

# ADVANCES IN ENDOSCOPY

Current Developments in Diagnostic and Therapeutic Endoscopy

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## The Role of the Functional Lumen Imaging Probe in Research and Clinical Practice



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### **G&H** When was the functional lumen imaging probe developed?

**KL** The concept of the functional lumen imaging probe was first demonstrated in 2006, while the endolumenal functional lumen imaging probe (EndoFLIP, Medtronic) device has been commercially available since 2009. It is a catheter-based device that uses impedance planimetry to assess the distensibility of hollow organs. The typical catheter is 240 cm long and 3 mm wide. On one end is an infinitely compliant balloon that is filled with a specialized conductive saline. Once the balloon has been positioned, it undergoes volume-controlled distention. Impedance planimetry electrodes then provide cross-sectional area measurements. Pressure is simultaneously measured using a solid-state pressure transducer; thus, clinicians are able to calculate distensibility by cross-sectional area and pressure. An evaluation of esophageal motility is also provided by the most current EndoFLIP machine.

There are currently 2 types of catheters: EndoFLIP is a measurement catheter, and EsoFLIP (Medtronic) is a dilation catheter.

### **G&H** For which indications does EndoFLIP currently have approval from the US Food and Drug Administration?

**KL** The US Food and Drug Administration has approved EndoFLIP to measure pressure and dimensions in the esophagus, pylorus, and anal sphincter, and to estimate the size of a gastric band stoma. The device has also received approval for use as an adjunctive test in patients with esophageal hypersensitivity.

### **G&H** What are the clinical applications of this device?

**KL** Among esophageal diseases, the most common application for EndoFLIP is in esophageal motility disorders that are characterized by esophagogastric junction outflow obstruction, such as achalasia. Distensibility measurements evaluating relaxation (or lack thereof) of the lower esophageal sphincter as well as esophageal motility measurements via the EndoFLIP device often help confirm the diagnosis of achalasia prior to treatment. Additionally, recurrent symptoms after treatment can be assessed via this technology to help determine if further targeted therapy is warranted.

Clinically, the EndoFLIP device is invaluable when the typical workup for lower esophageal sphincter dysfunction is discrepant. For example, a patient may present with dysphagia, regurgitation, and other symptoms of achalasia, but have results from an upper endoscopy, high-resolution manometry, and barium swallow that

are not in concordance. EndoFLIP can also be used intraoperatively during treatments for achalasia, providing real-time measurements during peroral endoscopic myotomies and laparoscopic Heller myotomies. Another

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er major use of this device is in patients with eosinophilic esophagitis. Distensibility measurements in these patients have been shown to be a stronger predictor of food impaction than endoscopic and histologic findings.

Importantly, as per the American Gastroenterological Association Clinical Practice Update Expert Review, EndoFLIP is a complementary tool. It is not meant to make initial diagnostic or treatment decisions alone.

#### **G&H** How effective is the device in assessing achalasia and other conditions?

**KL** Because the device is used mainly as an adjunct tool, it is difficult to evaluate its efficacy in assessing certain diseases. There is no gold standard for distensibility measurements to which the device can be compared, and data are lacking.

#### **G&H** What other indications or clinical uses does the functional lumen imaging probe have?

**KL** EsoFLIP, the dilation catheter, has a more rigid balloon with a maximum diameter catheter of 30 mm, which is useful for allowing real-time positioning of the balloon at the lower esophageal sphincter. Because the balloon size is large enough to perform a pneumatic dilation, it can be employed to treat achalasia without the use of fluoroscopy.

Clinical indications that are being investigated include assessing properties of the pylorus and anal sphincter. EndoFLIP can be used surgically as well; for example, clinicians can use the device to tailor antireflux surgery intraoperatively, to estimate the size of the stoma produced by the gastric band, and to monitor treatment

success in foregut surgery. There has been some research evaluating the opening dynamics of the upper esophageal sphincter, but the data are not yet strong.

#### **G&H** What are the main benefits and limitations of the EndoFLIP device?

**KL** The major benefit of the EndoFLIP device is that it allows clinicians to obtain distensibility information about the gastrointestinal tract lumen that is otherwise unobtainable. The device provides complementary testing to assess not only stiffness of the esophageal wall but also mechanical properties of the gastroesophageal junction, something that no other tool currently offers. Its use is not associated with any major risk, such as perforation. Because measurements with this device are often taken under anesthesia, patient discomfort is minimal.

However, because patients are sedated, only secondary peristalsis is evaluated. Additionally, various factors can affect measurements, including catheter movement, respiratory artifact, and vascular artifact. The main limitation, however, is the lack of automated data analysis. It is often necessary to have custom-tailored software in order to make data analysis less burdensome.

#### **G&H** Does the device have widespread or routine clinical use, or is it used mainly in specialized centers?

**KL** It is largely used in specialized academic centers; this is likely at least in part due to the nuances of data analysis.

#### **G&H** What is the future of this device?

**KL** The device has been on the market for 10 years, and I think its use will continue to grow. It is most useful among esophageal motility disorders characterized by esophagogastric junction outflow obstruction, and that is an area in which the device can thrive. We have not seen good data for EndoFLIP in gastroesophageal reflux disease; however, other clinical applications, such as tailoring various surgical and endoscopic treatments intraoperatively and objectively assessing treatment response, will continue to be useful and adaptable. Research is being conducted regarding assessing properties of the pylorus and anal sphincter as well as for other surgical uses. The device may also have future use in evaluating the upper esophageal sphincter.

#### **G&H** What are the priorities of research?

**KL** Larger studies would be appreciated for many of the device's indications. There is a lack of controlled

trials that could provide additional information on when and how best to utilize the functional lumen imaging probe. One hope in the near future is to use the functional lumen imaging probe to tailor myotomies when treating achalasia to help decrease dysphagia while also minimizing the risk of postprocedure gastroesophageal reflux disease. Additionally, the device will likely prove important in characterizing the manometric diagnosis of esophagogastric junction outflow obstruction. Overall, this is a promising and minimally invasive tool with much potential for advancing care in gastroenterology.

*Dr Lynch has no relevant conflicts of interest to disclose.*

## Suggested Reading

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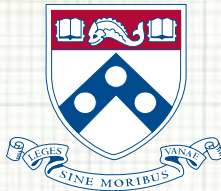
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