Communication from the ASGE Technology Committee

REPORT ON EMERGING TECHNOLOGY

Endoscopic anti-reflux devices (with videos)

Prepared by: ASGE TECHNOLOGY COMMITTEE

Nirav Thosani, MD, Adam Goodman, MD, FASGE, Michael Manfredi, MD, Udayakumar Navaneethan, MD, Mansour A. Parsi, MD, FASGE, Zachary L. Smith, DO, Shelby A. Sullivan, MD, Subhas Banerjee, MD, FASGE, previous Committee Chair, John T. Maple, DO, FASGE, Chair

This document was reviewed and approved by the governing board of the American Society for Gastrointestinal Endoscopy.

The American Society for Gastrointestinal Endoscopy (ASGE) Technology Committee provides reviews of existing, new, or emerging endoscopic technologies that have the potential to affect the practice of GI endoscopy. Evidence-based methodology is used, with a MEDLINE literature search to identify pertinent preclinical and clinical studies on the topic and a MAUDE (Food and Drug Administration Center for Devices and Radiological Health) database search to identify the reported adverse events of a given technology. Both are supplemented by accessing the "related articles" feature of PubMed and by scrutinizing pertinent references cited by the identified studies. Controlled clinical trials are emphasized, but in many cases, data from randomized controlled trials are lacking. In such cases, large case series, preliminary clinical studies, and expert opinions are used. Technical data are gathered from traditional and Web-based publications, proprietary publications, and informal communications with pertinent vendors. For this review, the MEDLINE database was searched through December 2015 by using the keywords "gastroesophageal reflux disease," "GERD," "endoscopic surgery," "minimally invasive treatment," "endoscopic treatment," "radiofrequency," "radiofrequency energy," "Stretta," "endoscopic fundoplication," "endoscopic incisionless fundoplication," and "fundoplication." Reports on Emerging Technologies are drafted by 1 or 2 members of the ASGE Technology Committee, reviewed and edited by the committee as a whole, and approved by the governing board of the ASGE. These reports are scientific reviews provided solely for educational and informational purposes. These reports on emerging technologies are not rules and should not be construed as establishing a legal standard of care or as encouraging, advocating, requiring, or discouraging any particular treatment or payment for such treatment.

0016-5107/$36.00
http://dx.doi.org/10.1016/j.gie.2017.08.001

BACKGROUND

GERD is one of the most common GI diseases, accounting for 7 million annual outpatient visits in the United States.[1] Lifestyle modification and medical therapy, including acid-suppressive medications, are first-line treatments for GERD.[2,3] In approximately 30% to 40% of patients with GERD, medical therapy provides only partial relief of symptoms.[4] Laparoscopic anti-reflux surgery remains an option for patients with GERD, but only approximately 1% of all patients with GERD opt for surgical intervention.[5] To address this GERD treatment gap, minimally invasive endoscopic anti-reflux devices have been developed, which allow endoscopic fundoplication or reduction in lower esophageal sphincter (LES) compliance.

Endoscopic anti-reflux devices are intended to target patients with GERD with mild gastroesophageal junction (GEJ) defects. These devices do not alter the anatomy of the esophagus, GEJ, or stomach and, thus, should not be considered as alternatives to surgical fundoplication for patients with significant anatomic abnormalities including large hiatal or paraesophageal hernias. Use of these devices has not been systematically evaluated in patients with active erosive esophagitis, Barrett's esophagus, esophageal motility disorders, or hiatal hernias >2 cm in length. Limited data exist regarding use of these devices to treat patients with nonerosive reflux disease and laryngopharyngeal reflux disease. This document focuses on endoscopic anti-reflux devices to treat patients with GERD.

Although many endoscopic anti-reflux devices have undergone testing in bench models, animal models, and human trials, only a few are available currently in the United States for clinical use. The currently available U.S. Food and Drug Administration (FDA) approved devices for the endoscopic treatment of GERD are: transoral incisionless fundoplication (TIF) (EsophyX device; EndoGastric Solutions, Redmond, Wash, USA), Medigus Ultrasonic Surgical Endostapler (MUSE) (Medigus Ltd, Omer, Israel), and Stretta (Mederi Therapeutics, Greenwich, Conn, USA). Several

previously developed endoscopic anti-reflux devices including the EndoCinch device (CR Bard, Inc, Murray Hill, NJ, USA), Endoscopic Suture device (Wilson-Cook, Winston-Salem, NC, USA), Endoscopic Plication System (Plicator; NDO Surgical, Inc, Mansfield, Mass, USA), Enteryx (Boston Scientific Corp, Boston, Mass, USA), and Gatekeeper reflux repair system (Medtronic Inc, Minneapolis, Minn, USA) are no longer marketed because of safety concerns and lack of efficacy.

TECHNOLOGY UNDER REVIEW

EsophyX device

TIF, with the use of the EsophyX device, was introduced as an endoscopic substitute for surgical reconstruction of the LES. The procedure aims to restore the angle of His (the acute angle between the cardia and the esophagus). The TIF procedure has evolved over time from a gastrogastric plication to an esophagogastric plication. In the initially described TIF procedure (TIF 1.0), fasteners were placed 1 cm above the GEJ, and no circumferential wrap was created. In the TIF 2.0 procedure, fasteners are placed 1 to 3 cm above the GEJ, and additionally, a circumferential wrap is created. The TIF 2.0 procedure improves the anti-reflux barrier by reducing small hiatal hernias ($\leq$2 cm), if present, and by creating a valve 2 to 4 cm in length with a >270° circumferential fundoplication. The FDA cleared the EsophyX device in September 2007. TIF requires general anesthesia and is routinely performed in the operating room, with patients requiring postprocedure hospitalization for observation.

Description of device. The EsophyX device is a single-use device and consists of multiple parts, including a tissue mold and chassis, a helical retractor, an invaginator, and a stylet-fastener assembly (Fig. 1A and B). The tissue mold can be flexed and extended to approximate and compress together esophageal and gastric fundal tissue during the procedure. The tissue mold and chassis are rotated around the GEJ during the procedure to create a circumferential wrap. The helical retractor is used to anchor and pull down the GEJ tissue into the tissue mold during fundoplication. The invaginator is connected to wall suction and allows anchoring of the esophagus to the chassis of the EsophyX device and facilitates reduction of small hiatal hernias (by means of advancing the EsophyX device caudally into the stomach) and placement of fasteners (by anchoring the distal esophagus to the device). The EsophyX device uses SerosaFuse fasteners (EndoGastric Solutions, Redmond, Wash, USA) to plicate esophageal and gastric tissue. SerosaFuse fasteners are nonbiodegradable, H-shaped, polypropylene fasteners, available in 6.5 mm and 7.5 mm lengths (Video 1, available online at www.giejournal.org).

The original EsophyX device and the subsequent EsophyX$_2$ device have been replaced by 2 newer versions of the EsophyX$_2$ device. The EsophyX$_2$ HD is compatible with gastroscopes with outer diameters ranging from 10.6 mm to 12.3 mm and with both lengths of SerosaFuse fasteners. The EsophyX Z device is compatible with gastroscopes with outer diameters ranging from 4.7 mm to 7.2 mm, is compatible only with 7.5 mm–length fasteners, and includes a fastener delivery trigger (Fig. 2A and B).

Description of technique. Two endoscopists are necessary for this procedure; the first operates a gastroscope to provide visual guidance to the second who uses the EsophyX device to achieve the fundoplication. The EsophyX device is loaded over the shaft of a compatible gastroscope. The gastroscope and the EsophyX device (with its tissue mold extended) are advanced to the stomach under direct vision. Once in the stomach, the gastroscope is retracted back into the chassis, and the tissue mold is flexed, exposing a dedicated opening between the chassis and tissue mold, through which the gastroscope can be advanced. The gastroscope is then retroflexed to provide an endoscopic view of the gastric cardia, while the second endoscopist uses the EsophyX device to create a fundoplication.

The helical retractor is inserted into the tissue of the GEJ by means of corkscrew-like rotation and is then used to pull the tissue down and/or caudally. This leads to folding of the cardiac notch of the stomach, with approximation of the serosal surfaces of the gastric fundus and lower esophagus. The tissue mold and the invaginator buttress this approximation from the gastric and esophageal sides, respectively. Finally, the stylet-fastener assembly places 2 SerosaFuse fasteners through this newly formed fold (Fig. 3). The EsophyX device is then rotated on its long axis, and the process is repeated 9 to 10 times until approximation is achieved around 270° (200°-300°) of the GEJ. Approximately 20 fasteners are implanted during the procedure to create fusion of the esophageal and gastric fundal tissue (Fig. 3).

MUSE

MUSE is an endoscopic stapling system that creates a partial fundoplication. Although the surgical and anatomic principles behind MUSE are similar to that of TIF, the apparatus used differs significantly. The FDA cleared the MUSE system in January 2015. The MUSE procedure requires general anesthesia and is typically performed in the operating room, with patients requiring postprocedure hospitalization for observation.

Description of device. MUSE is made up of a single-use flexible endostapler, a light source, and a control unit, the MUSE console (Fig. 4A). The endostapler resembles an endoscope and has a handle with tip deflection controls, an 80 cm–long shaft, and a 66 mm–long rigid section in the midportion of the endoscope shaft. The rigid section contains an ultrasonic mirror, a surgical stapler oriented perpendicular to the endoscope, a cartridge carrying five 4.8-mm standard B-shaped