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Endoscopic full-thickness plication for the treatment of gastroesophageal reflux disease using multiple Plicator implants: 12-month multicenter study results

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Abstract
Background The full-thickness Plicator® (Ethicon Endosurgery, Sommerville, NJ, USA) was developed for endoscopic treatment of gastroesophageal reflux disease (GERD). The goal is to restructure the antireflux barrier by delivering transmural pledgeted sutures through the gastric cardia. To date, studies using this device have involved the placement of a single suture to create the plication. The purpose of this study was to evaluate the 12-month safety and efficacy of this procedure using multiple implants to restructure the gastroesophageal (GE) junction.
Methods A multicenter, prospective, open-label trial was conducted at four tertiary centers. Eligibility criteria included symptomatic GERD [GERD Health-Related Quality-of-Life (GERD-HRQL) questionnaire, off of medication], and pathologic reflux (abnormal 24-h pH) requiring daily proton pump inhibitor therapy. Patients with Barrett's epithelium, esophageal dysmotility, hiatal hernia >3 cm, and esophagitis (grade III or greater) were excluded. All patients underwent endoscopic full-thickness plication with linear placement of at least two transmural pledgeted sutures in the anterior gastric cardia.
Results Forty-one patients were treated. Twelve months post treatment, 74% of patients demonstrated improvement in GERD-HRQL scores by ≥50%, with mean decrease of 17.6 points compared with baseline (7.8 vs. 25.4, $p < 0.001$). Using an intention-to-treat model, 63% of patients had symptomatic improvements of ≥50%, with mean GERD-HRQL decrease of 15.0 (11.0 vs. 26.0, $p < 0.001$). The need for daily proton pump inhibitor (PPI) therapy was eliminated in 69% of patients at 12 months on a per-protocol basis, and 59% on an intention-to-treat basis. Adverse events included postprocedure abdominal pain (44%), shoulder pain (24%), and chest pain (17%). No long-term adverse events occurred.
Conclusions Endoscopic full-thickness plication using multiple Plicator implants can be used safely and effectively to improve GERD symptoms and reduce medication use.

Keywords Digestive · GORD/GERD (Gastro-oesophageal reflux disease) · Hernia · Barrett-s oesophagus, oesophageal · Therapeutic/palliation, endoscopy · Endoscopic reflux therapy

Gastroesophageal reflux disease (GERD) is a common and chronic condition that can substantially reduce quality of life among sufferers [1–3]. Patients with GERD are at risk for the development of Barrett's metaplasia or eventual adenocarcinoma [4, 5]. Long-term acid suppression using

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proton pump inhibitors (PPIs) is effective in the majority of GERD sufferers [6–8]. Nonetheless, many patients seek alternatives to pharmacological treatment due to incomplete symptom resolution or medication side-effects [9–11]. Surgical fundoplication is a highly effective option in appropriately selected patients [12–16], but is associated with operative morbidity and significant postoperative side-effects in some patients [17–19].

Recently, a variety of endoluminal procedures have been developed in an effort to treat GERD symptoms and reduce or eliminate the use of antisecretory medication [20–38]. One procedure involves the delivery of a transmural suture in the anterior gastric cardia to create a full-thickness tissue plication to recreate the valvular mechanism of the gastroesophageal (GE) junction (Plicator®; former distributor NDO Surgical, Inc., Mansfield, MA, USA; current product of Ethicon Endosurgery, Sommerville, NJ, USA). The Plicator procedure has been shown to significantly reduce GERD symptoms, medication use, and distal esophageal acid exposure in both prospective open-label and randomized controlled trials [39, 40]. Three- and 5-year durability of the treatment effect (sustained symptom relief and medication use reduction) has also been demonstrated in a multicenter study wherein a single Plicator suture was applied [40, 41].

Although the single-implant technique has yielded favorable clinical outcomes, the ability to place multiple sutures would allow clinicians to treat a broader range of patients with variable anatomy. The purpose of this study was to evaluate the 12-month therapeutic effect of placing multiple de novo transmural sutures with the Plicator for the treatment of patients with symptomatic GERD.

Patients and methods

Study design

A prospective, multicenter, open-label trial was conducted following ethics committee approval at four tertiary referral centers in Germany. The primary study objective was to determine the safety and efficacy of the Plicator procedure for the treatment of symptomatic GERD by delivering multiple sutures to restructure the antireflux barrier. Primary 12-month efficacy was determined through analysis of the validated GERD Health-Related Quality-of-Life (HRQL) questionnaire. Patients achieving $\geq$50% improvement in their GERD-HRQL score at 12 months compared with baseline were considered responsive to treatment. Secondary 12-month efficacy outcomes were GERD medication use, and heartburn/regurgitation visual analog scale (VAS) scores. Trial sample size was calculated to yield 87% power in detecting a 50% mean reduction in GERD-HRQL scores with an α of 0.05.

Study eligibility

Patients with a history of heartburn or regurgitation requiring daily PPI therapy were eligible. Additionally, patients had to meet the following criteria: GERD-HRQL score $\geq$15 off of PPI therapy and an increase of at least six points compared with scores on medication; distal esophageal acid exposure pH <4.0, $\geq$4.5% for a 24- or 48-h monitoring period, or DeMeester score $\geq$14.7; lower esophageal resting pressure $\geq$5 mmHg; American Society of Anesthesiologists physical status classification I or II; and age $\geq$18 years.

Exclusion criteria were: esophagitis grade III or IV (Savary–Miller), Barrett's epithelium; hiatal hernia >3 cm; persistent dysphagia; esophageal bleeding; chronic vomiting; severe bloating; esophageal or gastric varices; esophageal stricture; long-term use of anticoagulants (other than for cardiac prophylaxis); previous endoscopic or surgical antireflux procedure and pregnancy. All study participants provided written informed consent.

Baseline assessment and follow-up

During baseline evaluations, patients completed four sets of questionnaires while on their maintenance daily PPI therapy regimen. The GERD-HRQL assessed heartburn severity and the impact of GERD-specific symptoms on patient quality of life using a 45-point scale (0 = no symptoms, 45 = symptoms incapacitating). A 100-point visual analog scale (VAS) questionnaire was administered to measure patient discomfort during heartburn episodes (0 = no discomfort, 100 = extreme discomfort). Additionally, heartburn- and regurgitation-specific symptoms were assessed using separate four-point scales (0 = no symptoms, 1 = occasional symptoms, 2 = frequent symptoms, 3 = daily symptoms). Each of these four questionnaires was readministered after patients had discontinued their GERD medication [7 days for PPIs; 24 h for histamine-2 receptor antagonists (H2RAs) and antacids]. Baseline upper endoscopy was performed to determine hiatal hernia size and presence of mucosal abnormalities. Ambulatory pH studies and esophageal manometry were also conducted for patients who had not undergone these tests within the previous 6 months.

Patients were reevaluated at 1, 6, and 12 months post procedure by completing the GERD-HRQL, VAS, heartburn, and regurgitation questionnaires, each administered upon discontinuation of any GERD medications [7 days for PPIs; 24 h for histamine-2 receptor antagonists (H2RAs) and antacids]. At each follow-up interval, the use of any GERD medications (type, dose, frequency) was documented. Repeat endoscopy was performed at 6 months to determine posttreatment esophagitis grade and to evaluate the integrity of the tissue plication at the GE junction.

Table 1 Study design

	Pre procedure		Plicator treatment	Post procedure		
	On meds	Off meds		1 month	6 months	12 months
Patient history/consent	✔					
Questionnaires:	✔	✔		✔	✔	✔
GERD-HRQL						
VAS						
Heartburn score						
Regurgitation score						
GERD medication status	✔			✔	✔	✔
GERD medications discontinued		✔		✔	✔	✔
Esophageal pH/manometry		✔			✔	
EGD			✔		✔	

Esophageal pH and manometry studies were also performed at 6 months. A study design summary is shown in Table 1.

Intervention

All procedures were performed under intravenous propofol and midazolam sedation with continuous monitoring of vital signs [blood pressure, electrocardiograph (ECG) and SO_2]. Before endoscopic full-thickness plication, 0.5 mg atropine was administered subcutaneously, and antibiotic prophylaxis with 2 g ceftriaxone was provided. Esophagogastroduodenoscopy (EGD) was performed using a 5.8-mm video-endoscope, and a Savary guidewire was placed upon endoscope withdrawal. The Plicator (45-Fr insertion tube diameter) (Fig. 1) was advanced directly over the guidewire into the stomach. The 5.8-mm video-endoscope was inserted through the Plicator scope channel and the stomach was distended with air. Under direct endoscopic visualization, the Plicator distal end was retroflexed to the GE junction. The Plicator arms were opened and the endoscopic tissue retractor was advanced into the anterior gastric cardia, approximately 1 cm below the GE junction. With the cardia engaged, the endoscopic tissue retractor was pulled back to gather the tissue between the Plicator arms. Excess air in the stomach was evacuated. The Plicator arms were then closed and a pre-tied, pledgeted suture was deployed transmurally through the gastric cardia (Fig. 2). The Plicator and gastroscope were removed and the gastroscope was reintroduced to evaluate the resulting plication. One or two additional transmural sutures were placed for maximum restructuring of the antireflux barrier (Fig. 3). Additional sutures were placed incrementally closer to the GE junction in a longitudinal fashion along the anterior gastric cardia. For this protocol, all plications were placed de novo, and retreatment was not permitted.

Following the procedure, patients were instructed to continue their baseline PPI dose for 2 days, and then to halve their dose for the next 5 days. All heartburn medications were discontinued on the 8th day following the plication procedure. Thereafter, patients experiencing GERD symptom recurrence were provided with antacid rescue medication. If antacid rescue medication failed to provide adequate symptom relief over a minimum 7-day period, patients were treated with H2RA medication. If symptom recurrence persisted for an additional week, patients were instructed to resume PPI therapy.

Fig. 1 The Plicator system

Statistical analysis

Primary efficacy was based on results of the GERD-HRQL questionnaire. Percentage improvement at each follow-up was compared with the corresponding pretreatment score.

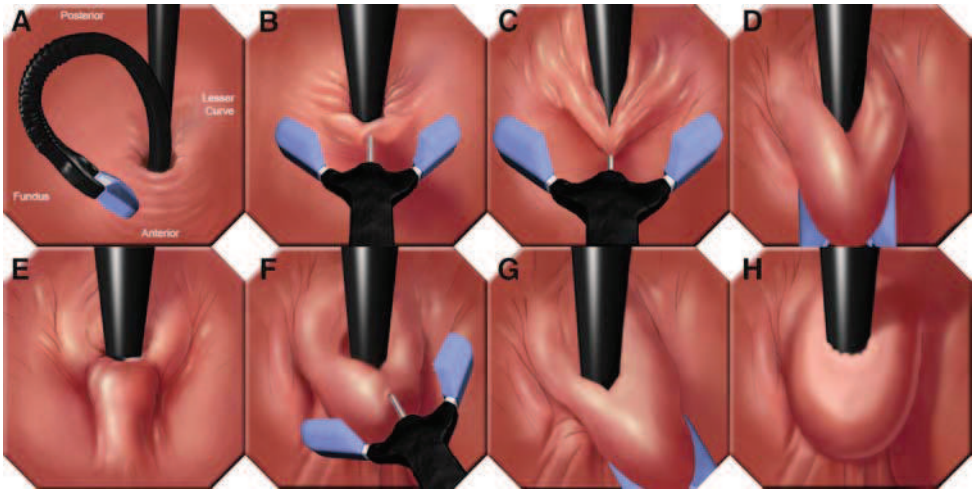

Fig. 2 Endoscopic full-thickness plication utilizing two implants. **A** Plicator and gastroscope retroflexed to gastroesophageal junction (GEJ) in anterior position. **B** Plicator arms are opened, tissue retractor is advanced to serosa. **C** Gastric wall is retracted into the Plicator arms. **D** The first, pre-tied implant is deployed. **E** Full-thickness serosa-to-serosa plication after the first implant is restructuring the GE junction. **F** For serial plication, the instrument arms are opened and the tissue retractor is again advanced to serosa. **G** Gastric wall is again retracted into the Plicator arms and the second suture deployed. **H** The serial plication technique restructures antireflux barrier

Data were analyzed using the Wilcoxon signed-rank test and a one-sided 95% confidence interval. The null hypothesis stated that the mean percentage reduction in GERD-HRQL score was less than or equal to 50%. The Plicator treatment was considered a success if the statistical test rejected the null hypothesis with a one-sided p-value of 0.05 or less. Primary outcome success was thus related to the statistical conclusion that the mean percentage reduction in GERD-HRQL score was greater than 50%. Secondary outcomes were analyzed using the Wilcoxon signed-rank test of the percentage improvement in a given outcome based on paired patient data of pretreatment versus posttreatment values. Outcomes were analyzed based on both per-protocol and intention-to-treat groups. The intention-to-treat analysis considered patients with missing data values as treatment failures. Adverse events were collected throughout the course of the study and were categorized by preferred term according to the MedDRA 7.0 coding system. Processing and analysis of study data was provided by QST Consultations, Ltd. (Allendale, MI).

Results

Forty-one patients underwent the Plicator procedure with placement of multiple transmural sutures at the GE junction (Table 2). A total of 33 patients (80%) received two sutures, and 8 patients (20%) received three sutures. Sutures were placed in a linear fashion along the anterior gastric cardia until a tight closure of the GE junction around the 5.8-mm video endoscope was achieved. The average procedure time, defined as the time from initial insertion of the Plicator instrument to final instrument withdrawal, was 27.5 ± 12.3 min.

A total of 35 patients completed the 12-month follow-up, with missing data values for questionnaires analyzed on an intention-to-treat basis. Two of the patients who did not complete their 12-month follow-up elected to undergo laparoscopic Nissen fundoplication surgery after their 6-month study visit. In both patients, the surgery was performed without incident.

Symptoms

Based on a per-protocol analysis, 74% (26/35) of patients achieved a minimum 50% reduction in their baseline GERD-HRQL score at 12 months post procedure, and were therefore considered responsive to treatment. On an intention-to-treat basis, 63% (26/41) of patients met these criteria. Mean 12-month GERD-HRQL scores improved significantly compared with off-PPI baseline (11.0 versus 26.0, $p < 0.001$) (Table 3) and were also statistically superior when compared with on-PPI baseline scores (8.3 versus 11.4, $p = 0.015$). At 12 months post procedure, 27/41 (66%) of patients demonstrated GERD-HRQL score $\leq$12.0.

Mean heartburn episode symptom severity assessed using a 100-point visual analog scale (VAS) showed a significant improvement at 12-months versus off-medication baseline (24.9 versus 82.8, $p < 0.001$) on a per-protocol basis and (33.0 versus 82.4, $p < 0.001$) on an intention-to-treat basis (Table 3). There were no differences between mean 12-month VAS scores and on-PPI baseline scores (24.8 versus 27.4, $p =$ ns). Mean heartburn symptom scores improved significantly at 12 months

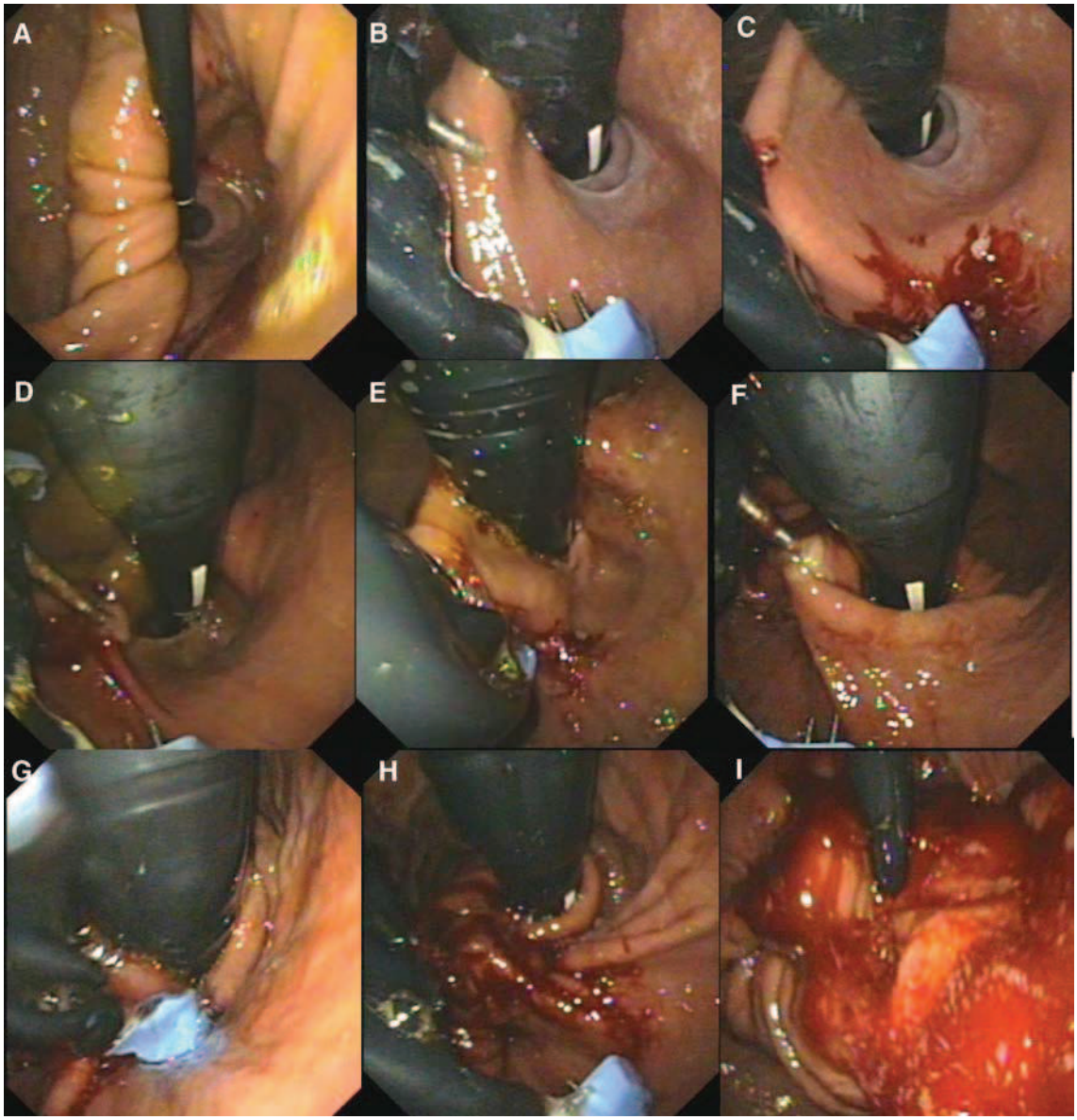

Fig. 3 Endoscopic full-thickness plication and hernia repair utilizing three implants. **A** Endoscopic view before plication. **B** Retractor placement before deployment of the first suture. **C** Retraction of tissue into the Plicator arms and deployment of the first suture. **D**, **E** Retractor placement and deployment of the second suture. **F**, **G** Retraction of tissue into the Plicator arms and deployment of the third suture. **H** Restructured GE-junction directly after deployment of the third suture. **I** Endoscopic view showing a tight remodeled GE junction around a 5.8-mm video-endoscope

compared with off-medication baseline (1.0 versus 2.7, $p < 0.001$), with 83% (29/35) of patients reporting less frequent heartburn symptoms (71% on an intent-to-treat basis). Mean 12-month regurgitation scores improved significantly compared with both off- medication baseline (0.9 versus 2.5, $p < 0.001$) as well as on-PPI baseline (0.8 versus 2.5, $p = 0.008$). Additionally, 86% (30/35) of patients reported less frequent regurgitation at 12 months compared with their off-medication baseline (73% on an intention-to-treat basis).

GERD medication use

Per study entry criteria, all patients undergoing the Plicator procedure were dependent on daily PPI therapy at baseline. At 12 months post treatment, 69% (24/35) of patients had eliminated their daily PPI dependency. Using intention-to-treat analysis [missing patients ($n = 6$) were considered to be medication use failures], 59% (24/41) of patients had eliminated their daily PPI dependency (Table 4).

Table 2 Baseline patient characteristics

Age (years), mean ± SD	49.80 ± 10.23
Weight (kg), mean ± SD	85.19 ± 13.64
Gender	
Male, *n* (%)	24 (59%)
Female, *n* (%)	17 (41%)
GERD symptom duration	
>2 years, *n* (%)	37 (90%)
6 months to 2 years, *n* (%)	3 (7%)
Daily PPI use, *n* (%)	41 (100%)

SD standard deviation

Extra-esophageal symptoms

Patients reported extra-esophageal symptoms at baseline and again 12 months post procedure. At 12 months post treatment patients reported improvement in cough, hoarseness, chest-pain, dysphagia, belching, nausea, vomiting, asthma, and persistent bad breath (Table 5).

Patient satisfaction

At baseline 12% of patients off of GERD medications and 59% on medication were satisfied with their GERD symptom control. At 12 months post treatment, 71% of patients reported satisfaction with their GERD symptom control.

Safety

As reported previously, all procedure-related adverse events occurred within the first postprocedure week except one [39]. A single patient reported ongoing shoulder pain 6 months post procedure, which persisted at 12-month follow-up. The pain was determined not to be related to the procedure, and the patient was referred to an orthopedist for further treatment. There were no late-onset device-related adverse events at 12-month follow-up.

Discussion

GERD treatment goals are to control symptoms, heal the injured esophageal mucosa, and prevent complications. Therapy with either daily medications or surgical fundoplication, though highly effective for the majority of patients, is not without long-term shortcomings. The development of endoscopic antireflux therapies has been fueled by the hope of providing safe, effective, long-term symptomatic relief [35–38, 42–44]. Although it is appropriate to reflect that the development of endoscopic GERD treatment techniques has led to several failures along the way, the ambition of finding a successful minimally invasive endoscopic GERD treatment remains reasonable.

A previous randomized controlled trial has shown endoscopic full-thickness plication to be significantly better compared with sham treatment for control of GERD symptoms, antisecretory medication use, and distal esophageal acid exposure [39]. Three- and 5-year durability of the pledgeted sutures and the treatment effect (sustained symptom relief and decreased medication use) has been demonstrated in previous studies [40, 41].

Due to variability in patient anatomy, and especially in the setting of hiatal hernias, the GE junction can remain patulous if a single implant is utilized. Therefore, we hypothesized that use of multiple Plicator implants might lead to improved restructuring of the GE junction. Using multiple implants patients with hiatal hernias up to 3 cm can be treated with success [45, 46]. Hiatal defect repair is routinely performed during surgery [25, 47]. This contributes to restoring the antireflux barrier, stabilizes the antireflux wrap into the abdominal cavity, and is considered as an important component of surgical therapy in its ability to provide sustained, long-term efficacy. Thus, it seems necessary to compare the long-term durability of the endoscopically achieved hernia repair with surgery in randomized controlled trials.

The presented data shows a sustained treatment effect with regards to medication use, GERD-HRQL, and VAS scores compared with the previously published 6-month data [46]. In addition, treatment effect, evidenced by the proportion of patients (89%) who eliminated daily PPI therapy at 6 months ($n = 27$) and remained off daily PPI therapy at 12 months ($n = 24$), was sustained. This treatment effect after 12 months in the study at hand, in conjunction with the previously reported 5-year follow-up of single-implant trials [39, 40], fuels the hope that through endoscopic transmural suturing sustained long-term efficacy can be achieved in about 70% of patients.

The multiple-implant technique has shown significant improvement in reflux symptoms, esophagitis, medication use, and esophageal acid exposure at 6 months post treatment in two uncontrolled trials [45, 46]. Long-term data demonstrating significant improvement in acid suppression are, however, rather limited. Therefore, an endoluminal approach might be considered for selected patients at present. Endoluminal therapy may prove to be an effective bridge between medical therapy and surgery, providing a durable barrier to reflux in a subgroup of GERD patients not yet ready for an operation [48]. In this study, two patients underwent successful Nissen fundoplication at least 6 months post plication. Accordingly, endoscopic full-thickness plication does not preclude surgical treatment alternatives and might offer a minimally invasive first approach in patients with unsatisfactory PPI symptom control.

Table 3 GERD symptoms

(Per protocol)	Baseline on med	Baseline off med	12 months post treatment	Reduction from baseline off med at 12 months
GERD-HRQL score				
Mean ± SD	11.4 ± 5.59	25.4 ± 6.9	7.8 ± 7.5	17.6 ± 9.53
Median	11	25	8	17
95% CI[a]	(8.0, 14.0)	(22.0, 27.0)	(2.0, 10.0)	(14.3, 20.8)
p-Value[b]				<0.001
VAS score				
Mean ± SD	27.9 ± 22.39	82.8 ± 15.78	24.9 ± 25.23	57.9 ± 31.28
Median	27	84	19	68
95% CI[a]	(20.2, 35.6)	(77.4, 88.2)	(16.2, 33.6)	(47.2, 68.7)
p-Value[b]				<0.001
Heartburn score				
Mean ± SD	1.3 ± 0.83	2.7 ± 0.58	1.0 ± 0.8	1.7 ± 0.99
Median	1	3	1	2
95% CI[c]	(1.0, 2.0)	(3.0, 3.0)	(1.0, 1.0)	(1.0, 2.0)
p-Value[d]				<0.001
Regurgitation score				
Mean ± SD	1.3 ± 0.80	2.5 ± 0.85	0.9 ± 0.91	1.6 ± 1.22
Median	1	3	1	2
95% CI[c]	(1.0, 2.0)	(2.0, 3.0)	(0.0, 1.0)	(1.0, 2.0)
p-Value[d]				<0.001
(Intent-to-treat)	Baseline on med	Baseline off med	12 months post treatment	Reduction from baseline off med at 12 months
GERD-HRQL score				
Mean ± SD	11.4 ± 5.45	26.0 ± 7.10	11.0 ± 10.80	15.0 ± 10.81
Median	11	25	9	16
95% CI[a]	(9.7, 13.1)	(23.8, 28.3)	(7.6, 14.4)	(11.6, 18.4)
p-Value[b]				<0.001
VAS score				
Mean ± SD	27.4 ± 21.57	82.4 ± 14.88	33.0 ± 30.68	49.5 ± 35.52
Median	27	84	22	58
95% CI[a]	(20.6, 34.2)	(77.7, 87.1)	(23.3, 42.7)	(38.3, 60.7)
p-Value[b]				<0.001
Heartburn score				
Mean ± SD	1.3 ± 0.88	2.7 ± 0.55	1.3 ± 1.03	1.4 ± 1.10
Median	1	3	1	2
95% CI[c]	(1.0, 2.0)	(3.0, 3.0)	(1.0, 10.)	(1.0, 2.0)
p-Value[d]				<0.001
Regurgitation score				
Mean ± SD	1.2 ± 0.83	2.5 ± 0.84	1.1 ± 1.07	1.4 ± 1.26
Median	1	3	1	2
95% CI[c]	(1.0, 2.0)	(2.0, 3.0)	(1.0, 1.0)	(1.0, 2.0)
p-Value[d]				<0.001

SD standard deviation, *CI* confidence interval

[a] CI are two-sided

[b] *p*-Value from a one-sample *t*-test

[c] CI are two-sided

[d] *p*-Value from a Wilcoxon signed-rank test

Table 4 Medication use

Medication type	Baseline daily medication use		Per-protocol follow-up medication use at 12 months ($N = 35$)				
	($N = 35$)	($N = 35$)	PPI	H2RA	Antacid	Non-daily med use	None
PPI	35 (100%)	35 (100%)	11 (31%)	0 (0%)	2 (6%)	6 (17%)	16 (46%)
Medication type	Baseline daily medication use		Intent-to-treat follow-up medication use at 12 months ($N = 41$)				
	($N = 41$)	($N = 41$)	PPI	H2RA	Antacid	Non-daily med use	None
PPI	41 (100%)	41 (100%)	17 (41%)	0 (0%)	2 (5%)	6 (15%)	16 (39%)

Table 5 Extra-esophageal symptoms

Symptoms	Baseline (%)	12 months post treatment (%)
Coughing	37	17
Hoarseness	37	17
Chest pain	37	17
Dysphagia	10	3
Belching	49	34
Nausea	22	9
Vomiting	15	0
Asthma	15	3
Persistent bad breath	20	3

In the presented study, it is evident that a significant proportion of patients were only partial responders to PPI therapy by the fact that: postplication HRQL scores were statistically improved versus on-medication baseline scores. In addition, postplication regurgitation scores were statistically improved compared with on-medication baseline scores, and two patients went on to have Nissen fundoplication surgery even though they were taking the same PPI dose at 6 months that they were taking pre plication.

A previous study has shown that patients with a positive symptom index resistant to PPIs with nonacid or acid reflux demonstrated by multichannel intraluminal impedance monitoring (MII) seem good candidates for laparoscopic Nissen fundoplication [49]. Additional data comparing endoscopic full-thickness plication to medical therapy and surgery are desirable to gain additional information on the Plicator's role as a therapeutic alternative for symptomatic non-acid-reflux patients.

Endoscopic full-thickness plication utilizing multiple transmural sutures appears to be largely free of major complications. No new adverse events were encountered during the 12-month follow-up of this study. The majority of adverse events regarding endoscopic full-thickness plication were mild and resolved spontaneously. Given the lack of a second treatment arm utilizing a single implant, no direct comparison can be drawn from this study.

In addition to GERD treatment, the Plicator device can be used for endoluminal suturing of gastrointestinal (GI) wall perforations or for natural orifice transluminal endoscopic surgery (NOTES) gastrotomy closure [50–54]. A recent study evaluating the Plicator with modified pledgets and resorbable sutures demonstrated successful and reliable NOTES gastrotomy closure in an animal survival trial [55]. Because the device enables rapid and easy placement of leakproof transmural sutures with serosal apposition, the device seems suitable for closure of GI wall defects or NOTES gastrotomy. For reliable NOTES gastrotomy or perforation closure, a transmural suturing device enabling serosal apposition is of fundamental importance to achieve reliable closure strength [51–57].

In conclusion, endoscopic full-thickness plication using serially placed Plicator implants is safe and effective in reducing GERD symptoms, medication use, and esophageal acid exposure at 12 months post treatment. Endoscopic full-thickness plication offers a minimally invasive therapeutic alternative for GERD patients with hiatal hernias up to 3 cm who are poorly controlled on antisecretory medications or in whom lifelong PPI therapy is not an option. The long-term durability of the endoscopically restructured GE junction and the long-term effects on esophagitis and pH-metry should be compared with surgical therapy. These data are necessary to define the value of the Plicator compared with established GERD therapies.

Conflict of interest statement The authors Daniel von Renteln, Ingolf Schiefke, Karl-Hermann Fuchs, Susanne Raczynski, Michael Philipper, Wolfram Breithaupt, and Horst Neuhaus declare that they have no conflict of interest including any financial interest in the product being discussed.

Karel Caca declares that he has served in the capacity as a member of the NDO Surgical, Inc. Medical Advisory Board from October 3, 2006, to October 3, 2007 and has received honoraria for speaking and training. Research funding was granted by NDO Surgical, Inc, Mansfield, MA. Research funding contained material support (Plicator device and sutures), financing of the Plicator procedures, and costs for data processing and statistical analysis by QST Consultations, Ltd. (Allendale, MI).

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