Endoscopic Treatment of Gastroesophageal Reflux Disease

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KEYWORDS

• Gastroesophageal reflux disease • Endoluminal devices • Stretta • EsophyX

KEY POINTS

- Gastroesophageal reflux disease (GERD) is a disease that affects over 20% of the US population on at least a weekly basis.
- Laparoscopic Nissen fundoplication has been the gold standard for treatment of refractory GERD, but endoluminal therapies are gaining popularity and showing significant symptom control, at least in short-term data.
- There are 2 predominant devices currently in production for endoluminal treatment of GERD: Stretta, using radiofrequency ablation, and EsophyX, a transoral incisionless fundoplication; studies show improved symptom control and decreased proton pump inhibitors use but lack consistent long-term data demonstrating a decrease in esophageal acid exposure.
- Future studies are needed to demonstrate long-term efficacy of radiofrequency ablation (Stretta) and transoral incisionless fundoplication (EsophyX).

INTRODUCTION

Gastroesophageal reflux disease (GERD) is the most common disorder of the esophagus, affecting over 20% of the North American and Western European populations. More recent studies indicate the prevalence of GERD, defined as at least weekly heartburn and/or regurgitation, to be as high as 18% to 27% in the United States alone.[1] Current treatment of GERD costs close to $10 billion annually, with antireflux medication accounting for over one-half of the total cost.[2]

GERD is a chronic medical condition stemming from one or more factors:

1. Incompetent lower esophageal sphincter (LES) secondary to a hypotensive LES, increased intra-abdominal pressure that overwhelms a near normal LES, or inappropriate transient LES relaxations (TLESRs)

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2. Decreased contractile response of the diaphragmatic sphincter
3. Hiatal hernia
4. Poor esophageal clearance of acid as is seen in scleroderma

These physiologic disturbances cause a burning sensation in the chest or throat and/or regurgitation as the most common symptoms but may also be associated with extra-esophageal symptoms including chest pain, cough, hoarseness, and aspiration pneumonia. Prolonged acid exposure or bile reflux also increases the susceptibility of strictures, erosion, ulceration, Barrett esophagus, and even esophageal cancer.

Medical treatment consists of proton pump inhibitors (PPIs), which largely replaced the role of H2-blockers discovered in the 1970s. PPIs are effective in reducing gastric secretion of acid, yielding symptom relief in the majority of patients compliant with a daily or twice daily regimen. Many PPIs are now available over the counter and have affordable generic counterparts. In 2012, Nexium alone earned nearly $6 billion in sales, making it a top seller among all US medications.[3] Adjuncts to medical therapy include lifestyle changes such as smoking cessation and limiting meal sizes and alcohol intake. Overall, PPIs have adequate long-term safety, although the prolonged use has been linked to osteoporosis and susceptibility to *Clostridium difficile* colitis and, committing patients to a lifetime of PPI therapy can be expensive over time, and even cost-prohibitive in some patients. Also, despite lifestyle changes and optimized medical treatment, up to 20% of GERD patients have refractory or recurrent symptoms.[4]

Surgery for GERD is indicated when medical treatment fails or is no longer feasible (because of adverse effects, patient intolerance, or cost), when complications of GERD such as strictures, aspiration pneumonia, refractory asthma, esophageal bleeding occur, or at the patient's request when objective evidence of pathologic GERD has been diagnosed. The gold standard for surgical treatment of GERD is the laparoscopic Nissen fundoplication with hiatal hernia repair if indicated. The fundoplication increases lower esophageal sphincter pressure, decreases compliance of the gastroesophageal junction (GEJ), decreases frequency of TLESRs, increases the length of the intra-abdominal segment of the LES, reduces the sliding hiatal hernia, and restores the angle of His.[5] Although laparoscopic Nissen fundoplication (LNF) has excellent outcomes, with average cure rates in line with Kellokumpu's data of 87.7% at 5 years and 72.9% at 10 years,[6] it does carry inherent surgical and anesthetic risks. Postoperative dysphagia is the most commonly reported complication (although often transient, this may affect over 70% of patients in some studies),[6] followed by bloating, inability to belch, increased flatus, and need for repeat antireflux surgery. In a large cohort analysis based on 7531 patients between 2005 and 2009 from the National Surgical Quality Improvement Program (NSQIP) database, overall surgical mortality was less than a fraction of a percent, and in patients younger than 70 years of age, it was less than 0.05%.[7]

While the laparoscopic Nissen fundoplication was introduced into clinical practice in 1991 and remains the most frequently utilized operation for GERD,[8] the risks associated with surgery and adverse effects of dysphagia, bloating, and increased flatus are deterrents for many patients, thereby urging the surgical community to further pursue laparoscopic and endoscopic alternatives. Endoluminal techniques fall into 3 major categories: implantation or injection of foreign materials, radiofrequency ablation, and endoscopic tissue apposition techniques. Most endoluminal procedures are reserved for patients with documented symptomatic GERD, positive esophageal pH studies, and hiatal hernias less than 2 to 3 cm. Patients with evidence of pulmonary disease, Barrett esophagus, large hiatal hernias, obesity or morbid obesity, severe medical comorbidities, or esophageal dysmotility disorders are often excluded.

IMPLANTATIONS AND INJECTIONS

The theory of implantation and injection devices is to instill a bulking agent to augment the natural mechanical barrier to reflux. In 1984, O'Conner and colleagues,[9,10] reported an experimental model to control reflux using a bulk-forming agent of either bovine dermal collagen or Teflon (DuPont, Wilmington, Delaware) (PTFE resin) in the distal esophagus of dogs with surgically induced GERD. This required multiple, sometimes large-volume injections with fleeting results. Over the years, further attempts were made, but none remain on the market secondary to serious adverse events and/or lack of sustainable clinical efficacy.[11–13] These 4 products included

- Enteryx (Boston Scientific Corporation, Marlborough, MA): biopolymer of ethylene vinyl alcohol
- Gatekeeper (Medtronic Europe, Tolochenaz, Switzerland, Incorporated): hydrogel prosthesis
- Plexiglas microspheres (Artes Medical, San Diego, CA, Incorporated): polymethyl methacrylate
- Polytef (Mentor O&O, Santa Barbara, CA): polytetrafluoroethelyne

Radiofrequency Ablation

The Stretta system (Mederi Therapeutics, Norwalk, Connecticut, previously Curon Medical) was approved in April 2000 as an endoscopic procedure for treatment of GERD patients. The device uses a flexible catheter with a balloon–basket assembly fitted with needle–titanium electrodes to deliver the radiofrequency energy by way of a 4-channel generator into the esophageal wall and LES complex while irrigating the overlying mucosa to prevent thermal injury as shown in **Fig. 1**. The ablation is repeated by rotating the device and varying its linear position between 2 cm above and 2 cm below the Z-line (video: https://www.youtube.com/watch?v=lbsn7VhBJXE&feature=youtu.be). The mechanisms of action are complex and not fully understood, but involve tissue



Fig. 1. The Stretta device used for radiofrequency energy treatment of GERD. (*Courtesy of* Mederi Therapeutics Inc., Norwalk, CT; with permission. © 2015 Mederi Therapeutics Inc.)

remodeling and contraction at the LES, causing reduced compliance and tightening of the sphincter (see Fig. 1; Fig. 2).

Decreased frequency of TLESRs has also been demonstrated, likely a sequela of alterations to vagal efferent fibers, inhibiting the motor component of reflux episodes.[14–16] The Stretta procedure has been proven safe, with few adverse events being reported early, and after 2005, major adverse reactions were reported in less than 0.1% of patients.[14,17]

Review of Recent Literature

Perry and colleagues[18] performed a systematic review and meta-analysis of radiofrequency energy from 20 studies (2 randomized controls and 18 cohort studies) including 1441 patients between 2001 and 2010. Investigators found an overall decrease in heartburn symptoms in 525 patients over 24.1 months, decreased GERD health-related quality-of-life (GERD-HRQL) scores in 433 patients in 9 studies over average follow-up of 19.8 months, and improved DeMeester scores from 44.37 pre-Stretta to 28.53 post-Stretta in 267 patients evaluated over an average of 13.1 months. Average LES pressure in 263 patients over 7 studies increased from 16.54 to 20.24, with a mean follow-up of 8.7 months. Overall conclusions were that Stretta improves GERD symptoms, improves but does not normalize esophageal acid exposure, and does not significantly increase LES pressure.

In another article by Dughera and colleagues,[19] investigators reported 8-year follow-up of 26 patients (from 56 with 4-year follow-up and 86 patients originally studied). Primary outcomes were GERD-related symptoms and GERD-HQRL. Secondary outcomes were medication use, LES pressure at esophageal manometry, and esophageal acid exposure at pH-metry. There was a significant decrease in heartburn scores (6-point Likert scale), with mean decrease of 2.8 points at 4 years and 1.8 points at 8 years. GERD-HQRL scores also decreased by a mean of 14 points at 4 years and 11 points at 8 years. The median LES pressure did not show significant changes at either 4 or 8 years. Mean esophageal acid exposure time initially improved at 4 years but returned to baseline at 8 years. None of the patients at 4 or 8 years had esophagitis on esophagoscopy. After 4 and 8 years, 21 and 20 of 26 patients, respectively, were completely off PPIs, with the remainder using occasional oral antacids or PPIs. The only complication reported was a case of severe gastroparesis requiring long-term hospitalization (3 weeks); this patient reached full recovery at 8 weeks post-Stretta. Overall conclusions were that Stretta is safe, with some long-term improvement in GERD-HQRL.

SAGES (Society of American Gastrointestinal and Endoscopic Surgeons) Recommendations

"Stretta is considered appropriate therapy for patients being treated for GERD who are 18 years of age or older, who have had symptoms of heartburn, regurgitation, or

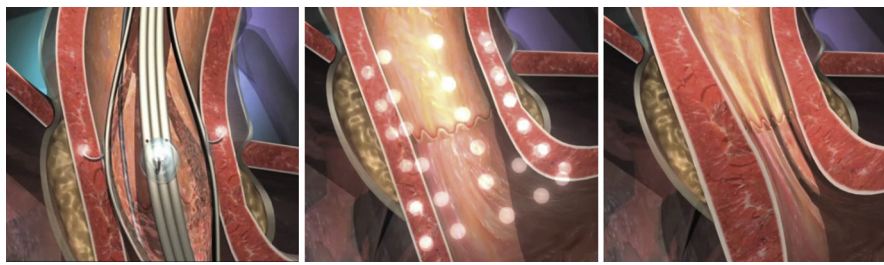


Fig. 2. Artist depiction of the mechanism of action of Stretta. (*Courtesy of* Mederi Therapeutics Inc., Norwalk, CT; with permission. © 2015 Mederi Therapeutics Inc.)

both for 6 months or more, who have been partially or completely responsive to antisecretory pharmacologic, and who have declined laparoscopic fundoplication. Quality of evidence ++++, Recommendation strong."[20]

ENDOSCOPIC TISSUE APPOSITION TECHNIQUES

Several endoscopic suturing and apposition devices have come to market. The goal of these procedures is to mechanically bolster the lower esophageal sphincter or improve the antireflux barrier by creating plication of tissue at or just below the GEJ.

Endoscopic Submucosal Suturing System

The EndoCinch (Bard Endoscopic Technologies, Murray Hill, NJ) suture system is attached to the end of a standard flexible endoscope and has a cavity into which a tissue fold can be suctioned. A T-tag secures the submucosal tissue, and the physician lowers the suturing system to the GEJ, where a series of adjacent sutures are placed below the LES. The 2 sutures are then opposed, resulting in stomach plication. The plicated tissues tighten the GEJ and LES, forming a valve to create a barrier against GERD. Additional plication may be performed below the sphincter.[21] Although it had a good safety profile, long-term efficacy was lacking, and EndoCinch is no longer manufactured.

Endoscopic Full-Thickness Plication System

The NDO Plicator (NDO Surgical, Inc., Mansfield, MA) was designed to create a transmural, full-thickness, serosa-to-serosa plication below the GEJ at the angle of His. The plication is created under direct retroflexed visualization provided by a pediatric gastroscope that is inserted through a dedicated channel of the instrument. A pretied, suture-based pledget is delivered to create the plication, which is typically placed between the anterior gastric wall and the fundus, thereby avoiding major branches of the gastric arteries and vagus nerves.[22] The procedure was relatively safe but is no longer available for commercial use.[21]

Endoluminal Fundoplication

The EsophyX device (Endogastric Solutions, Redmond, WA) enables the creation of a 270°, 2 to 3 cm esophagogastric fundoplication by using proprietary tissue-manipulating elements and a minimum of 12 full-thickness polypropylene H-fasteners in conjunction with a flexible video endoscope providing visualization throughout the procedure. The procedure is fully described Bell and Cadière,[23] and illustrations of the procedure are shown in **Figs. 3–5**.

The procedure, transoral incisionless fundoplication (TIF), attempts to mimic the effects of the laparoscopic fundoplication by elongating the intra-abdominal esophagus, reducing a small (<2–3 cm) hiatal hernia if present by positioning the distal esophagus and stomach below the diaphragm, approximating and tightening the fundus around the distal esophagus, recreating the dynamics of the angle of His, and restoring the distal high pressure zone. Manufacturers claim benefits of TIF over traditional LNF:

- TIF provides a more physiologic repair than a 360° wrap, allowing for decreased dysphagia or gas bloat after the procedure.
- No dissection is performed.
- It has a better safety profile than LNF.
- It can be revised if required.
- Comparable outcomes to LNF have been reported.[24]

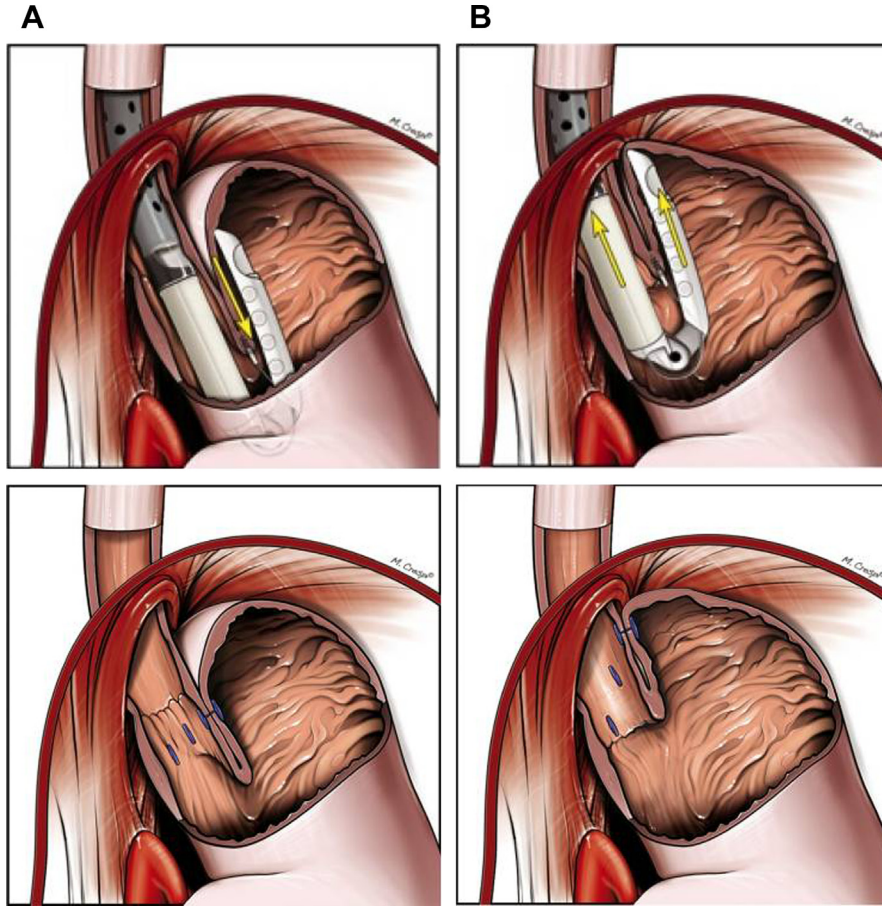


Fig. 3. Artist depiction of the EsophyX device creating the transoral incisionless fundoplication. (*A*) TIF 1 procedure with gastrogastric plications placed at the level of the Z-line. (*B*) TIF 2 technique creates an esophagogastric fundoplication proximal to the Z-line. (*From* Bell RC, Cadiere GB. Transoral rotational esophagogastric fundoplication: technical, anatomical, and safety considerations. Surg Endosc 2011;25(7):2390.)

Review of Recent Literature

In 2011, Bell and Freeman[25] retrospectively evaluated clinical and pH-metric outcomes after TIF for the treatment of GERD in 37 consecutive patients. Sixty-eight percent of patients had GERD-associated cough, asthma, or aspiration, and 32% of patients had heartburn or regurgitation. All patients remained on PPIs for 2 weeks after the procedure, then stopped administration of all antacid therapy. There were 2 complications (1 mediastinal abscess and 1 patient with postoperative bleeding). Outcomes at 6 months showed improvement in atypical symptoms in 64% of patients and typical symptoms in 70% to 80% of patients, measured by greater than or equal to 50% reduction in either GERD-HRQL or reflux symptom index (RSI), compared with baseline on PPIs. Eighty-two percent of patients were off PPIs at the 6-month interval. Of the 37 patients enrolled, 24 were evaluated endoscopically and with pH probe at 6 months. The mean esophageal acid exposure decreased from 10.4 to 5.2 and normalized in 61% of patients. Four patients had increased esophageal acid

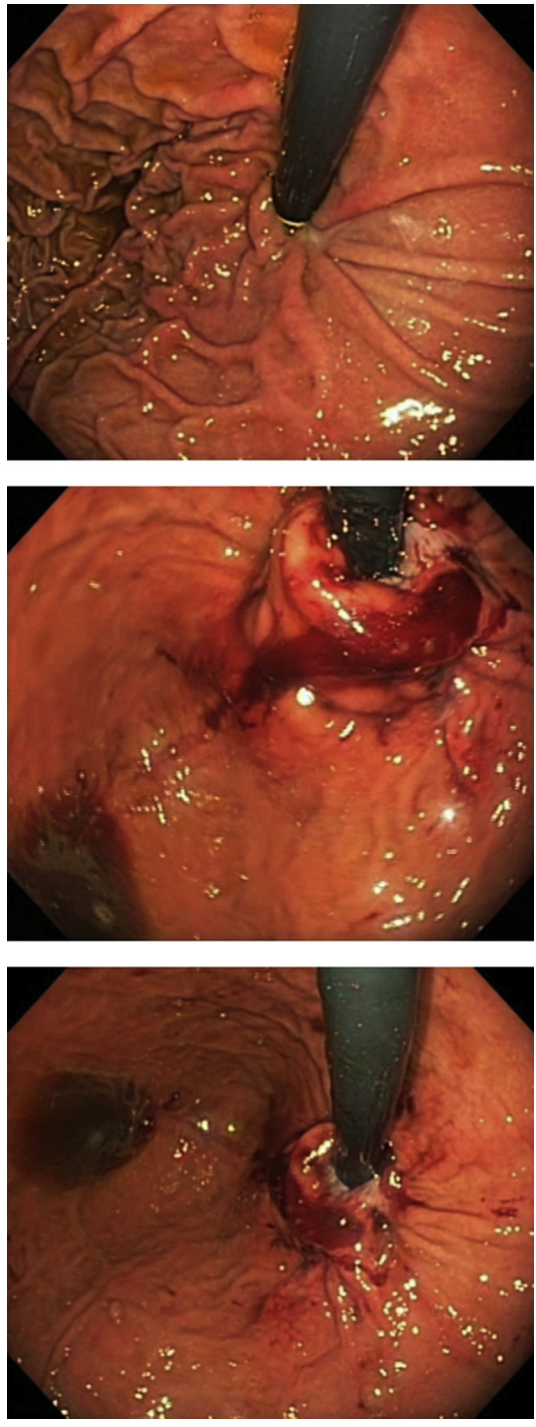


Fig. 4. Endoscopic view before TIF demonstrating a flat GE valve and after the TIF procedure demonstrating the 270° fundoplication.

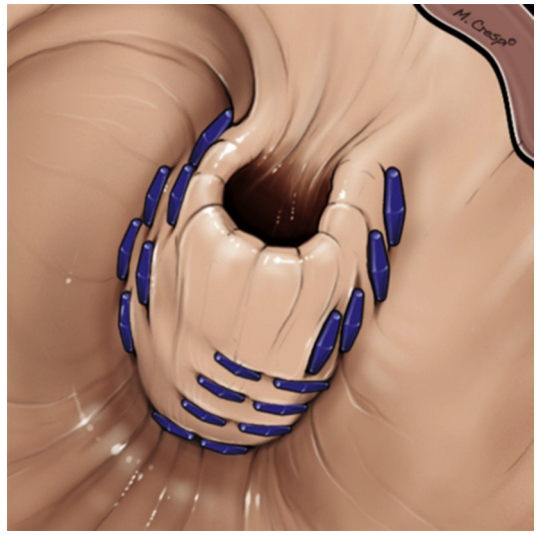


Fig. 5. Artist depiction of the plications inserted into the gastric mucosa creating the transoral incisionless fundoplication. (*Courtesy of* EndoGastric Solutions, Inc., San Mateo, CA. © 2015 EndoGastric Solutions, Inc.)

exposure. The average reflux episodes per 24-hour period decreased from 82.4 to 20.8 and normalized in 89% of patients. DeMeester scores reduced from 37.1 to 16.9 and normalized in 56% of patients.

Testoni and colleagues[26] reported on 42 patients followed at 6, 12, and 24 months after TIF. Thirty-five completed the 6 month follow-up, and 26 patients completed the 24-month follow up. At 6 months, 60% of patients were off PPIs completely, and 17% of patients were on one-half of their previous dose. At 24 months, only 42% remained off PPIs, and 27% were on one-half dose. There was no significant difference in DeMeester scores, and there were 2 complications (both pneumothoraces). Authors also found correlation between increased risk of recurrent symptoms in those with hiatal hernia and ineffective esophageal motility, and noted that a larger number of fasteners placed is predictive of positive outcomes.

In a prospective multi-institutional cohort study enrolling 100 patients from January 2010 until February 2011, Bell and colleagues[27] evaluated outcomes at 6 months. Seventy three percent of patients with typical GERD normalized their GERD-HRQL score, and 71% completely discontinued PPI usage. In atypical GERD patients, 65% experienced elimination of daily bothersome symptoms and 69% normalized their RSI scores. Eighty-two percent of atypical GERD symptom patients were able to discontinue PPIs at 6 months. Of the 35 patients with elevated percent total time of esophageal acid exposure, 28 underwent postoperative testing. A significant reduction in the mean number of refluxes, fraction of time pH less than 4 (%), and DeMeester score was demonstrated. A decreased duration of the longest reflux (55–24 minutes) was not significant. On endoscopy, 6 months after procedure, Hill grade classification of the GEJ was improved compared with baseline in 80% of patients, and hiatal hernia was either completely reduced (29 of 43 patients, 67%) or partially reduced (7 of 43 patients, 16%) in 84% (36 of 43 patients) of patients diagnosed with Hiatal hernia before the procedure.

More recently, Rinsma and colleagues[28] reported on the effects of TIF on TLESRs from the Netherlands. From 2008 to 2012, TIF was performed on 60 patients. Only

15 agreed to participate in the investigation of the effects of TIF on reflux mechanisms, focused on TLESRs and esophagogastric junction (EGJ) distensibility. Stationary esophageal manometry and impedance pH monitoring (90 min postprandial) were performed. TIF resulted in reduction of both the number of TLESRs (mean 16.8 to 9.2) and the number of TLESRs associated with liquid-containing reflux after the procedure (mean 11.1 to 5.6). Basal LES pressure in the fasted state was also increased after TIF, from mean of 13.9 to 20.5 mm Hg. As in previous studies, TIF did not significantly reduce mean esophageal acid exposure time, but analysis of 24-h impedance pH tracings showed a reduction in the number of liquid-containing reflux episodes after TIF without affecting the number of gas reflux episodes. Authors also observed a reduction in the proximal extent of reflux episodes during postprandial and ambulatory settings, leading to a significant improvement of acid exposure in the upright position but not the supine position.

In a systematic review by Welding and colleagues,[29] researchers evaluated 4 retrospective and 11 prospective studies on endoscopic fundoplication for GERD. They found that GERD-HRQL scores reduced on average from 21.9 on PPI therapy to 5.9 after TIF. RSI scores fell (in 4 retrospective studies) from 24.5 to 5.4 after TIF with a mean follow-up of 7.6 months. Cessation of PPI therapy in 14 studies yielded an overall rate of 67% at a mean follow-up of 8.3 months. pH data collected from 7 studies showed a statistically significant decrease in acid exposure, but no data demonstrated normal esophageal acid exposures. Overall complications in 559 total patients were hemorrhage (6, 1.1%), mediastinal abscess (1, 0.2%), esophageal perforation (4, 0.7%), dysphagia (3, 0.5%), and bloating (7, 1.3%). Forty patients (7.2%) failed treatment with TIF and later required Nissen fundoplication. Five patients required a redo TIF procedure, and the overall failure rate requiring reintervention was 8.1% at 9.5 months.

Trad and colleagues[30] reported on the TEMPO trial (TIF EsophyX vs Medical PPI Open label trial), a randomized clinical trial involving 63 patients at 7 US community hospitals. Forty patients were randomized to the TIF arm (performed by general surgeons in 4 centers and gastroenterologists at 3 centers), and 23 were randomized to the PPI arm (maximum standard dose) using a 2 to 1 ratio. Three patients were lost to follow-up at 6 months, leaving 39 in the TIF arm and 21 in the PPI arm. Primary outcomes were measured by GERD-HRQL, RSI, and RDQ (reflux disease questionnaire) instruments. Troublesome regurgitation was eliminated in 97% of patients in the TIF group versus 50% of patients in the PPI group. GERD-HQRL scores decreased from 19 to 2 on average in the TIF group and from 17 to 11 in the PPI group. Secondary outcomes were measured by normalization of esophageal acid exposure, PPI usage, and healing of esophagitis. At 6 months, 90% of patients were off PPIs. Fifty-four percent of TIF patients had normalized esophageal acid exposure, compared with 52% of patients on maximum-dose PPIs. There was also complete healing of esophagitis in 90% of TIF patients compared with 38% in the PPI group. TIF had significant improvement in 48-hour pH parameters but did not reach levels of pH normalization reported after laparoscopic fundoplication. The authors concluded that TIF was more effective than PPIs in elimination of troublesome regurgitation and that TIF was equivalent to PPIs in normalizing distal esophageal acid exposures (EAEs).

Sufficient long-term data are lacking, but Muls and colleagues[31] reported results from a multicenter prospective study enrolling 86 patients, with 66 available for 3-year follow-up. Twelve of those patients underwent repeat operation (2 laparoscopic fundoplication, 10 TIF) for treatment failure. Compared with median and mean scores at baseline off PPIs, they demonstrated clinically significant improvement in GERD-HRQL scores in 80% of patients at 3 years. Patient satisfaction was maintained at

Table 1
Summary of studies

Author	Study Type	Symptom Improvement	Esophageal Studies	PPI Use	Complications
Bell and Cadière,[23] 2011	Retrospective 37 patients 6 mo follow-up	Improved atypical symptoms in 64% and typical symptoms: 70%–80% (improved = >50% reduction in RSI or GERD-HRQL score)	Mean EAE (% time pH<4) decreased from 10.4 to 5.2 and normalized in 61% patients Average reflux episodes/24-h decline from 82.4 to 20.8 & normalized in 89% of patients DeMeester scores reduced from 37.1 to 16.9 & normalized in 56% of patients	82% off PPI @ 6 mo	Mediastinal abscess (1) Postoperative bleeding (1)
Testoni et al,[26] 2012	Prospective cohort 42 patients 35 at 6 mo 26 at 24 mo 6 & 24 mo follow-up	Improved mean GERD-HRQL scores from 22 pre-TIF on PPIs to 15 at 6 mo 18 at 24 mo off PPI therapy	Improved Hill grade at 6, 12 and 24 mo compared with before TIF	At 6 mo: 60% off PPIs 17% on half-dose PPI At 24 mo: 42% off PPIs 26.9% on half-dose PPI 30.8% on same dose as pre-procedure	Pneumothorax (2) 4 patients unresponsive to TIF underwent LNF
Bell et al,[27] 2012	Multi-institutional cohort 100 patients 6 mo follow-up	73% normalized GERD-HRQL scores 69% normalized RSI scores	Of 35 patients with elevated EAE, 28 underwent postoperative testing and demonstrated a significant reduction in mean number of refluxes, fraction of time pH<4, and DeMeester scores Hiatal hernia completely reduced in 29/43 patients and partially reduced in 7/43 patients	At 6 mo: 71% total off PPI (82% of atypical GERD patients off PPI)	No serious adverse reactions Nausea, pain, and anxiety in 12% of patients requiring prolonged stay Urinary retention in 1 patient

Rinsma et al,[28] 2013	Prospective cohort 60 patients (15 underwent post-TIF endoscopic evaluation) 6 mo follow-up	80% normalized GERD-HRQL scores mean GERD-HQRL score reduced from 27.5 to 13.2	Reduction in: Number of TLESRs from (mean 16.8 to 9.2) Number of TLESRs associated with liquid containing reflux (mean 11.1 to 5.6) Increased basal LES in fasting state (mean 13.9–20.5 mm Hg) No significant decrease in mean EAE	At 6 mo 67% off PPI 1/15 patients used antacids daily for mild symptoms 27% (4/15) continued daily PPI 3/15 were at lower doses	None reported
Wendling et al,[29] 2013	Systematic review 563 patients Mean follow-up 9.5 mo	Overall decrease in mean GERD-HRQL compared with baseline on PPIs (decreased 21.9 to 5.9) Overall decrease in RSI score from 24.5 to 5.4 after TIF at average follow-up of 7.6 mo	Significant improvement in DeMeester scores in 3 of 4 studies None demonstrated normal post-procedure esophageal acid exposures or mean esophageal acid exposure time	Overall rate of PPI discontinuation was 67% at mean follow-up of 8.3 mo	Overall major complication rate 3.2% Hemorrhage in 6 patients Mediastinal abscess in 1 patient Esophageal perforation in 4 patients Overall patient failure 7.2%

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Table 1
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Author	Study Type	Symptom Improvement	Esophageal Studies	PPI Use	Complications
Trad et al,[30] 2015	RCT 63 patients 6 mo follow-up	Regurgitation eliminated in 97% TIF patients vs 50%PPI patients GERD-HRQL scores decreased from a mean of 19 to 2 in TIF patients vs 17 to 11 in PPI group	54% TIF patients had normalized EAEs 52% PPI patients had normalized EAEs Complete healing in esophagitis in 90% TIF patients vs 52% of patients on max PPI	90% TIF patients off PPI at 6 mo	No serious adverse events reported
Muls et al,[31] 2013	Multicenter prospective study 86 patients 66 @ 3-y follow-up	Improved GERD-HRQL scores in 80% of patients at 3 y. Patient satisfaction 70% at 3 y post-TIF vs 36% on PPI therapy alone	Esophagitis reduced from 78% to 38% at 3 y with complete resolution in 62% of patients Of 11 patients who underwent pH testing at 3 y, 9 demonstrated normalized pH (% time pH<4); the other 2 underwent a revisional procedure	86% off daily PPI at 1 y 74% off daily PPI at 3 y	12 patients underwent repeat operation (2 LNF, 10 repeat TIF) for treatment failure

Data from Refs.[23,26–31]

70% after 3 years compared with 36% on PPI therapy at baseline. Discontinuation of daily PPI use was maintained in 74% of patients at 3 years compared with 86% at 1 year. Overall esophagitis was reduced from 78% to 38% at 3 years, with complete resolution in 62% of those patients.

Data from recently reviewed articles are summarized in **Table 1**.

SAGES Recommendations

"Long term data is not yet available for EsophyX. In short-term follow-up, from 6 months to 2-years, EsophyX may be effective in patients with a hiatal hernia <2 cm with typical and atypical GERD. Further studies are required to define optimal techniques and most appropriate patient selection criteria, and to further evaluate device and technique safety. Quality of evidence (++), Grade recommendation: weak."[20]

DISCUSSION

The evolution of GERD treatment over the last 40 years has seen many therapeutic options come and go. From H2 blockers and PPIs, to the current surgical and endoscopic procedures, physicians have a variety of tools to attain symptom control of a life-changing disease. Despite recent advances, however, there is not a treatment with sustained efficacy and minimal risk. Endoscopic approaches including implants and injectables used as bulking agents have come and gone, while simple suturing or plicating techniques along with radiofrequency ablation have lacked sustainable efficacy. The EsophyX, which attempts to mimic LNF, has shown the most promise, reducing or eliminating need for antacid therapy, improving symptom control, and decreasing the number of TLESRs. Despite symptom improvement, trials have failed to show significant reduction of esophageal acid exposure, leaving laparoscopic Nissen fundoplication as the gold standard for management of refractory GERD. Other limitations of endoscopic therapies are the restrictive criteria, which exclude patients with hiatal hernias greater than 2 or 3 cm, significant pulmonary disease, Barrett esophagus, and moderate-to-severe esophageal dysmotility disorders. While data on endoscopic therapies slowly accumulates, proceduralists are improving their techniques, and devices are undergoing revisions to attempt the recreation of physiologic lower esophageal barrier in the management of GERD. While in this interim, TIF and Stretta both appear to be safe and have at least short term evidence to support use in patients refractory to medical therapy unwilling or unable to undergo LNF.[32,33]

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