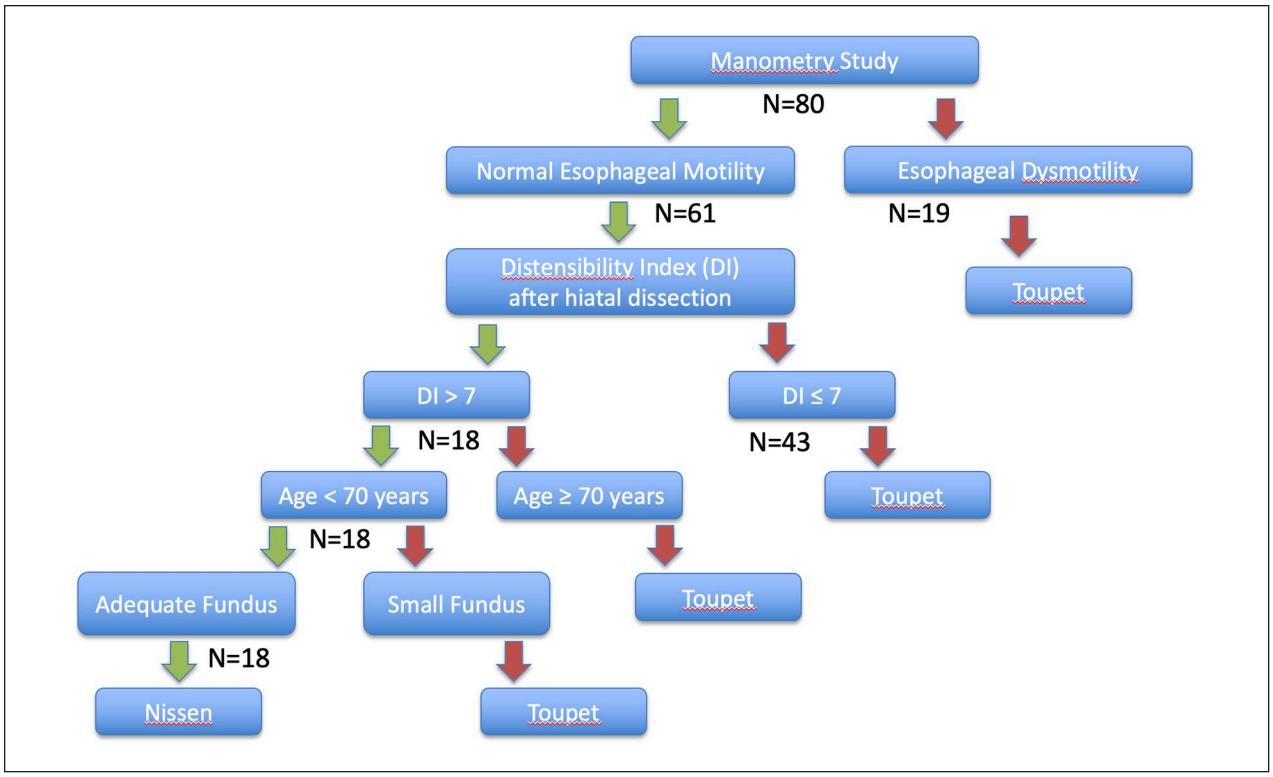

Figure 1. Tailored Fundoplication Algorithm with FLIP, DI (mm^2/mmHg). Our criteria for normal esophageal motility: peristalsis >70%, with no Ineffective Motility, Diffuse Esophageal Spasm, or Jackhammer Esophagus based on Chicago Classification v3.0. Number of patients from Table 3.

yet the balloon fill volume and pressure readings are significantly different.

The age cut-off of 70 years old is garnered from the fact that more Nissen fundoplication patients suffer from severe postoperative dysphagia requiring re-operation, whereas no Toupet patients had severe dysphagia shown in Tian et al's meta-analysis.[9] In addition, Broeders et al[8] reported a pooled 7.1% versus 3.1% of Nissen versus Toupet fundoplication requiring surgical re-intervention. Laparoscopic anti-reflux surgery is safe in elderly patients.[19,20] Except another operation to address postoperative dysphagia due to an overly tight sphincter is an unnecessary risk given a different option with equivalent efficacy and lower re-operative rate. One randomized control trial even suggested that elderly patients should undergo Toupet.[21] After fundus mobilization, if a 360° wrap is positioned around the GEJ without undue tension, signifying an adequate amount of fundus, then a Nissen fundoplication is performed.

Operative Steps

All patients undergo a comprehensive esophageal workup before their operation. The workup includes an esophagram or CT scan, manometry, acid-reflux testing (impedance or BRAVO study, unless the patient had symptomatic paraesophageal hernia), and upper endoscopy. A single surgeon performed the operations.

After laparoscopic port placement and liver retraction, we start with the hiatal dissection and reduction of hiatal hernia (if necessary), resulting in at least 3 cm of intra-abdominal esophagus. Both vagus nerves are identified and preserved. The short gastric vessels are ligated to complete fundus mobilization. The crura are approximated with permanent sutures unless there is a paraesophageal hernia. Biosynthetic mesh in a rectangular configuration is posteriorly placed and incorporated into a horizontal mattress closure with 3 permanent sutures with pledgets. Before either fundoplication begins, a bougie (52-60 French) is advanced carefully through the oropharynx and GEJ under laparoscopic vision.

The posterior fundus was tacked to the crus during Nissen fundoplication, and crotch stitches were placed between the esophagus and fundus bilaterally. Three interrupted permanent sutures include a partial-thickness bite of the esophagus while preserving both vagus nerves, completing a floppy Nissen fundoplication. During Toupet fundoplication, a posterior gastropexy to the median arcuate ligament is done with a permanent suture. Bilateral permanent coronal sutures incorporating fundus, crus, and

the esophagus are placed. Two additional sutures were placed bilaterally about a centimeter inferior to each other incorporating fundus and esophagus. We aim for a total length of 2 to 3 cm for each fundoplication.

Clinical Follow-up

Patients are seen for postoperative clinic follow-up within 3 weeks. Quality of Life (QOL) questionnaires are routinely distributed electronically at 3 weeks, 6 months, 1 year, and 2 years. Reflux Symptom Index (RSI), Gastroesophageal Reflux Disease-Health Related Quality of Life Questionnaire (GERD-HRQL), Dysphagia Score, and Satisfaction Score responses are recorded in our quality database. RSI assesses for "atypical" symptoms of reflux, a score >13 represents severe reflux.[22] The GERD-HRQL evaluates for "typical" reflux symptoms.[23] A higher score indicates worse symptomatic disease. The gas-bloat score is extrapolated from the GERD-HRQL question #7, the response range from a score of 0 (no symptoms) to 5 (symptoms are incapacitating). Dysphagia score measures the severity of dysphagia on a 5-point scale from 1 (I am able to eat a normal diet/no dysphagia) to 5 (I am unable to swallow anything/total dysphagia). For the Satisfaction score, patients are asked how satisfied they are with their current condition in regards to the anti-reflux operation with a score that ranges from 1 (dissatisfied) to 3 (satisfied).

Statistical Analysis

Patient and clinical characteristics were summarized using mean with standard deviation, median with interquartile range or frequency with percentage. Differences between groups and measurements at different time points were made using Wilcoxon rank-sum or independent samples *t*-tests and chi-square or Fisher's exact tests. Unadjusted multiple comparisons for measurements and QOL were made using the Dwass. Steel. Critchlow-Flinger method. Multivariable linear regression, with the Tukey–Kramer method for multiple comparisons, was used to assess differences in measurements and QOL while controlling for hernia type, fundoplication type, and motility. All statistical tests were 2-tailed and performed using SAS 9.4 (SAS Institute, Cary, NC). Statistical significance was set at $P < .05$.

Results

Patient Demographics

Three hundred fifty-seven patients underwent laparoscopic fundoplication between 2008 and June 2021 by a single surgeon. The algorithm group includes patients from the January 2017 to June 2021, while the non-FLIP group consists of patients from 2008 to December 2016. Both groups had similar preoperative patient characteristics such as age, body mass index, and medical history (Table 1). The non-FLIP group had a majority of Nissen fundoplication compared to the FLIP group (81.5 vs 32.1 %, $P < .001$). Also, all preoperative symptoms resolved at the first postoperative visit for the same percentage of patients in each group. Additional peri- and postoperative data are in Table 2. There were three 30-day mortalities in the non-FLIP group: sepsis secondary to chronic lymphocytic leukemia, respiratory failure secondary to severe pulmonary disease, and cardiac event during the operation likely due to thrombosis present in multiple coronary arteries. The non-FLIP group had a higher incidence in 30-day emergency room visits with the reasons being surgical pain (15%), per oral intolerance (11%), shortness of breath (11%), constipation/bloating (9%), and urinary retention (9%).

Impedance Planimetry Measurements Were Similar for Fundoplications After 2017

In order to evaluate the geometric differences of the gastroesophageal junction dictated by the algorithm, patients were separated into the Nissen, Normal Motility Toupet (NMT), and Dysmotility Toupet (DT) groups. Compared to the NMT and DT groups, the Nissen patients had a significantly larger minimum diameter and cross-sectional area and lower balloon pressure, leading to a higher distensibility index after hernia reduction (Table 3). Higher distensibility index after hernia reduction in normal motility patients would move forward in the algorithm toward a Nissen fundoplication. There were no differences in impedance planimetry measurements between any groups after crural closure. Upon fundoplication, the distensibility index of the Nissen and both Toupet groups were similar as well.

Significant **Symptom Score** *Differences After Implementation of the Algorithm*

Symptom scores of the FLIP and non-FLIP groups were compared at different time points. The most significant finding included patients in the FLIP group reporting significantly less gas-bloat symptoms, such as flatulence and bloating, compared to the non-FLIP group (0.9 ± 1.1 vs 1.8 ± 1.4, $P = .01$) at 2-year follow-up (Table 4). Preoperative scores were similar between both groups. At 6 months postoperative follow-up, the algorithm group reported a slightly worse Dysphagia score compared to the non-FLIP group (1.4 ± 0.8 vs 1.0 ± 0.1, $P < .05$), even after multivariable analysis controlling for dysmotility. The disparity in Dysphagia score became

Table 1. Preoperative Characteristics by Group.

	Non-FLIP	FLIP	*P*-value
Total patients, N	248	109	—
Age, years [Mean ± SD]	66 ± 13	67 ± 11	.329
Body mass index [Mean ± SD]	29.3 ± 5.1	29.6 ± 4.1	.609
Male [N (%)]	72 (29.0)	28 (25.7)	.517
Smoking status [N (%)]			.753
Never	139 (56.0)	63 (57.8)	
Former	101 (40.7)	44 (40.4)	
Current	8 (3.2)	2 (1.8)	
Prior medical history [N (%)]			
Myocardial Infarction/Coronary Artery Disease	23 (9.3)	8 (7.3)	.550
Hypertension requiring Medication	17 (6.9)	38 (34.9)	<.001
Pneumonia	14 (5.6)	10 (9.2)	.220
Chronic obstruction pulmonary disease	15 (6.0)	6 (5.5)	.841
Diabetes	26 (10.5)	9 (8.3)	.515
Preoperative symptoms [N (%)]			
Reflux	219 (88.3)	93 (85.3)	.434
Heartburn	165 (66.5)	87 (79.8)	.011
Regurgitation	159 (64.1)	74 (67.9)	.490
Dysphagia	106 (42.7)	34 (31.2)	.040
Cough	81 (32.7)	35 (32.1)	.918
Epigastric/Chest pain	89 (35.9)	30 (27.5)	.123
Preoperative proton pump inhibitor use [N (%)]	212 (85.5)	95 (87.2)	.675
Normal motility [N (%)]	198 (79.8)	82 (75.2)	.330
ASA Class 3 or 4 [N (%)]	97 (39.1)	48 (44.0)	.383
Hiatal Hernia Type [N (%)]			<.001
None	18 (7.3)	30 (27.5)	
I	69 (27.8)	13 (11.9)	
II	3 (1.2)	1 (0.9)	
III	134 (54.0)	62 (56.9)	
IV	24 (9.7)	3 (2.8)	
Preoperative DeMeester score [Median (Q1-Q3)]	41 (33-17)	37 (18-53)	.740

SD = standard deviation; ASA = American society of anesthesiologists.

insignificant upon 1-year follow-up after multivariable analysis, adjusting for fundoplication type, hernia type, and motility. The patients in the FLIP group were older, had a shorter time to returning to activities of daily living, were more likely to have history of cardiac disease, hypertension, pneumonia, and receive a Toupet fundoplication. At 2-year follow-up, the FLIP group had a significantly better GERD-HRQL score versus the non-FLIP group, except this was not significant after multivariable analysis. Satisfaction in both groups was similar at all time points.

For patients that had a preoperative gas-bloat score > 1 (0 or 1 not bothersome symptoms and >1 would be bothersome), 56.9% (29/51) continued to have symptoms at 1 year, and 75.6% (34/45) at 2 years. For patients that did not have a preoperative gas-bloat symptoms (score 0 or 1), 32.3% (10/31) developed symptoms at 1 year, and 31.0% (9/29) at 2 years.

For patients that had dysphagia symptoms, preoperative score >1, dysphagia persisted in 11.1% (1/9) at 1 year, and 22.2% (2/9) at 2 years. For patients that did not have dysphagia, preoperative score of 1, 4.1% (3/73) developed symptoms at 1 year, and 3.0% (2/67) at 2 years. There was a significant difference for patients that did not have preoperative dysphagia between before 2017 versus 2017+ at 1 year (1.1 ± 0.5 vs 1.2 ± 0.4, $P = .0128$).

The Algorithm Led to Less Gas-Bloat Symptoms in Patients With Normal Esophageal Motility

At 2-year follow-up, patients in the FLIP group (N = 16) had less gas-bloat symptoms versus the non-FLIP (N = 82) group (0.9 ± 1.1 vs 1.9 ± 1.4, $P < 0.01$). There were no other differences in the remaining symptom

Table 2. Peri- and Postoperative Characteristics by Group.

	Non-FLIP	FLIP	*P*-value
Total patients, N	248	109	—
Nissen fundoplication [N (%)]	202 (81.5)	35 (32.1)	<.001
Operating room time, minutes [Mean ± SD]	128 ± 43	121 ± 32	.093
Estimated blood loss, ml [Median (Q1-Q3)]	25 (5-50)	10 (5-20)	<.001
Mesh use [N (%)]	157 (63.3)	67 (61.5)	.741
Intraoperative complication [N (%)]	8 (3.2)	0 (0.0)	.112
Length of stay, days [Median (Q1-Q3)]	2 (1-3)	1 (0-1)	<.001
Pain at discharge, VAS [Median (Q1-Q3)]	2 (1-4)	2 (0-3)	.062
Medication stopped, days [Median (Q1-Q3)]	3 (1-7)	1 (1-3)	<.001
Return to ADL, days [Median (Q1-Q3)]	5 (2-8)	4 (2-7)	.155
30-Day mortality [N (%)]	3 (1.2)	0 (0.0)	.556
30-Day complication [N (%)]	30 (12.1)	6 (5.5)	.057
30-Day ED visit [N (%)]	46 (18.5)	10 (9.2)	.025
30-Day readmission [N (%)]	26 (10.5)	6 (5.5)	.129
Off proton pump inhibitor [N (%)]	194 (90.7)	92 (92.0)	.697
All symptoms resolved at FU1 [N (%)]	93 (60.8)	56 (67.5)	.309
Follow-up, months [Median (Q1-Q3)]	20 (3-49)	4 (1-10)	<.001

VSA = visual analog scale; ADL = activities of daily living; FU1 = first follow-up visit.

Table 3. FLIP Measurements by Group.

		Nissen and Toupet	Nissen	Normal Motility Toupet	Dysmotility Toupet	Unadjusted *P*-value	Adjusted *P*-value[†]
Timepoint	Measurement	Mean ± SD	Mean ± SD	Mean ± SD	Mean ± SD	—	—
Hernia Reduction	N	N = 80	N = 18	N = 43	N = 19		
	Dmin, mm	13.0 ± 2.9	14.7 ± 2.0	12.3 ± 2.7	13.0 ± 3.3	.006[a]	.018[a,b]
	Pressure, mmHg	33 ± 10	30 ± 12	33 ± 10	35 ± 9	.045[b]	.061
	CSA, mm^2	140 ± 57	174 ± 46	125 ± 52	142 ± 65	.006[a]	.016[a,b]
	DI, mm^2/mmHg	4.7 ± 2.4	6.5 ± 2.4	4.0 ± 2.1	4.4 ± 2.4	.002[a,b]	<.001[a,b]
Crural Closure	N	N=83	N=19	N=44	N=20		
	Dmin, mm	9.2 ± 1.7	9.7 ± 1.8	9.2 ± 1.7	8.7 ± 1.7	.232	.283
	Pressure, mmHg	41 ± 10	41 ± 12	42 ± 9	41 ± 10	.822	.258
	CSA, mm^2	69 ± 27	76 ± 30	67 ± 26	64 ± 25	.511	.345
	DI, mm^2/mmHg	1.7 ± 0.8	2.0 ± 0.9	1.7 ± 0.8	1.6 ± 0.7	.255	.127
Fundoplication	N	N=83	N=19	N=44	N=20		
	Dmin, mm	11.9 ± 1.6	11.4 ± 1.5	12.2 ± 1.6	11.8 ± 1.8	.185	.389
	Pressure, mmHg	45 ± 11	48 ± 14	44 ± 9	46 ± 12	.780	.983
	CSA, mm^2	112 ± 32	104 ± 27	118 ± 29	107 ± 41	.176	.439
	DI, mm^2/mmHg	2.7 ± 0.8	2.4 ± 0.8	2.8 ± 0.7	2.6 ± 0.8	.297	.609

Dmin = Minimum Diameter; CSA = Cross Sectional Area; DI = distensibility index; SD = standard deviation.
[†]Multivariable *P*-values are adjusted for: Hernia Type.
[a]Nissen versus Normal Motility Toupet.
[b]Nissen versus Dysmotility Toupet.

scores at 1 and 2-year follow-up. Upon comparing only patients with dysmotility in both groups at 1-year, the FLIP group (N = 7, 1 Nissen, 6 Toupet) had a worse dysphagia score compared to the non-FLIP group (N = 21, 8 Nissen, 13 Toupet) (1.4 ± 0.8 vs 1.0 ± 0.0, $P = .01$). Patients with severe dysmotility (peristalsis < 60%, N = 12) had worse 1-year GERD-HRQL (7.7 ± 9.5 vs 2.0 ± 2.0, $P = .049$) compared to mild dysmotility patients (peristalsis ≥ 60%, N = 5). In addition, the RSI score in patients with severe dysmotility (N = 6) was worse (10.2 ± 9.8 vs 0.6 ± 0.9, $P = .04$) than patients with mild dysmotility (N = 5) at 2-years.

Subgroup Analyses of Nissen and Toupet Fundoplication Before and After the Algorithm

Similar to the analysis above, patients in the FLIP group were older, had a shorter time to returning to activities of

Table 4. Symptom Scores by Group.

	Non-FLIP	FLIP	Unadjusted *P*-value	Adjusted *P*-value*
	Mean ± SD	Mean ± SD	—	—
Preop	**N = 122**	**N = 62**		
RSI	17.4 ± 11.6	17.1 ± 10.0	.954	.988
GERD-HRQL	14.0 ± 11.9	13.6 ± 9.2	.695	.895
Gas/Bloat	2.2 ± 1.6	1.9 ± 1.4	.369	.497
Dysphagia Score	1.2 ± 0.6	1.3 ± 0.7	.757	.897
Satisfaction	1.3 ± 0.6	1.2 ± 0.5	.200	.077
1 Year	**N = 94**	**N = 30**		
RSI	8.2 ± 8.2	8.2 ± 8.7	.998	.855
GERD-HRQL	4.2 ± 5.3	3.9 ± 4.5	.802	.851
Gas/Bloat	1.6 ± 1.3	1.7 ± 1.3	.529	.381
Dysphagia Score	1.1 ± 0.5	1.3 ± 0.5	.005	.547
Satisfaction	2.5 ± 0.8	2.6 ± 0.6	.714	.886
2 Years	**N = 100**	**N = 20**		
RSI	8.7 ± 8.8	6.7 ± 9.1	.252	.296
GERD-HRQL	4.6 ± 5.7	3.3 ± 4.9	.044	.244
Gas/Bloat	1.8 ± 1.4	0.9 ± 1.1	.006	.010
Dysphagia Score	1.1 ± 0.4	1.2 ± 0.5	.518	.813
Satisfaction	2.4 ± 0.8	2.5 ± 0.8	.769	.754

*Multivariable *P*-values are adjusted for: Fundoplication Type, Hernia Type, and Motility.
RSI = Reflux Symptom Index; GERD-HRQL = Gastroesophageal Reflux Disease—Health Related Quality of Life; SD = standard deviation; YPO = years postoperatively.

daily living, were more likely to have history of cardiac disease, hypertension, pneumonia and receive a Toupet fundoplication. At 2-year follow-up, Toupet patients in the FLIP group (N = 7, 2 with dysmotility) had better symptomatic control of GERD (0.7 ± 1.0 vs 6.0 ± 8.3, *P* = .03) compared to the non-FLIP Toupet patients (N = 16, 12 with dysmotility). When analyzing the Nissen patients in both groups, the FLIP group (N = 8, 1 with dysmotility) had a slightly worse 1-year dysphagia score (1.3 ± 0.5 vs 1.1 ± 0.3, *P* = .04) than the non-FLIP group (N = 78, 8 with dysmotility). The Toupet and Nissen fundoplications within the algorithm group showed similar outcomes at 6-months and 1-year, however, at 2-years, the Toupet patients (N = 7, 2 with dysmotility) had a better GERD-HRQL score (0.7 ± 1.0 vs 4.6 ± 5.7, *P* = .09) than Nissen patients (N = 13, 2 with dysmotility), however not statistically significant (Table 5).

Discussion

Laparoscopic fundoplication is the surgical management for GERD, which aims to recreate the native anti-reflux barriers by tightening the GEJ. This operative technique is highly effective in addressing GERD yet is not without life-changing side effects such as dysphagia and gas-bloat syndrome. Surgeons continue to aim for a short floppy fundoplication in the hopes of decreasing these side effects by using a larger bougie to size the fundoplication, shortening the length of the wrap, and mobilizing the gastric fundus.[1]

A randomized prospective trial aimed to examine the degree of wrap and competence of the lower esophageal sphincter.[7] Thor et al stated that the Nissen fundoplication creates a nipple-like deformity, making it challenging to belch or vomit, creating gas-bloat syndrome. A partial fundoplication such as the Toupet restores gastroesophageal junction competence through having the esophagus enter the stomach obliquely, creating a flap valve. During increased intragastric pressure, the flap valve tightly opposes the lesser curve aspect of the GEJ, preventing pathologic reflux.[7] Both procedures effectively treated GERD, apart from Nissen having higher rates of dysphagia. Since this study, the emergence of numerous trials have compared Toupet and Nissen fundoplication where 2 meta-analyses encompassing 13 randomized clinical trials from 1997 to 2013 declared Toupet fundoplication is just as effective as Nissen with lower rates of postoperative dysphagia, gas-bloat, and reoperation.[8,9]

After a Nissen fundoplication, the GEJ was shown to have a more extended high-pressure zone and integrated relaxation pressure leading to a higher esophageal tone and incomplete relaxation of the lower esophageal sphincter manufacturing a pseudo-obstruction.[24-26] Patients with esophageal dysmotility may represent

Table 5. Symptom Scores by Subgroup Analysis.

	Toupet non-FLIP	Toupet FLIP	p-value	Nissen non-FLIP	Nissen FLIP	p-value	Toupet FLIP	Nissen FLIP	*P*-value
	Mean ± SD	Mean ± SD	—	Mean ± SD	Mean ± SD	—	Mean ± SD	Mean ± SD	—
1 Year	N = 17	N = 22		N = 78	N = 8		N = 22	N = 8	
RSI	8.0 ± 7.1	9.1 ± 9.8	0.953	8.2 ± 8.5	5.9 ± 4.3	0.765	9.1 ± 9.8	5.9 ± 4.3	.833
GERD-HRQL	4.9 ± 4.9	3.5 ± 4.2	0.501	4.1 ± 5.4	5.0 ± 5.5	0.498	3.5 ± 4.2	5.0 ± 5.5	.290
Gas/Bloat	1.4 ± 1.5	1.8 ± 1.3	0.295	1.6 ± 1.3	1.5 ± 1.1	0.945	1.8 ± 1.3	1.5 ± 1.1	.646
Dysphagia	1.2 ± 1.0	1.3 ± 0.6	0.190	1.1 ± 0.3	1.3 ± 0.5	0.042	1.3 ± 0.6	1.3 ± 0.5	.949
Satisfaction	2.5 ± 0.8	2.6 ± 0.6	0.633	2.5 ± 0.8	2.5 ± 0.8	0.908	2.6 ± 0.6	2.5 ± 0.8	.692
2 Years	N = 16	N = 7		N = 84	N = 13		N = 7	N = 13	
RSI	9.7 ± 10.1	5.3 ± 4.8	0.568	8.5 ± 8.6	7.5 ± 10.9	0.427	5.3 ± 4.8	7.5 ± 10.9	.872
GERD-HRQL	6.0 ± 8.3	0.7 ± 1.0	0.038	4.3 ± 5.1	4.6 ± 5.7	0.573	0.7 ± 1.0	4.6 ± 5.7	.087
Gas/Bloat	1.8 ± 1.6	0.3 ± 0.5	0.069	1.8 ± 1.4	1.2 ± 1.3	0.082	0.3 ± 0.5	1.2 ± 1.3	0.157
Dysphagia	1.3 ± 0.8	1.0 ± 0.0	0.339	1.1 ± 0.3	1.2 ± 0.6	0.139	1.0 ± 0.0	1.2 ± 0.6	0.287
Satisfaction	2.3 ± 0.9	2.9 ± 0.4	0.092	2.5 ± 0.8	2.3 ± 0.9	0.460	2.9 ± 0.4	2.3 ± 0.9	0.134

RSI = reflux symptom index; GERD-HRQL = gastroesophageal reflux disease—health related Quality Of Life; SD = standard deviation.

severe or chronic disease due to ineffective esophageal acid clearance. A study compared patients with dysmotility who underwent Toupet and Nissen fundoplication and found a decreased moderately to severe dysphagia rate in Toupet patients (9% vs 44%).[27] In a single-institution study, Schwameis et al reviewed 25 patients who required conversion to Toupet from Nissen due to dysphagia and gas-bloat. Dysphagia was alleviated in 84% and bloating 100% in patients, along with a rare recurrence of symptomatic GERD. Interestingly, 56% of patients in that series suffered from esophageal motility abnormalities.[28] Therefore, the initial step of our algorithm begins by separating patients with esophageal dysmotility, described in the methods, to have Toupet fundoplication. Multiple studies suggested that esophageal motility should not dictate a tailored approach since there were no differences in outcomes, even though Toupet patients had a better quality of life.[29-34] There is no clear consensus regarding the tailored approach and heterogeneity in defining dysmotility. We believe that performing a Nissen fundoplication on a patient with dysmotility can expose the patient to unnecessary risk of severe new-onset dysphagia that may require re-operation.

With that said, Nissen fundoplication objectively eliminates GERD. Multiple trials have shown objective resolution of GERD after Toupet and Nissen with clearance of esophagitis on endoscopy and acid monitoring with BRAVO; however, DeMeester scores were still higher in Toupet patients.[5,21,29,35,36] A meta-analysis pooled a symptomatic GERD recurrence rate of 22.72% after Nissen and 32.96% after Toupet.[9] One patient characteristic that we did not account for in our algorithm was Body Mass Index (BMI), given that both groups had similar BMI. Patients classified as obese (BMI $>$ 30) have been shown to have a higher rate of recurrent reflux and increased risk of postoperative hiatal hernia due to increased intra-abdominal pressure from visceral adiposity.[37,38] Conflicting results from other studies report that morbid obesity does not adversely affect outcomes after anti-reflux surgery and is safe.[35,39] However, long-term control of reflux with laparoscopic fundoplication may not be as effective in morbidly obese patients compared to normal-weight patients.[35]

The algorithm harnesses the power of quantifying the GEJ tightness with impedance planimetry. Kwiatek et al reported that the GEJ DI of 20 patients with GERD was 2 to 3 times more distensible than healthy volunteers.[10] Lottrup et al[16] showed that the distensibility of the GEJ in hiatal hernia patients was significantly larger than asymptomatic controls. Carlson et al described that patients in the GEJ DI range of 9.3 mm^2/mmHg were more susceptible to GERD. Our thought is that a significantly higher DI will require a tighter sphincter through hiatus repair and Nissen fundoplication to control pathologic reflux effectively. With the higher DI after hiatal dissection, Nissen fundoplication results in a more considerable reduction in DI relative to Toupet. Nissen fundoplication strengthens the GEJ so much so resulting in a lower distensibility index compared to Toupet fundoplication.[15,40,41] Work from our group identified a DI range from 2.0 to 3.5 mm^2/mmHg leading to a better quality of life after fundoplication. Patients in the previous work are included in this study, so we aimed for that final distensibility target range regardless of fundoplication type, which led to similar final fundoplication DIs in each operation. With that said, postoperative side effects are multifactorial in nature, so that outcomes may be different based on inherent patient differences such as motility and final anatomical configurations per fundoplication type. Upon endoscopic evaluation, a Toupet fundoplication leads to exaggeration of the angle of His re-establishing a flap valve while exhibiting anterior radial expansion

for venting of swallowed air. In contrast to a full wrap that leads to a one-way tight nipple valve.[4]

Our study utilizes impedance planimetry to decide the type of fundoplication a patient receives. In general, patients were satisfied at all times points regardless of fundoplication type. When analyzing patient-reported outcomes of the FLIP group versus the non-FLIP group at different time points, the algorithm group had slightly worse dysphagia at 6 months even when controlling for dysmotility, fundoplication, and hernia type. This mild postoperative dysphagia became insignificant after 1 year between the 2 groups. The algorithm gave patients in our study a better quality of life in terms of significantly reduced gas-bloat symptoms. The result is due to the careful selection of the appropriate individual for the precise operation during a specific time point in their disease process. GERD is multifactorial, and esophageal dysmotility can result from chronic GERD damaging the esophagus. Patients in the algorithm group with normal esophageal motility also enjoyed fewer gas-bloat symptoms than the non-FLIP patients. When investigating patients with dysmotility, the algorithm group reported a worse dysphagia score at 1 year. However, this was a small sample size comparison that may have introduced some bias. Patients with severe dysmotility had worse patient-reported 1-year GERD-HRQL and 2-year RSI scores regardless of fundoplication type, emphasizing the need for surgeons to manage patient expectations during the preoperative phase.

Currently, our subgroup analyses contain a minimal number of patients for comparison. FLIP Toupet patients reported better symptomatic GERD control than non-FLIP Toupet. Non-FLIP Nissen had better 1-year dysphagia score versus FLIP Nissen. FLIP Toupet patients had a better GERD-HRQL score than FLIP Nissen patients, even though it was not significant. Given the small number of patients in each subgroup analysis, it is difficult to draw meaningful conclusions. Continued data collection may elucidate much-needed answers in the debate between partial and complete fundoplication.

Limitations in this study include being a retrospective review of a single institution prospectively maintained quality database. The algorithm led to most patients in the FLIP group receiving Toupet fundoplication, which led to a minority of patients receiving Nissen fundoplication. However, our multivariable analysis of all fundoplications in each group demonstrated a significantly better gas-bloat score in the FLIP group. Ideally, we hope to collect enough data for multiple subgroup analyses, especially between the Non-FLIP and FLIP Nissen patients. We highlighted the gas-bloat score from the GERD-HRQL due to it being a significant side effect after anti-reflux surgery however this is a single item on a validated questionnaire, which does not carry the same level of validation, so there may be potential for error and bias. Impedance planimetry is a relatively new technology in the operating room, so the DI threshold is theoretical given the lack of normal ranges with the 8-cm FLIP catheter. Clinical outcomes are subjective, and response rates varied at all postoperative time points resulting in a smaller sample size for comparison. Our surgical practice encompasses the surgical dogma of a floppy fundoplication with modifications that may differ from other practices. In Toupet fundoplication, our practice is to mobilize the fundus and use a bougie when creating the wrap, and this may inadvertently affect our analysis and decrease generalizability. The specific bougie is decided during the operation by visualizing the size of the esophagus laparoscopically. Within our data the distensibility index slightly increased due to the dilation of the diaphragmatic hiatus after bougie placement and creation of fundoplication. The distribution in bougie size primarily within 54 to 56 Fr with a low number of outliers, the final fundoplication distensibility is of importance, however the effect of bougie size and outcomes may be a future topic of study. We continue to balance the tightness of the gastroesophageal junction with regard to postoperative side effects and symptomatic resolution of GERD. This is why we create a wrap over a bougie regardless of the type of fundoplication performed. Our experience with creating a Toupet fundoplication over bougie led to a decreased rate of dysphagia and gas-bloat syndrome. This data is still in the collection phase as we hope to share this in the future. Finally, there is a lack of objective data in GERD resolution, such as postoperative acid monitoring or endoscopy. We routinely ask all patients to return for objective GERD surveillance at 1 year to continue monitoring this lifelong disease.

Conclusion

Incorporating FLIP into a tailored fundoplication algorithm led to significantly less gas-bloat symptoms at 2 years. Patients younger than 70 years old with normal esophageal motility who demonstrate a DI $>7\,mm^2$/mmHg after hiatal dissection should be considered for a Nissen fundoplication after adequate fundus mobilization. Thoughtful patient selection for an anti-reflux operation is paramount for optimal outcomes.

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