



# Comparison of the outcome of laparoscopic procedures for GERD

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## Abstract

A total laparoscopic fundoplication has become the procedure of choice for the surgical treatment of gastroesophageal reflux disease in patients with normal esophageal motility, with reduced postoperative pain, faster recovery and similar long-term outcomes compared to conventional open total fundoplication. Most controversial surgical aspects are the division of the short gastric vessels and the insertion of a bougie to calibrate the wrap. The anterior 180° and the posterior partial fundoplications lead to similar control of heartburn when compared to total fundoplication with lower risk of dysphagia. However, when performed, 24-h pH monitoring shows pathologic reflux more frequently after partial than total fundoplication. Disappointing results are achieved by anterior 90° partial fundoplication. More recently, a magnetic sphincter augmentation with the LINX Reflux Management System (Torax Medical) and the lower esophageal sphincter Electrical Stimulation (EndoStim) have been developed, seeking for a durable and effective minimally invasive alternative to laparoscopic fundoplication for the treatment of reflux. Both devices seem to be promising, with very low postoperative complications and good short-term functional outcomes. Large randomized controlled trials comparing them with laparoscopic fundoplication over a long period of follow-up are needed to verify their indications and outcomes.

**Keywords** Gastroesophageal reflux disease · Laparoscopic total fundoplication · Partial anterior fundoplication · Partial posterior fundoplication · Sphincter augmentation device · LES Electrical Stimulation

## Introduction

A laparoscopic total fundoplication (LTF) is the procedure of choice for the surgical treatment of gastroesophageal reflux disease (GERD), with reduced postoperative morbidity and comparable long-term outcomes to those achieved with open fundoplication [1, 2].

LTF controls reflux-related symptoms in about 80–90% of patients at 10 years after surgery [3, 4]; however, it is associated with a small but significant incidence of postoperative dysphagia and gas-related symptoms [5]. Several strategies have been developed to minimize these side effects, including the construction of a laparoscopic partial fundoplication (LPF). The current evidence is controversial, with some randomized clinical trials (RCTs), mostly from Australia, showing similar reflux control but higher incidence of dysphagia and gas-related symptoms after LTF [5], and several studies

from the United States reporting similar rates of dysphagia after LTF and LPF, and a better reflux control after LTF than LPF [6–8].

More recently, a magnetic sphincter augmentation (MSA) with the LINX Reflux Management System (Torax Medical) and the lower esophageal sphincter (LES) Electrical Stimulation (EndoStim) have been developed as a minimally invasive alternative to LTF for the treatment of GERD [9, 10].

The aim of this article is to review the surgical outcomes of laparoscopic fundoplication, MSA and LES Electrical Stimulation as minimally invasive approaches to GERD.

## Literature search

“The critical appraisal of the literature was performed searching the electronic PubMed/Medline databases and the Cochrane Library for articles published between January 1998 and March 2018 using the following medical subject headings (MeSH) and free-text words alone or in combination: “Gastroesophageal reflux disease”, “laparoscopic total fundoplication”, “partial anterior fundoplication”,

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“partial posterior fundoplication”, “Nissen”, “Toupet”, “Dor” “Sphincter augmentation device”, “LES Electrical Stimulation”.

## Study selection

Three authors (FR, MEA, and LC) independently performed the literature search including only articles published in English language. The authors manually checked the reference lists of the retrieved articles, including additional studies when appropriate. In case of multiple publications on the same data from a single institution, the most recent study was considered in the review.

## Laparoscopic fundoplication: controversial surgical aspects

Laparoscopic fundoplication is a standardized surgical procedure for the surgical treatment of GERD. However, some surgical steps, including the short gastric vessels division and the use of the bougie for the wrap calibration, are debated.

### Division of short gastric vessels

Long-term results of several RCTs failed to demonstrate any reduction of postoperative dysphagia in patients undergoing total fundoplication with short gastric division compared with those who underwent total fundoplication without short gastric vessel division [11–15]. Two of these RCTs have shown an association between short gastric vessel division and wind-related effects [11, 13]. However, level of evidence is low due to the heterogeneity and inherent poor methodological quality of these RCTs, and experts in North America advocate routine division of the short gastric vessels. Division of the short gastric vessels facilitates the creation of a floppy and tension-free fundoplication. When the short gastric vessels are left intact, the wrap could be pulled to the left because the gastric fundus is tethered to the spleen and a rotation on the gastroesophageal junction with a subsequent spiral deformity is determined [16].

### Insertion of the bougie into the esophagus and across the esophageal junction

The Society of American Gastrointestinal and Endoscopic Surgeons recommends the use of a bougie with a Grade B recommendation [17]. Patterson et al. randomized 171 GERD patients to a laparoscopic fundoplication with a 56 Fr bougie (81 patients) or without a bougie (90 patients). Overall complication and dysphagia rates at 1 month were

similar. The incidence of dysphagia after a mean follow-up of 11 months was significantly higher in the group without the bougie. These patients were also more likely to have severe or frequent dysphagia [18]. This study has some limitations, including lack of sample size calculation. Further large RCTs adequately powered and designed are requested to confirm these results.

## Laparoscopic fundoplication: total or partial?

An LPF (posterior, 180° anterior and 90° anterior) has been proposed to minimize or prevent postoperative dysphagia and gas-related symptoms that are associated with an LTF. Several RCTs aimed to find the ideal antireflux technique, comparing LTF to different variants of LPF.

### Anterior 180° vs. LTF

Five RCTs comparing anterior 180° and LTF have been published. The two with the largest number of patients enrolled and the longest follow-up are those published by Watson [19] and Baigrie [20]. Watson et al. [19, 21] compared 53 GERD patients treated with LTF and 54 GERD patients undergoing an anterior 180° LPF in a prospective double-blind RCT. At 6 months, LPF achieved equivalent control of reflux and was associated with improved clinical outcomes, with less dysphagia, reduced gas-related symptoms, and higher level of satisfaction than LTF [20]. The 5-year follow-up results of this RCT based on standardized questionnaires confirmed in 101 patients (51 LTF, 50 LPF) similar heartburn control in the two groups, lower incidence of dysphagia, abdominal bloating and inability to belch after LPF, proving the durability of the anterior 180° LPF [21]. At 10 years, heartburn control, use of proton pump inhibitors (PPIs), incidence of dysphagia, and overall satisfaction were similar after LPF and LTF [22]. However, a subsequent evaluation based on manometry and ambulatory 24-h impedance-pH monitoring at 14 year-follow-up showed lower mean LES resting and relaxation pressures and more common acid, weakly acidic, liquid and mixed reflux episodes after LPF. Heartburn was more frequently experienced by LPF than LTF patients, while dysphagia was less common [23].

Baigrie et al. [20] obtained similar results in 163 GERD patients randomized to an LTF (84 patients) or anterior 180° LPF (79 patients), with no division of the short gastric vessels. Patients after LPF had significantly less dysphagia at 3, 12, and 24 months, while the incidence of heartburn and patient satisfaction scores did not significantly differ between the two groups at each follow-up interval.

Broeders et al. [24] performed a meta-analysis of the 5 RCTs, including 227 LPF patients and 231 LTF patients.

Dysphagia and gas-related symptoms were less common after LPF than LTF, while pathologic esophageal acid exposure at 24-h pH monitoring and esophagitis occurred with similar rates between the two groups of patients at both 1- and 5-year evaluation.

### Anterior 90° vs. LTF

Although postoperative dysphagia and gas-related symptoms are reduced after anterior 180° LPF compared to LTF, they are still experienced by some patients. To further minimize these problems, a 90° anterior LPF was developed in the late 1990s.

Watson et al. [25] randomized 112 GERD patients to anterior 90° LPF (60 patients) or LTF (52 patients). Early postoperative morbidity and length of postoperative stay did not significantly differ between the two groups. At 6 months, dysphagia and flatulence were more frequently reported after LTF. Manometric data, acid exposure and endoscopic findings were similar at 3–4 months after both procedures, while overall patient satisfaction was higher after LPF. Based on these data, the authors concluded that anterior 90° LPF provides effective reflux control, and it is followed by less dysphagia and gas-related symptoms than LTF. At 12 months after surgery, patients were less likely to experience dysphagia after LPF than after LTF, while no differences were observed at 5 years. Incidence of heartburn was reduced after LTF compared to LPF at 12 months and 5 years. Overall satisfaction was similar in both groups of patients over time [26].

Spencer et al. [27] randomly compared 40 patients undergoing anterior 90° LPF and 39 patients treated with LTF without division of the short gastric vessels. At 1-year follow-up, dysphagia was more common after LTF, while no differences were reported for heartburn. However, 24-h pH monitoring showed a significantly better control of acid reflux after LTF. At manometry, postoperative LES resting pressure was similar in the two groups, while LES residual relaxation pressure was significantly higher after LTF. At 5 years, incidence of dysphagia and symptoms of bloating was higher after LTF, while the incidence of heartburn and overall satisfaction was similar, although PPIs were more frequently used after LPF. However, manometry and pH monitoring were not performed [28].

Broeders et al. [29] combined raw data sets from these two RCTs and used the original data to determine the clinical outcomes at 5 years follow-up. Heartburn and use of PPI were significantly more common after LPF, while side effects, such as dysphagia and gas-related symptoms, were less frequent. Overall patient satisfaction was similar. The number of endoscopic dilatations performed for dysphagia (2 vs. 6%,  $p = 0.202$ ), and the number of reoperations (10 vs. 4.9%,  $p = 0.212$ ) did not significantly differ between

the two groups. Most frequent indication for reoperation was recurrent reflux in the LPF group, and dysphagia in the LTF group.

In conclusion, the incidence of heartburn and use of PPIs after anterior 180° LPF and LTF are similar, while they are both higher after 90° anterior LPF than LTF at 5 years after surgery. Postoperative dysphagia is less common after both 180° and 90° anterior LPF than LTF at 5 years after surgery. However, at 10-year follow-up, the outcomes are similar. These results should be interpreted with caution. Indeed, the sample size of most RCTs is small, and 24-h pH monitoring was not used to evaluate the incidence of reflux at long-term follow-up. Many studies have in fact shown that pathological reflux is present in less than 40% of cases at ambulatory 24-h pH monitoring in patients with recurrent heartburn [30–33]. On the other hand, long-term studies have shown that gastroesophageal reflux is less effectively controlled by an LPF rather than an LTF, with recurrent reflux being confirmed by pH monitoring at 5 years in more than 50% of patients after LPF [6–8].

### Posterior vs. LTF

Laparoscopic posterior fundoplication has been proposed as an alternative to LTF to reduce the incidence of postoperative dysphagia and wind-related symptoms in GERD patients. A recent systematic review and meta-analysis of seven RCTs that compared LTF to Toupet (posterior partial) for GERD found similar reflux control and overall patient satisfaction after LTF and posterior LPF; postoperative dysphagia, inability to belch, gas bloating, need for endoscopic dilatations or surgical reoperations were more common after LTF [5]. These initial mechanical advantages, however, seem to disappear over time [34].

Several large comparative studies reported poorer long-term reflux control after Toupet fundoplication. For instance, Jobe et al. [35] found in 100 consecutive GERD patients abnormal 24-h pH monitoring in 51% of all patients and in 39% of asymptomatic patients after laparoscopic Toupet fundoplication. Similarly, Patti et al. [6] found at 70 months persistent reflux confirmed by 24-h pH monitoring in 56% of patients after laparoscopic posterior fundoplication and in only 28% after LTF. Use of PPIs was more common (25 vs. 8%) or reoperation was more frequently performed (9 vs. 3%) after posterior fundoplication. The incidence of postoperative dysphagia did not significantly differ between the two groups.

Table 1 summarizes the current evidence.

**Table 1** Outcomes after laparoscopic procedures for reflux

Procedure	Heartburn	Esophageal acid exposure	Esophagitis	Dysphagia	Gas-related symptoms
Partial anterior 180° vs. LTF	=	=	=	<	<
Partial anterior 90° vs. LTF	>	>	>	<	<
Partial posterior vs. LTF	=	=	=	<	<
Partial anterior 180° vs. partial posterior	>	>	>	=	=
MSA vs. fundoplication	=	NA	=	=	<

LTF laparoscopic total fundoplication, MSA magnetic sphincter augmentation, NA not available

## Laparoscopic partial fundoplication: anterior or posterior?

Based on the similar reflux control and reduced postoperative dysphagia after LPF, Hagedorn et al. [36] randomly evaluated the efficacy and mechanical consequences of an anterior 120° LPF (47 patients) or a posterior (Toupet) LPF (48 patients) for GERD. Heartburn and regurgitation were less frequently experienced after a posterior LPF. Similarly, a significantly better reflux control at 24-h pH monitoring was achieved after posterior LPF. Postoperative dysphagia and ability to belch were similar between the two groups. At 5 years, a posterior LPF was associated with significantly better symptom, reduced need for reoperations and use of PPIs [37] (Table 1).

## Novel laparoscopic procedures for gastroesophageal reflux disease

### Magnetic sphincter augmentation (MSA)

Magnetic sphincter augmentation (MSA) with the LINX Reflux Management System (Torax Medical) has been designed to be a minimally invasive surgical alternative to laparoscopic fundoplication, by augmenting the sphincter barrier with a standardized, reproducible, and reversible laparoscopic procedure that does not alter the gastric anatomy. Main indications are non-obese patients with GERD confirmed by 24-h ambulatory pH monitoring, incomplete relief of symptoms despite maximum medical therapy, without endoscopic Barrett esophagus, with normal motility, and a hiatal hernia smaller than 3 cm [38].

The MSA device consists of a series of magnetic beads interlinked with independent titanium wires, therefore, creating a dynamic flexible and expandable ring that mimics the physiological movement of the esophagus. It is implanted laparoscopically under general anesthesia [39]. Since the FDA approval of the MSA device in 2012, several case series with mid and long-term follow-up have been published. For instance, Ganz et al. [40] reported the 3-year

results in 100 GERD patients: Normalization of or at least a 50% reduction in total percent esophageal time pH < 4 was observed in 64% of patients. A reduction of 50% or more in PPIs use was achieved by 93% of patients, and there was improvement of 50% or more in quality-of-life scores in 92%, as compared with preoperative scores. Dysphagia was the most frequent adverse event and occurred in 11% at 1 year, and in 4% at 3 years. Dilatation was required in 19 patients. Serious adverse events occurred in 6 patients. Removal of the device occurred in six cases.

Bonavina et al. [41] reported the clinical outcomes for 100 consecutive patients treated with MSA for GERD in a single institution. No intraoperative complications were recorded. No postoperative morbidity related to the surgical procedure was observed. At 5 years, normalization of esophageal acid exposure or its reduction of 50% or greater was observed in 80% (25/30) of patients. Complete cessation of PPI therapy was reported by 85% of patients. There have been no long-term complications, such as device migrations or erosions. Three patients had the device laparoscopically removed for persistent GERD, odynophagia, or dysphagia, with subsequent resolution of symptoms. The results of both single institution studies show that MSA can be easily and safely implanted by laparoscopy. The device decreases esophageal acid exposure, improves reflux symptoms, and allows cessation of PPIs in the majority of patients.

During the last 5 years, several comparative studies have explored the early outcomes after MSA and laparoscopic fundoplication. In a recent meta-analysis of 7 observational studies including 686 MSA patients and 525 fundoplication patients, both procedures resulted to be equally effective at 1-year follow-up, with similar rates of PPI suspension, dysphagia requiring endoscopic dilatation, and quality of life. MSA seems to be associated with less gas-bloat syndrome-related symptoms [42] (Table 1). Even though MSA appears to be effective in the treatment of GERD, resumption of PPIs or esophagitis occurs in 10 to 25% of patients; the rates of erosion and MSA removal are about 0.1 and 3.5%, respectively [43]. The possible factors influencing the outcomes in patients undergoing MSA placement have been investigated [44]. Besides body mass index (BMI) that is a well-known

risk factor for poor functional outcomes in GERD patients undergoing antireflux surgery [45], structurally defective LES is an independent predictor of MSA failure. LES has three main characteristics: overall length, intra-abdominal length and basal pressure. Warren et al. [46] retrospectively evaluated manometric changes after MSA in 121 patients with pathologic esophageal acid exposure, BMI < 35 kg/m<sup>2</sup>, a small hiatal hernia, and no evidence of Barrett esophagus. An overall increase in the median LES resting pressure was observed after MSA (18 vs. 23 mmHg,  $p=0.0003$ ), residual pressure (4 vs. 9 mm;  $p<0.0001$ ), and distal esophageal peristalsis amplitude (80 vs. 90 mmHg,  $p=0.02$ ). Overall, 67% of patients with a preoperative defective LES had normalization of their defective component or components. However, the percentage was higher among those patients with a single structural defect than those with two or more defective components (77 vs. 56%).

In conclusion, MSA seems to be effective in selected patients with an LES without major functional defects. However, RCTs comparing MSA and laparoscopic fundoplication with large sample sizes and long follow-up are needed to clarify the role and the effects of MSA on reflux control and prevention of side effects associated with laparoscopic fundoplication.

## LES Electrical Stimulation

LES Electrical Stimulation (EndoStim, St. Louis, MO) is a novel technique that has been conceived along with MSA seeking for an effective, minimally invasive and less disruptive approach to GERD than laparoscopic fundoplication [47]. Temporary LES stimulation determines durable increase in LES pressure, without impairing LES relaxation and esophageal peristalsis [10]. This system has three different components: a bipolar electrical stimulation lead, an implantable pulse generator and an external programmer. This system delivers stimulation waves in 30-min sessions that can be adjusted in a non-invasive fashion tailored to each patient. The LES implant procedure has several steps: (1) laparoscopic exposure of the anterior right wall of the abdominal esophagus; (2) superficial implantation and fixation of two stitch electrodes into the LES along the longitudinal axis of the esophagus 1 cm apart; (3) upper endoscopy to check the correct electrode position at the LES level and to rule out esophageal perforation; (4) creation of a subcutaneous pocket for the generator implantation; (5) attachment of the connector to the pulse generator; (6) functional test with the external programmer.

To date, only a study has published outcomes after more than 6 months after surgery. Rodríguez et al. [10] have followed 23 patients for 2 years, reporting normalization or a decrease of 50% or more of acid exposure of the distal esophagus in 71% of patients. Complete cessation of PPI use

was observed in 76% of patients. A significant improvement of symptoms was observed in all patients. No major device-related complications occurred.

Based on these limited data, LES Electrical Stimulation seems a promising minimally invasive approach to GERD patients. However, it must be considered an experimental technique, until more robust data will confirm the preliminary outcomes.

In conclusion, laparoscopic fundoplication is the standard of care for the treatment of patients with GERD. During the last 10 years, many efforts have been done to develop a minimally invasive alternative to laparoscopic fundoplication with reduced less side effects. Both MSA and LES Electrical Stimulation have been proven to be safe. However, there are no long-term and robust studies comparing these two novel techniques to the laparoscopic fundoplication.

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## Compliance with ethical standards

**Conflict of interest** The authors declare that they have no conflicts of interest.

**Research involving human participants and/or animals** This article does not contain any studies with human participants performed by any of the authors.

**Informed consent** Since this manuscript is a review of the literature, no informed consent was obtained.

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