



Experience-based expert consensus on the intra-operative usage of the Endoflip impedance planimetry system

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Abstract

Introduction The Endoluminal Functional Lumen Imaging Probe (Endoflip™) is a balloon-based catheter that provides real-time, objective feedback regarding the distensibility of any sphincter in the gastrointestinal tract. Usage of the Functional Lumen Imaging Probe (FLIP) has not been standardized, which has limited the interpretation and generalizability of published data. The purpose of this consensus statement is to provide a standardized protocol for obtaining FLIP measurements in order to create a more uniform approach to data collection.

Methods Five expert foregut surgeons, all of whom utilize the FLIP system in their daily practice, convened on March 19, 2019, to create a standardized protocol for obtaining FLIP measurements during hiatal hernia repair and fundoplication, magnetic sphincter augmentation, laparoscopic Heller myotomy, and peroral endoscopic myotomy. Existing literature was presented and reviewed. Each step of the protocol was discussed in detail until a unanimous consensus was reached.

Results A standardized protocol was developed for obtaining FLIP measurements during hiatal hernia repair and fundoplication, magnetic sphincter augmentation, laparoscopic Heller myotomy, and peroral endoscopic myotomy.

Conclusion The FLIP impedance planimetry system is the only technology available that provides surgeons an objective way to assess the tightness of a fundoplication or adequacy of a myotomy during an operation. While considerable research remains to correlate FLIP measurements to patient outcomes, this consensus statement will provide standardization of data collection among FLIP users that will enhance the understanding of future study results.

Keywords Impedance planimetry · Endoflip · Flip · Foregut surgery · Reflux · Achalasia

The Endoluminal Functional Lumen Imaging Probe (Endoflip™) impedance planimetry system is an innovative tool

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that provides real-time, objective feedback regarding sphincter geometry in the operating room. While protocols for Functional Lumen Imaging Probe (FLIP) usage in the gastroenterology literature have been relatively well described, standardization regarding its usage in the operating room is lacking. This deficiency has resulted in inconsistent data reporting and confusion regarding data interpretation throughout the literature.

For this reason, an expert panel of five experienced foregut surgeons (Drs. Christy Dunst, Jon Gould, Blair Jobe, Paul Severson, and Michael Ujiki), with a total of over 1500 FLIP cases, convened in Las Vegas, Nevada on March 19, 2019. Using published data, unpublished data, and personal experience, protocols for using the FLIP impedance planimetry system in the operating room for fundoplication, magnetic sphincter augmentation (MSA), laparoscopic Heller myotomy (LHM), and peroral endoscopic myotomy (POEM) were developed. Institutional review board approval and

consent were not required as the conference did not require patient participation or patient health information.

Of note, it is unclear whether FLIP measurements are affected by types of anesthesia (e.g., conscious sedation vs general anesthesia). In our experience, we see much more variability in FLIP measurements with patients under conscious sedation compared to those under general anesthesia, but this has not been supported by the literature. Campagna et al. demonstrated that FLIP distensibility and motility patterns were largely consistent whether under conscious sedation or general anesthesia [1]. Similarly, Nathanson et al. performed FLIP on 50 healthy patients (i.e., no subjective symptoms of reflux) undergoing elective laparoscopic surgery and found no significant impact of anesthetic drugs on hiatal compliance [2]. Additionally, pre-operative medication use, such as chronic opioid use and sildenafil, can affect esophageal function and likely also affect FLIP measurements. Therefore, it is recommended to thoroughly review pre-operative and intra-operative medications and to consider their possible effect on and interpretation of FLIP measurements.

The FLIP impedance planimetry system

Originally developed in 2009 by Crospon Ltd (Dublin, Ireland) and purchased by Medtronic (Dublin, Ireland) in December 2017, the FLIP utilizes impedance planimetry technology to evaluate the geometry of any sphincter in the gastrointestinal tract (Fig. 1). The FLIP System (EF-100) uses a 240-cm long catheter with a 3 mm outer diameter. At the distal end, there are 17 impedance planimetry sensors that span a distance of 8 cm (EF-325 catheter) or 16 cm (EF-322 catheter), depending on catheter type. These sensors are housed within a highly compliant bag, along with a solid-state pressure transducer. The pressure transducer is used to measure intra-bag pressure and is located at the distal end of the catheter (Fig. 2).

The technology of impedance planimetry revolves around using electrical resistance (i.e., impedance) to find the cross-sectional area (CSA) of a plane (i.e., planimetry) [3, 4]. The bag is filled with a specially formulated solution (0.3% NaCl) of known conductivity and excitation electrodes at either end of the catheter emit a continuous low current. Because the distance between electrodes and fluid conductivity is known, the electrical resistance of the fluid is proportional to the CSA and can be determined from the voltage by leveraging Ohm's law (voltage = current \times resistance). Dividing the minimum CSA (i.e., smallest CSA) by intra-balloon pressure produces the distensibility index (DI).

Initially a concept in vascular physiology, distensibility in gastrointestinal physiology reflects the capacity of a sphincter to stretch as a result of pressure from inside (e.g., a

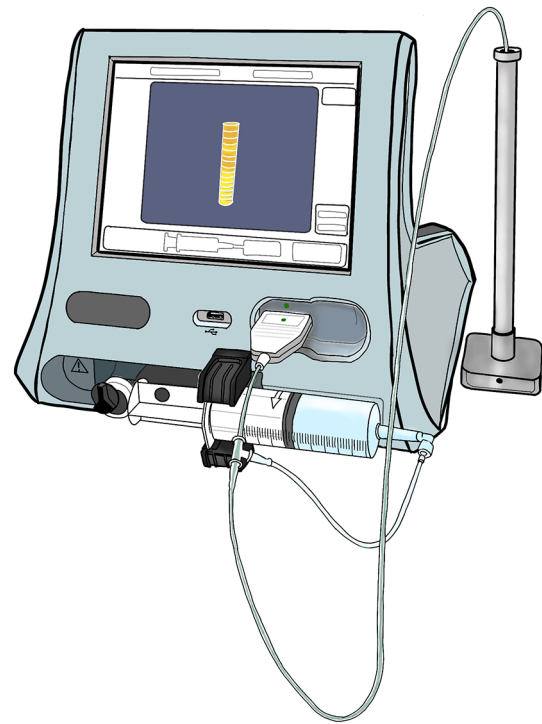


Fig. 1 Endoflip™ 1.0 Monitor (EF-100)

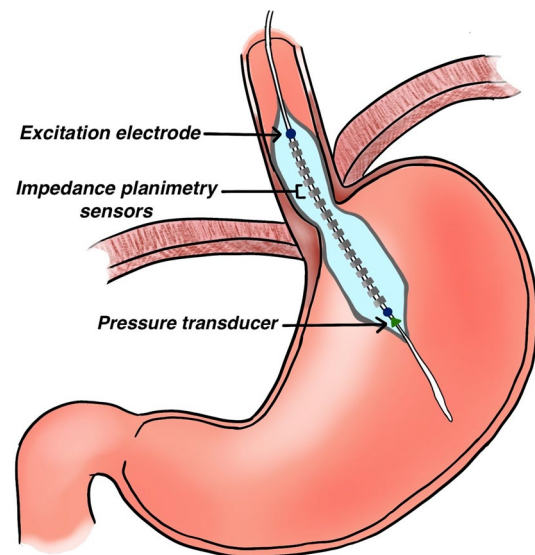


Fig. 2 FLIP catheter straddling the lower esophageal sphincter

food bolus). Sphincters with high distensibility are “looser” or “stretchy” whereas sphincters with low distensibility are “stiffer” or “tighter”. On the FLIP, the distensibility is calculated by dividing the smallest CSA by intra-bag pressure. While the intra-bag pressure can fluctuate, the distensibility is best measured when the intra-bag pressure is at its peak,

as this represents the lowest possible DI of the sphincter. Additionally, the diameter of each plane can be calculated by CSA, with the smallest diameter being reported as the minimum diameter (D_{min}).

The FLIP impedance planimetry system is FDA-approved for the following indications:

- For use in the clinical setting to measure pressure and dimensions in the esophagus, pylorus, and anal sphincters.
- It is intended to be used as an adjunct to other diagnostic methods as part of a comprehensive evaluation of patients with symptoms consistent with gastrointestinal motility disorders.

Contraindications to use include any setting in which endoscopy is contraindicated or in the setting of actively bleeding esophageal varices.

FLIP system configuration

For all of the following protocols, an 8-cm (EF-325) catheter is used. The longer length of the 16 cm (EF-322) catheter is typically more useful when using FLIP to evaluate motility along the body of the esophagus [5]. After purging the catheter, zero the pressure to atmospheric pressure while holding the catheter in the horizontal position.

Catheter placement

While catheters can be placed transnasally, catheters are typically placed transorally in the operative setting. Placement is similar to an orogastric tube, and can be made easier with jaw thrust assistance. When inserting the catheter, the amount of force required to advance the catheter should be minimal. Pushing the catheter against resistance risks kinking the catheter and/or damaging the pressure sensor (located at the distal end) which is relatively sensitive. A damaged pressure sensor will result in abnormally high pressure readings when the intra-bag pressure is clearly low. This will render the distensibility index inaccurate and requires catheter replacement.

Filters

There are several filters built into the FLIP system that assist with filtering out “noise” (Fig. 3). Without a filter, the FLIP measurements are reported instantaneously and vary dramatically with any respirations, peristalsis or movement of the catheter. The standard filter produces measurements that are averaged over time. The options include the following: 1, 2, 5, 10, or 20 s. For example, a “5 s” standard average

filter provides an average diameter over five seconds at any given electrode. The weighted average filter is also an average over time, but gives more weight to the most recently measured data points and less weight to the data points further back in time. The options include low, medium, or high. A “low” filter level produces less filtering and a jumpier but more responsive image, as opposed to a “high” filtering level which produces heavy filtering and a smoother but slower image response.

Unless otherwise stated, the following protocols utilize a high-weighted filter. The low-weighted filter can be useful when initially positioning the catheter in the correct place (i.e., straddled across the sphincter), as this allows the screen image to change more rapidly to ensure the catheter is not withdrawn beyond its desired location.

Data points

While it appears that distensibility index is the most useful measurement provided by the FLIP impedance planimetry system, it remains unclear which parameter correlates best with patient outcomes. It is possible that certain parameters correlate better with certain symptoms; therefore, we encourage the documentation of the following FLIP measurements during all procedures:

- Diameter of the narrowest luminal area (D_{min} , mm)
- Cross-sectional area of the narrowest luminal area (CSA, mm^2)
- Intra-bag pressure (mmHg) at the maximum diameter of the narrowest luminal area.
 - OF NOTE: The pressure should be greater than 15 mmHg in order to accurately assess distensibility.
- Distensibility index (DI, $mm^2/mmHg$) at the maximum intra-balloon pressure

Making note of the intra-bag pressure during FLIP use is of particular importance. Ensuring intra-bag pressure is > 15 mmHg indicates that there is adequate distention of the lumen to allow accurate assessment of distensibility (i.e., the luminal CSA/pressure relationship). Only once the more compliant ends of the bag are filled to capacity will the intra-bag pressure increase with added volume, allowing accurate evaluation of sphincter distention [6].

FLIP protocol during hiatal hernia repair and fundoplication or magnetic sphincter augmentation (MSA)

The ability of FLIP to measure luminal opening dimensions makes it ideal for intra-operative usage during hiatal hernia repair and fundoplication. The FLIP provides real-time

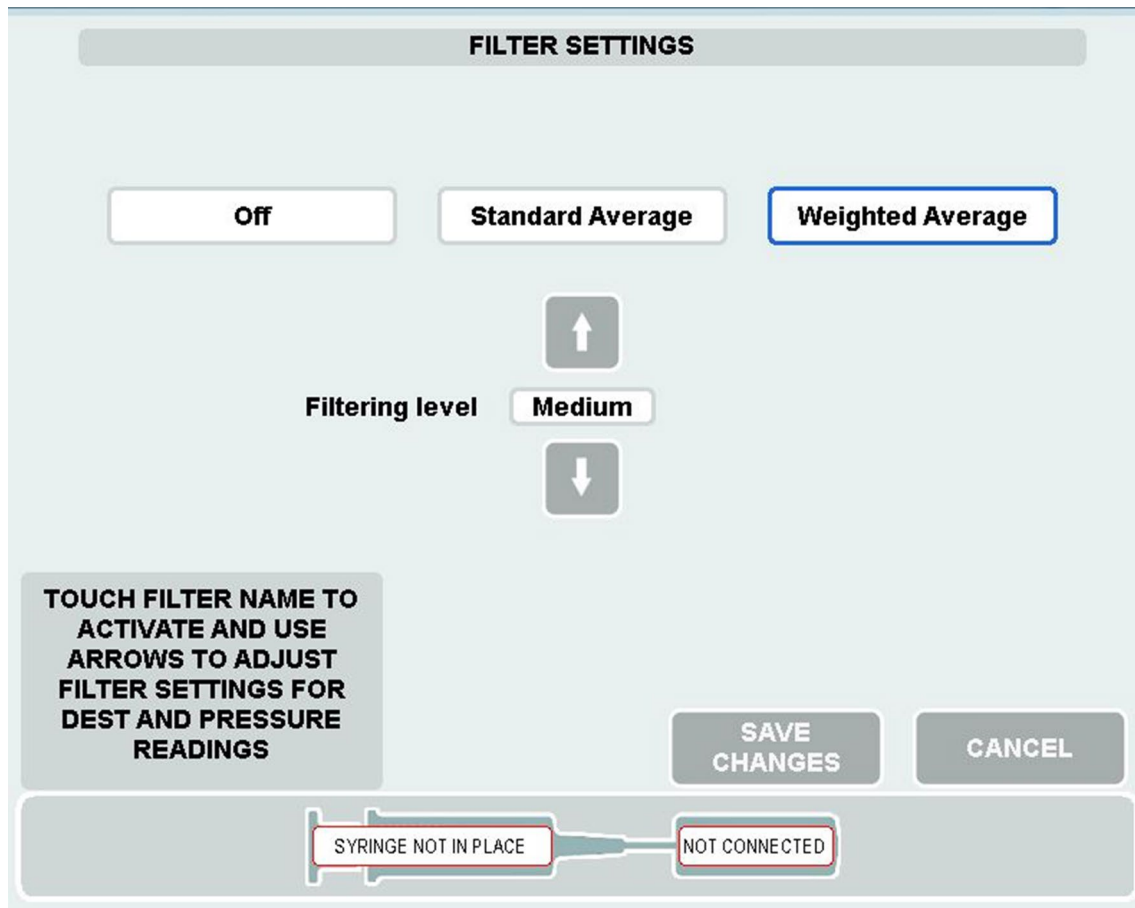


Fig. 3 Filter setting screen

objective information regarding wall properties of the gastroesophageal junction (GEJ) as well as the external constraints on the GEJ generated by repairing the diaphragmatic hiatus and creation of fundoplication [6].

- We advise performing measurements at both 30 and 40 ml fill volume; however, if measurements can only be done at one volume, we recommend 40 ml.
 - A 40 ml volume fill will maintain consistency with measurements obtained during other procedures (e.g., POEM) and ensures intra-bag pressure is always > 15 mmHg.
 - Timepoints to obtain measurements (Fig. 4):
 - After crural dissection ± hernia reduction is complete
 - After crural closure
 - After fundoplication or after MSA placement
 - When obtaining measurements:
 - Patient positioning: Reverse Trendelenburg (approx. 30 degrees)
 - Ventilation: Hold positive-pressure ventilation at end expiration
 - Pneumoperitoneum: No pneumoperitoneum (i.e., release insufflation)
 - Consider recording measurements both with and without pneumoperitoneum
1. Place catheter transorally into the stomach (usually around 45–50 cm)
 - a. If the catheter is difficult to advance, utilize jaw thrust and consider placement under endoscopic guidance. If an endoscope is used to facilitate catheter placement, the endoscope should be removed prior to initiating the following protocol.
 2. Inflate balloon to 30 ml.
 3. Slowly withdraw catheter until hourglass shape is seen (waist-like constriction should be at the LES) on the FLIP monitor (Fig. 4).

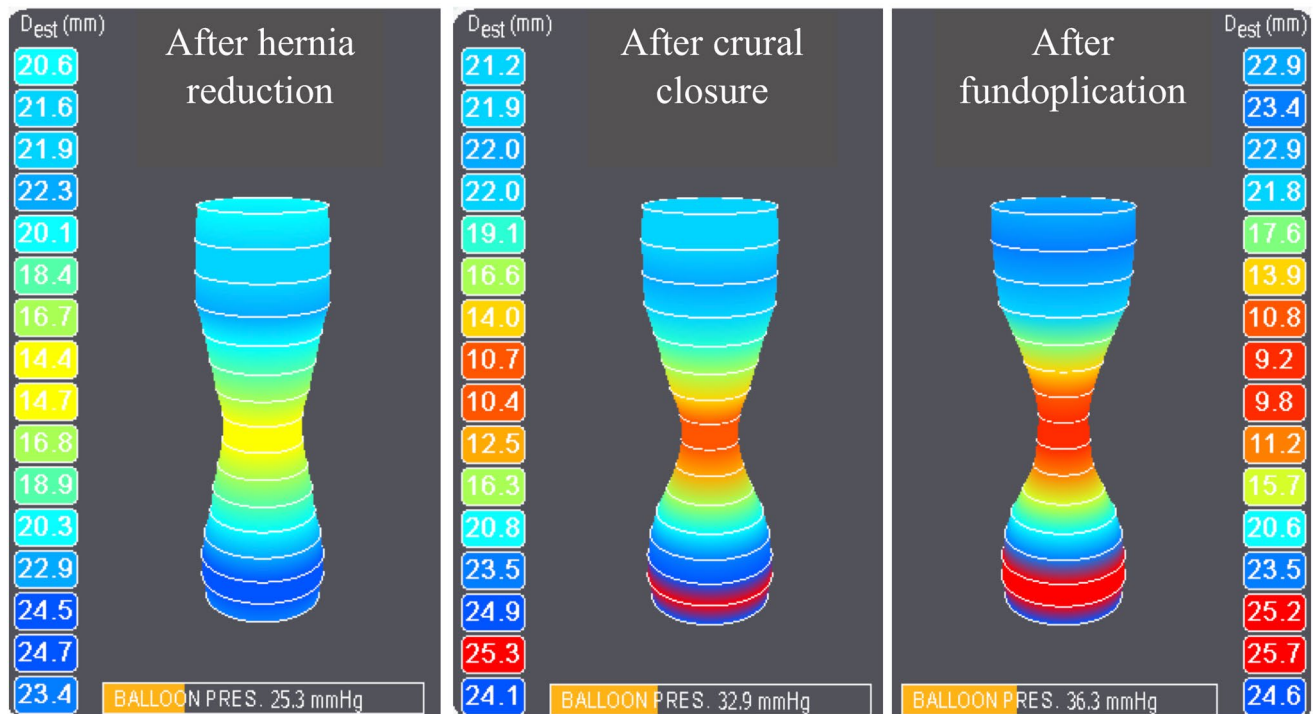


Fig. 4 Visual representation of changes in the gastroesophageal junction during hiatal hernia repair and fundoplication using a 40 ml volume fill

- a. A low-weighted filter is useful at this time, as the screen image changes more rapidly to reflect the precise location of the catheter and ensures the catheter is not withdrawn beyond the GEJ
4. Center the hourglass in the middle of the electrodes
 - a. Change filter back to a high-weighted filter
5. Leave in place for 30 s to allow stabilization.
6. The intra-bag pressure may increase and decrease in waves. Once the intra-bag pressure reaches its peak, press “pause” and record Dmin, intra-bag pressure, CSA, and DI.
7. Return to “run live” and inflate to 40 ml. Repeat steps 5–6.
8. Deflate balloon and remove catheter.

Initial measurements obtained prior to crural dissection or hernia reduction can be obtained at the discretion of the surgeon. The catheter may be difficult to pass, particularly in large paraesophageal hernias, and we do not feel initial measurements add much by way of intra-operative decision-making. We recommend measurements to be obtained in reverse Trendelenburg to minimize time required to reposition the patient and to obtain measurements without pneumoperitoneum, in order to maintain consistency with FLIP data from the gastrointestinal (GI) literature.

Several studies have reported FLIP measurements during hiatal hernia repair and fundoplication; however, it is important to be cognizant of the context in which the measurements were taken. Until now, there has not been a standardized protocol for obtaining measurements, which limits the generalizability and comparability of each study’s results. Measurements after crural dissection and hernia reduction can provide information regarding LES competence, now that it has now been returned to its native intra-abdominal location. This information can guide surgeons on how tightly to close the crura and/or what type of fundoplication to perform. Measurements recorded after crural closure (Table 1) can be helpful in evaluating whether the crural repair is too tight which may increase the risk of dysphagia. Similarly, measurements recorded after fundoplication (Table 2) can be used to assess wrap characteristics and assist the surgeon in deciding whether to loosen or tighten the wrap.

Even fewer studies have reported the correlation between FLIP measurements and patient outcomes (Table 3). Again, due to the heterogeneity in which measurements have been collected, interpretation and generalizability of the results are challenging.

The protocol for using FLIP during MSA placement is similar to that of fundoplication. While the MSA device uses its own measuring tool, FLIP evaluation following device placement can potentially be useful; however, there is no

Table 1 Summary of FLIP measurements after crural closure

Author [Ref.]	Year	Procedure (N)	Pressure reference	Pneumo-peritoneum	30 ml volume			40 ml volume					
					Dmin (mm)	CSA (mm ²)	Pressure (mmHg)	Distensibility (mm ² /mmHg)	Dmin (mm)	CSA (mm ²)	Pressure (mmHg)	Distensibility (mm ² /mmHg)	
Iiczyszyn et al. [7]	2013	Nissen (17)	Atmosphere	15 mmHg	–	–	–	–	–	–	–	1.86	
Kim et al. [8]	2018	Nissen and Toupet (40)	Not reported	15 mmHg	6.22	30.9	–	–	–	–	–	–	1.46

All studies utilized an 8 cm (EF-325) catheter that was placed transorally. *Dmin* Minimum diameter, *CSA* Cross-sectional area

Table 2 Summary of FLIP measurements after fundoplication

Author [Ref.]	Year	Procedure (N)	Pressure reference	Pneumo-peritoneum	Wrap	30 ml volume			40 ml volume					
						Dmin (mm)	CSA (mm ²)	Pressure (mmHg)	Distensibility (mm ² /mmHg)	Dmin (mm)	CSA (mm ²)	Pressure (mmHg)	Distensibility (mm ² /mmHg)	
Iiczyszyn et al. [7]	2013	Nissen (17)	Atmosphere	15 mmHg	None	–	–	–	–	–	–	–	–	0.83
DeHaan et al. [9]	2017	Nissen (48)	Gastric	15 mmHg	Bougie	6.5	32.8	26.7	1.4	9.1	68.2	37.6	2.0	1.45
Kim et al. [8]	2018	Toupet (27) Nissen (18)	Gastric Not reported	15 mmHg 15 mmHg	Bougie 30 ml FLIP	7.8 5.78	48.4 26.5	29.4 –	1.9 1.23	10.6 –	85.9 –	38.9 –	2.4 –	–
Su et al. [10]	2019	Toupet (22) Nissen (50) Toupet (28)	Not reported Atmosphere Atmosphere	15 mmHg 0 mmHg 0 mmHg	30 ml FLIP Bougie Bougie	6.12 8.6 8.5	29.7 – –	– 30.8 25	1.29 2.1 2.8	– – –	– – –	– – –	– – –	–

All studies utilized an 8 cm (EF-325) catheter that was placed transorally. *Dmin* Minimum diameter, *CSA* Cross-sectional area

Table 3 Summary of FLIP measurements and patient outcomes after fundoplication

Author [Ref.]	Year	Procedure (N)	Pressure reference	Final Measurement Settings			Follow-up	Results
				Pneumo-peritoneum	Balloon volume	Wrap		
Kim et al. [8]	2018	Nissen and Toupet (40)	Not reported	15 mmHg	30 ml	30 ml FLIP	1 month	Final average D_{min} of 5.97 mm and DI of 1.26 mm ² /mmHg resulted in resolution of reflux symptoms and no significant dysphagia
Turner et al. [11]	2019	Nissen and Toupet (43)	Gastric	15 mmHg	30 ml	Bougie	≥ 6 months	After fundoplication, a decrease in D_{min} of ≤ 0.15 mm or decrease in CSA ≤ 1.5 mm ² (compared to pre-insufflation measurements) was associated with severe heartburn
Su et al. [10]	2019	Nissen and Toupet (71)	Atmosphere	0 mmHg	30 ml	Bougie	2 years	Final DI between 2.0–3.5 mm ² /mmHg resulted in the best reflux control with the least amount of dysphagia and gas bloat

All studies utilized an 8 cm (EF-325) catheter that was placed transorally. D_{min} Minimum diameter, DI Distensibility index, CSA Cross-sectional area

published data regarding FLIP measurements following MSA and patient outcomes.

FLIP protocol during laparoscopic Heller myotomy (LHM)

The introduction of FLIP has provided an innovative way for surgeons to objectively evaluate the adequacy of myotomy during operations for achalasia. FLIP can be used during LHM to assess real-time changes in lower esophageal sphincter (LES) distensibility as the myotomy is being performed. Additionally, because the fluid in the balloon preferentially distributes to areas of less resistance, as the myotomy is performed, fluid distends the esophagus, separating the muscle fibers and allowing for better visualization of the myotomy plane.

- We advise performing measurements at 40 ml fill volume.

- When performing measurements at 30 ml fill volume, post-myotomy intra-balloon pressure is often too low (i.e., < 15 mmHg), which results in inaccurate reporting of the distensibility index.
- Timepoints to obtain measurements:
 - After crural dissection
 - After myotomy is complete
 - Consider leaving the catheter in place with 40 ml volume fill during myotomy. This can provide real-time feedback about the change in lower esophageal sphincter distensibility and also distends the esophagus to facilitate the myotomy by improving exposure to muscle fibers.
 - After myotomy, the catheter should always be placed under visual guidance (endoscopic or laparoscopic) to decrease the risk of perforation.
 - After fundoplication (if applicable)

- When obtaining measurements:
 - Patient positioning: Reverse Trendelenburg (approx. 30 degrees)
 - Ventilation: Hold positive-pressure ventilation at end expiration
 - Pneumoperitoneum: No pneumoperitoneum (i.e., release insufflation)
 - Consider recording measurements both with and without pneumoperitoneum
1. Place catheter transorally into the stomach (usually around 45 -50 cm)
 - a. If the catheter is difficult to advance, consider jaw thrust and placement under endoscopic guidance. If an endoscope is used to facilitate catheter placement, the endoscope should be removed prior to initiating the following protocol
 2. Inflate to 30 ml
 3. Slowly withdraw catheter until hourglass shape is seen on the FLIP monitor
 - a. A low-weighted filter is useful at this time, as the screen image changes more rapidly to ensure the catheter is not withdrawn beyond the GEJ
 4. Center the hourglass in the middle of the electrodes
 - a. Change filter back to a high-weighted filter
 5. Inflate to 40 ml.
 6. Leave in place for 30 s to allow stabilization
 7. The intra-bag pressure may increase and decrease in waves, wait for the intra-bag pressure to be at its highest
 8. Press “pause” and record Dmin, intra-bag pressure, CSA, and DI
 9. Deflate balloon and remove catheter

Again, presence or absence of insufflation should be noted when interpreting FLIP measurements during LHM. Measurements should be obtained in reverse Trendelenburg position to minimize time required to adjust patient positioning, and without pneumoperitoneum to maintain consistency with the GI literature. There are only two studies that report FLIP parameters during LHM (Table 4), and there is only one study that reports a relationship to patient outcomes. Teitelbaum et al. evaluated 11 LHM and 21 POEM patients who had undergone FLIP evaluation intra-operatively and were more than 6 months post-procedure. Using a 40 ml volume fill without pneumoperitoneum, they determined that a final GEJ distensibility between 4.5 and 8.5 mm²/mmHg produced the “optimal” symptom outcome (i.e., Eckardt symptom score ≤ 1 and a GerdQ score ≤ 7) [14].

FLIP protocol during peroral endoscopic myotomy (POEM)

In 2010, Inoue et al. described POEM as a novel endoscopic intervention for achalasia [15]. Despite the benefits of POEM, a common criticism is the high rate of post-operative reflux, which is reported to be around 40% [16, 17]. Similar to LHM, FLIP can be used intra-operatively to assess adequacy of myotomy but there is also potential to use FLIP measurements to predict which patients will develop reflux, or to tailor the myotomy to reduce incidence of reflux.

- We advise performing measurements at 40 ml fill volume.
 - As previously mentioned, using a 30 ml fill volume often results in inadequate intra-balloon pressure after myotomy.
 - Timepoints to obtain measurements (Fig. 5):
 - After intubation, prior to mucosotomy.
 - After myotomy is complete, prior to closure of mucosotomy
 - **Once the mucosotomy has been made, the FLIP catheter should *always* be placed under endoscopic guidance. Advancing the catheter blindly can result in esophageal perforation**
 - When obtaining measurements:
 - Patient positioning: Flat
 - Ventilation: Hold positive-pressure ventilation at end expiration
1. Place catheter transorally into the stomach (usually around 45 -50 cm)
 - a. If the catheter is difficult to advance, consider placement under endoscopic guidance. If an endoscope is used to facilitate catheter placement, the endoscope should be removed prior to initiating the following protocol.
 2. Inflate to 30 ml
 3. Slowly withdraw catheter until hourglass shape is seen on the FLIP monitor
 - a. A low-weighted filter is useful at this time, as the screen image changes more rapidly to ensure the catheter is not withdrawn beyond the GEJ
 4. Center the hourglass in the middle of the electrodes
 - a. Change filter back to a high-weighted filter

Table 4 Summary of FLIP measurements during Laparoscopic Heller Myotomy

Author [Ref.]	Year	N	Pressure reference	Myotomy length	Procedure time point	30 ml volume			40 ml volume														
						Dmin (mm)	CSA (mm ²)	Pressure (mmHg)	Distensibility (mm ² /mmHg)	Dmin (mm)	CSA (mm ²)	Pressure (mmHg)	Distensibility (mm ² /mmHg)										
Teitelbaum et al. [12]	2013	11	NR	4–5 cm	2–3 cm	Initial (no insufflation)	–	–	–	–	–	–	–	–	–	–	–	–	–				
						Post-myotomy (insufflated)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	
						Post-Toupet fundoplication (insufflated)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
						Final (no insufflation)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–
DeHaan et al. [13]	2016	14	NR	6 cm	2–3 cm	Initial (no insufflation)	7.8	28.0	24.1	1.4	7.8	46.1	33.0	1.4	–	–	–	–	–	–			
						Post-myotomy (insufflated)	10.5	87.4	23.9	4.0	13.1	126.9	28.2	5.2	–	–	–	–	–	–	–	–	
						Post-Dor fundoplication (insufflated)	7.2	42.4	25.9	1.6	9.7	75.9	33.6	2.3	–	–	–	–	–	–	–	–	–
						Final (no insufflation)	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–	–

All studies utilized an 8-cm (EF-325) catheter that was placed transorally. NR Not reported, Dmin Minimum diameter, CSA Cross-sectional area

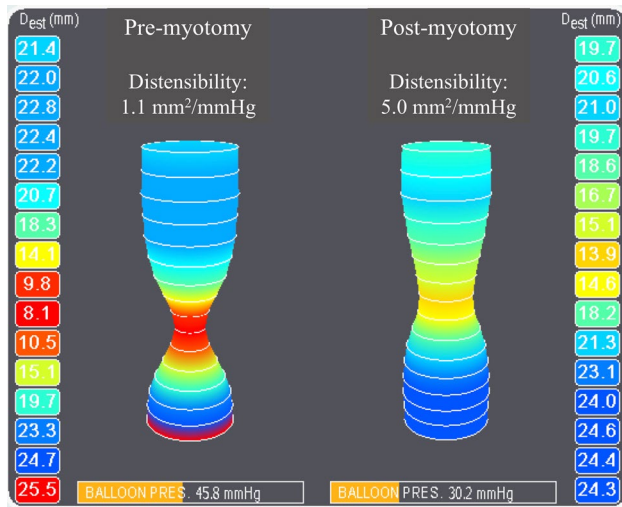


Fig. 5 Visual representation of changes in the lower esophageal sphincter before and after myotomy for achalasia using a 40 ml volume fill

5. Inflate to 40 ml
6. Leave in place for 30 s to allow stabilization
7. The intra-bag pressure may increase and decrease in waves, wait for the intra-bag pressure to be at its highest.
8. Press “pause” and record Dmin, intra-bag pressure, CSA, and DI
9. Deflate balloon and remove catheter

There are several studies that report intra-operative FLIP measurements during POEM (Table 5), and three studies that report outcomes after POEM based on intra-operative FLIP measurements. As mentioned prethat patients with a post-operatively, Teitelbaum et al. described an ideal final distensibility of 4.5–8.5 mm²/mmHg (using a 40 ml volume fill) for patients who had undergone both LHM and POEM. Final DI within this range produced the best symptomatic outcomes with regard to low Eckardt and GerdQ scores [14]. Additionally, Ngamruengphong et al. performed a retrospective multi-center study of 63 patients who underwent POEM with intra-operative FLIP assessment and subsequent upper endoscopy and/or pH testing at a later date. Using a 30 ml volume fill, they found that those with reflux esophagitis had a larger final CSA and Dmin compared to those without reflux esophagitis (99.5 mm² vs 79.3 mm², 11.2 mm vs 10.1 mm; *p* < 0.05) [19]. Lastly, Su et al. performed a retrospective single-institution study of 77 patients who underwent LHM or POEM and found that patients with a post-operative Eckardt Score ≥ 3 were significantly more likely to have a final DI ≤ 3.1 mm²/mmHg (*p* = 0.014) or a change in DI ≤ 3.0 mm²/mmHg (*p* = 0.010) when using a 30 ml volume fill. Additionally, a final CSA > 96 mm² or Dmin > 11.0 mm was predictive of worse reflux at two years

Table 5 Summary of intra-operative FLIP measurements during Peroral Endoscopic Myotomy (POEM)

Author [Ref.]	Year	N	Pressure reference	Myotomy length		Balloon volume	Dmin (mm)		CSA (mm ²)		Pressure (mmHg)		Distensibility (mm ² /mmHg)	
				Esophageal	Gastric		Pre	Post	Pre	Post	Pre	Post	Pre	Post
Rieder et al. [18]	2013	4	Not reported	4–5 cm	2–3 cm	30 ml	5.3	9.1	22	71.5	29.4	23.7	0.8	3.1
Teitelbaum et al. [12]	2013	14	Not reported	6 cm	2–3 cm	40 ml	6.5	10.1	41.5	86	40.4	38.6	1	2.4
Ngamruengphong et al. [19]	2016	63	Atmosphere	Not reported	≥ 2 cm	40 ml	7.0*	14.4*	38.8	163.6	34	21.8	1.4	7.9
Su et al. [20]	2020	71	Atmosphere	8 cm	3 cm	30 ml	6.57	10.49	53.32	142.43	–	–	1.7	6.22
							6.3	10.9	36.4	88.5	–	–	1.53	4.75
									33.4	96.0	35.0	26.0	1.2	4.1

*For the purposes of this table, Dmin was calculated based on reported CSA. All studies utilized an 8-cm (EF-325) catheter and were placed transversally
Dmin Minimum diameter, CSA Cross-sectional area

based on Reflux Symptom Index scores [20]. Only the data from Teitelbaum et al. were obtained using a 40 ml volume fill as recommended in our protocol. Their results are difficult to compare against the other two studies as they were obtained following a different protocol, and hopefully future reports will be more consistent.

Conclusion

The FLIP impedance planimetry system is unique in that it provides real-time, objective feedback to surgeons during an operation. Until now, there has not been a way to objectively assess the tightness of a fundoplication or adequacy of a myotomy. We feel that this innovative device provides information that can be used in the operating room to improve patient outcomes for a multitude of foregut pathologies. While considerable research remains to correlate FLIP measurements to patient outcomes, standardization of the FLIP impedance planimetry system usage in the operating room will enhance interpretation and generalizability of future study results.

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Compliance with ethical standards

Disclosures Dr. Jon Gould is a consultant for Ethicon and a speaker for Gore Medical. Dr. Blair Jobe is a consultant for Ethicon. Dr. Paul Severson is a consultant and speaker for Mauna Kea Technologies, a consultant for DyaMX, a speaker for Ethicon, and a St. Jude Preceptor for Abbott Pharmaceuticals. Dr. Michael Ujiki is a speaker for Medtronic, a consultant for Olympus, a scientific advisory board member for Boston Scientific, a consultant and speaker for Apollo Medical Devices, and a speaker for Gore Medical. Drs. Bailey Su, Christy Dunst, Kirsten Newhams, and Aaron Sachs have no conflicts of interest or financial ties to disclose.

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