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REVIEW

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Comparative analysis of surgical treatments for GERD in patients with hiatal hernia: Nissen fundoplication, Toupet fundoplication, LINX, and RefluxStop™

Prezentacja dostępnych metod chirurgicznego leczenia GERD: fundoplikacja Nissena, fundoplikacja Toupeta, LINX i RefluxStop u pacjentów z przepukliną rozworu przełykowego

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Abstract:

Introduction: Gastroesophageal reflux disease (GERD) is a chronic condition of alimentary tract, that can lead to major complications. Surgical treatment of patients with GERD and concomitant hiatal hernia is commonly employed when pharmacotherapy is not effective. Available surgical treatment options consist of Nissen fundoplication, Toupet fundoplication, and newer procedures such as LINX system or RefluxStop™.

Aim: The aim of this review is to present four surgical treatment methods of GERD in patients with concomitant hiatal hernia. The analysis consists of the assessment of reduction of GERD symptoms, improvement in the quality of life and postoperative complication indicators.
Materials and methods: Analysis was conducted using data from clinical trials, meta-analyses and systematic reviews, concerning patients with GERD concomitant with hiatal hernia, who underwent one of four treatment methods: Nissen fundoplication,

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Toupet fundoplication, LINX system or RefluxStop™. Included results consist of reflux disease symptoms control, heartburn relief, and safety of procedures. **Results:** The analysis showed that all four surgical treatment methods effectively relieve symptoms of GERD, but they differ among factors such as: level of invasiveness, postoperative complications and long term effectiveness. Nissen and Toupet fundoplications, more traditional approaches, offer solid results in reflux control, but may be linked to a greater risk of complications, such as dysphagia or gas-bloat syndrome. Methods such as LINX and RefluxStop™ are less invasive, and their clinical results show lesser risk of complications, which may be a significant benefit for the patients.
Conclusions: Newer treatment methods, such as LINX and RefluxStop™, may offer an effective alternative to traditional fundoplication procedures, especially in patients with smaller hiatal hernias. Choice of an optimal treatment method should be tailored to the individual patients characteristics and to the severity of the disease.

Keywords: gastroesophageal reflux disease (GERD); hiatal hernia; surgical treatment of GERD in patients with hiatal hernia; Nissen fundoplication; Toupet fundoplication; LINX system; RefluxStop implant; laparoscopic antireflux surgery; postoperative complications; patient quality of life; dysphagia; gas-bloat syndrome

Streszczenie:

Wstęp: Choroba refluksowa przełyku (GERD) jest przewlekłym schorzeniem przewodu pokarmowego, które może prowadzić do istotnych komplikacji zdrowotnych. U pacjentów z GERD i współistniejącą przepukliną rozworu przełykowego często stosuje się leczenie chirurgiczne gdy leczenie farmakologiczne nie przynosi oczekiwanych rezultatów. Wśród dostępnych metod chirurgicznych znajdują się fundoplikacja Nissena, fundoplikacja Toupet, a także nowoczesne procedury, takie jak system LINX oraz RefluxStop.
Cel: Celem niniejszego przeglądu jest przedstawienie czterech metod chirurgicznego leczenia GERD u pacjentów z przepukliną rozworu przełykowego. Analiza obejmuje ocenę redukcji objawów GERD, poprawę jakości życia oraz wskaźniki powikłań pooperacyjnych.
Materiały i metody: Przeanalizowano dane z badań klinicznych, metaanaliz oraz przeglądów systematycznych, dotyczących pacjentów z GERD i przepukliną rozworu przełykowego, którzy byli leczeni jedną z czterech metod: fundoplikacją Nissena, fundoplikacją Toupet, systemem LINX lub RefluxStop. Uwzględniono wyniki związa-

ne z kontrolą objawów refluksu, zmniejszeniem nasilenia zgagi, redukcją przepukliny oraz bezpieczeństwem procedur.

Wyniki: Analiza wykazała, że wszystkie cztery metody chirurgiczne skutecznie zmniejszają objawy GERD, jednak różnią się pod względem stopnia inwazyjności, powikłań pooperacyjnych oraz długoterminowej skuteczności. Fundoplikacja Nissena i Toupet, jako bardziej tradycyjne metody, oferują solidne wyniki w kontrolowaniu refluksu, ale mogą wiązać się z większym ryzykiem powikłań, takich jak dysfagia czy gaz bloat syndrome. Metody LINX i RefluxStop są mniej inwazyjne, a ich wyniki kliniczne wskazują na mniejsze ryzyko powikłań, co może stanowić istotną korzyść dla pacjentów.

Wnioski: Nowoczesne metody leczenia, takie jak LINX i RefluxStop, mogą stanowić skuteczną alternatywę dla tradycyjnych procedur fundoplikacyjnych, szczególnie u pacjentów z mniejszymi przepuklinami rozworu przełykowego. Wybór optymalnej metody leczenia powinien być dostosowany do indywidualnych cech pacjenta oraz stopnia nasilenia choroby.

Słowa kluczowe: choroba refluksowa przełyku (GERD); przepuklina rozworu przełykowego; leczenie chirurgiczne GERD u pacjentów z przepukliną; fundoplikacja Nissena; fundoplikacja Toupet; system LINX; implant RefluxStop; laparoskopowa chirurgia antyrefluksowa; powikłania pooperacyjne; jakość życia pacjentów; dysfagia; zespół wzdęć

Introduction

GERD is a chronic condition of alimentary tract, characterized by reflux of chyme to the esophagus, which leads to symptoms such as: heartburn, chest pain, sour taste in mouth and discomfort in the epigastric region [1, 2]. GERD can lead to serious complications, including Barrett's esophagus and esophageal cancer, when not treated correctly [3, 4]. Causes of GERD are complex and consist of functional disorders such as lower esophageal sphincter dysfunction and of structural abnormalities like hiatal hernia (HH) [5].

In the case of patients, in whom pharmacotherapy and lifestyle modifications do not bear expected results, surgical treatment is taken into consideration [6, 7]. Traditional surgical methods consist of Nissen fundoplication, which is achieved by wrapping the upper part of the stomach around the esophagus in order to strengthen lower esophageal sphincter (LES) [8, 9], and Toupet fundoplication, which is a partial fundoplication (270 degrees), conducted in order to lower the risk of complications such as dysphagia [10, 11].

Recent years showed an advent of newer surgical techniques, such as LINX system, that employs a magnetic ring to strengthen LES, and RefluxStop™, an innovative method preventing reflux through modifying the angle of the cardiac orifice. These two less invasive techniques gain on popularity due to a potentially lower risk of complications and shorter postoperative recovery time [12, 10].

The aim of this review is to show four surgical methods used in treating GERD in patients with concomitant HH, which include Nissen fundoplication, Toupet fundoplication, LINX system and RefluxStop™. The analysis consists of the assessment of reduction of GERD symptoms, improvement in the quality of life and postoperative complications incidence, which allows better understanding of the advantages and limitations of particular surgical methods.

Material and methods

Analysis was conducted using data from clinical trials, metanalyses and systematic reviews, concerning surgical treatment of patients with GERD concomitant with HH, which met the inclusion criteria.

Study inclusion criteria

The inclusion criteria encompassed studies published between 1999 and 2024 that focused on the surgical treatment of GERD using one of four specified methods, conducted on patients with confirmed HH. Eligible study types included randomized controlled trials, cohort studies, retrospective analyses, systematic reviews, and meta-analyses. To be considered, studies had to report at least one outcome related to GERD symptom control (such as heartburn, regurgitation, or chest pain), improvement in quality of life, or the incidence of complications, including dysphagia, gas-bloat syndrome, and disease relapse.

Data sources

Data was gathered from medical databases such as PubMed, Cochrane Library, Scopus and Google Scholar. Search terms included keywords such as „Nissen fundoplication", „Toupet fundoplication", „LINX", „RefluxStop" and „hiatal hernia".

Selection procedure

Initial review was conducted in order to eliminate studies that did not meet inclusion criteria. Data from studies which met inclusion criteria was analyzed and compared.

Analysis

Each method was assessed in terms of effectiveness of GERD symptom reduction, improvement of results in standardized quality of life scales (such as GERD-HRQL), incidence of postoperative complications and duration of hospitalization. In case of studies covering different patient groups, the results were compared, with factors such as HH size and alimentary tract comorbidities taken into account.

Fundoplication Techniques – Nissen and Toupet

The Nissen and Toupet fundoplication procedures are surgical techniques aimed at treating GERD by reinforcing the anti-reflux barrier. In the Nissen fundoplication, a complete 360° wrap of the gastric fundus is created around the lower esophagus. In contrast, the Toupet procedure involves a partial 270° posterior wrap. The selection of the technique depends on factors such as esophageal motility, presence of a normotonic lower esophageal sphincter, and gastric anatomy [13].

The procedures are performed laparoscopically using standard trocar placement and under general anesthesia. Each technique begins with dissection of the esophageal hiatus and mobilization of the abdominal esophagus. In all cases, the diaphragmatic crura are identified and approximated with nonabsorbable sutures to close the hiatal defect [1]. Posterior hiatal repair is routinely performed, often with preservation of the hepatic branch of the vagus nerve [2].

In the Nissen fundoplication, the gastric fundus is mobilized, frequently requiring division of the short gastric vessels [13]. After ensuring a tension-free intra-abdominal esophageal length of 3–4 cm [14], the fundus is wrapped 360° around the esophagus, forming a “floppy” wrap to avoid postoperative dysphagia. The wrap is then secured with 2-0 nonabsorbable sutures, often using pledgets for reinforcement [15] (Fig.1), (Fig.2).

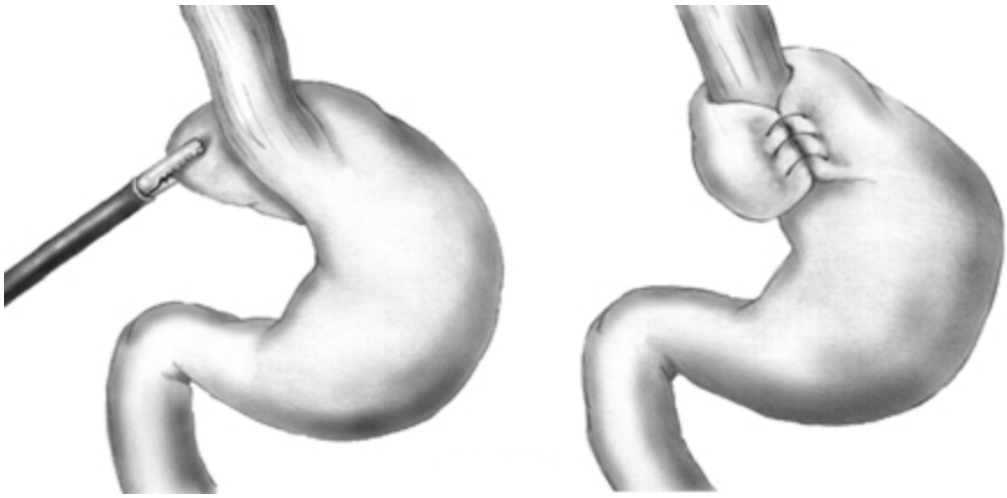

Figure 1. Nissen fundoplication , wrapping the fundus of the stomach around the lower esophagus and suturing in place. Gray JP. Nissen fundoplication.png [ilustracja]. Public domain. Wikimedia Commons; 2007 [cyt. 2025-06-08]. Dostępny na: *https://commons.wikimedia.org/wiki/File:Nissen_fundoplication.png*

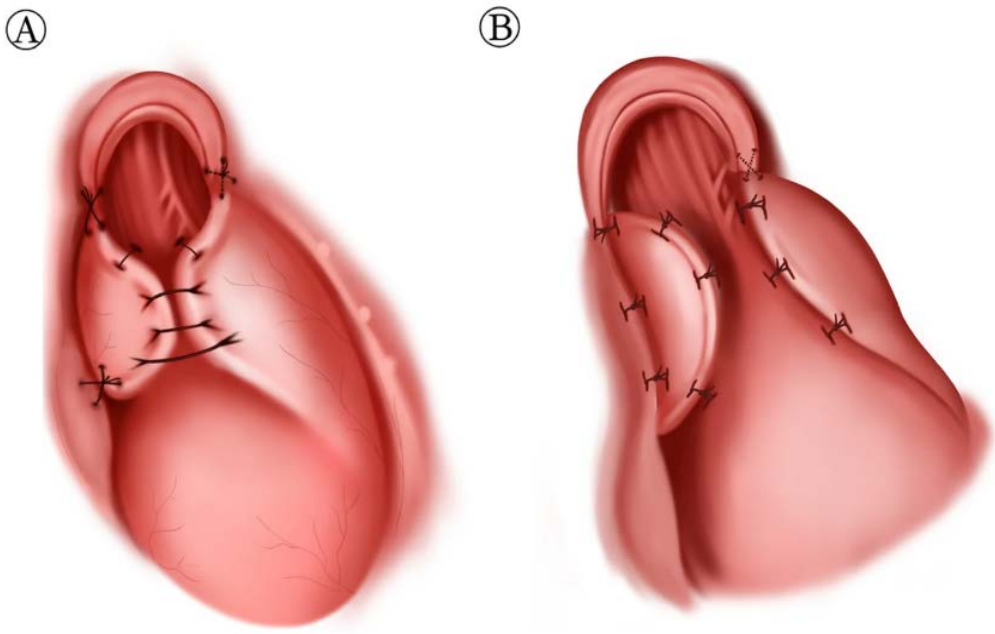

Figure 2. The suture technique and three-point fixation with Nissen fundoplication (A); with Toupet fundoplication (B). Tzortzis N, Eleftheriadis E. Evaluation of the efficacy of partial posterior fundoplication (Toupet) in the treatment of GERD. BMC Surg. 2025;25:124.

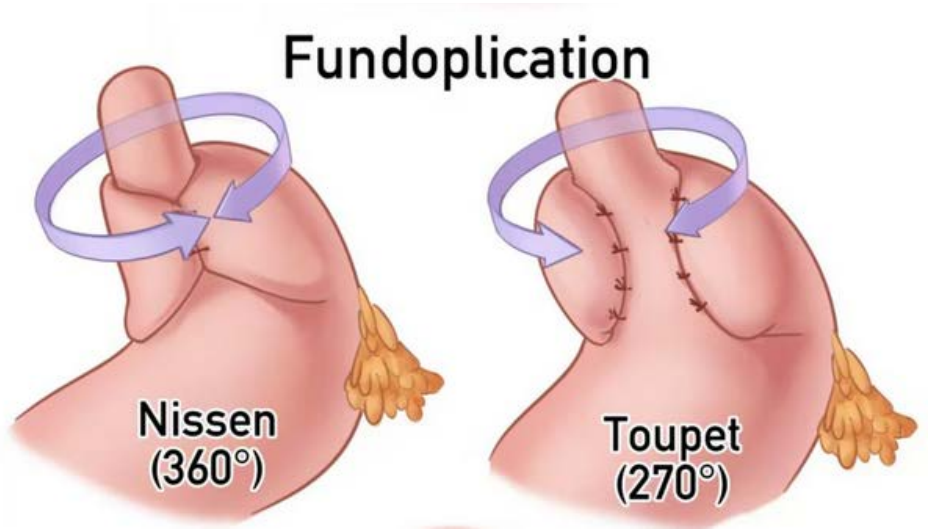

Figure 3. Schematic representation of Nissen (360°) and Toupet (270°) fundoplication techniques. Chen Y, Liu Y, Zhang R, Li X. Long-term outcomes of Toupet fundoplication in GERD patients: a retrospective cohort study. BMC Surg. 2025;25:139.

The Toupet fundoplication involves mobilization of the gastric fundus and posterior wrapping around the esophagus to form a 270° partial wrap. The fundus is then anchored to the right and left crura and the esophageal wall with two to three nonabsorbable sutures on each side [3] (Fig.2), (Fig.3). This method is especially suitable for patients with impaired esophageal motility or those with anatomical limitations.

A key technical consideration in both procedures is ensuring that the wrap is not too tight. The esophagus must remain mobile within the wrap, and it should be possible to pass grasping forceps between the fundus and the esophagus to verify adequate laxity [3]. In some cases, a bougie is used intraoperatively to calibrate the wrap and prevent postoperative obstruction. However, its use is not universal [13]. Postoperatively, patients are usually allowed to consume oral fluids on the evening of surgery and soft solids the next day. Early mobilization and discharge by postoperative day two is often encouraged [2].

A prospective randomized study by Granderath et al. (2005) compared two groups of patients: those who underwent laparoscopic Nissen fundoplication with simple hiatoplasty and those who underwent laparoscopic Nissen fundoplication with prosthetic closure of the esophageal foramen. The objective of the study was to assess the incidence of post-operative intraluminal band migration, which represents the most prevalent morphological complication following laparoscopic anti-reflux surgery. The study

included 100 patients diagnosed with gastroesophageal reflux disease who underwent laparoscopic Nissen fundoplication and hiatal hernia repair (HHR). A total of 100 patients with gastroesophageal reflux disease underwent laparoscopic Nissen fundoplication with either simple sutured sacral closure (Group 1, n=50) or simple sutured sacral plication and application of polypropylene mesh (Group 2, n=50). The efficacy of the procedure was evaluated based on the following parameters: recurrence, complications, results of esophageal manometry, 24-hour pH monitoring, esophagogastroduodenoscopy and barium swallow test, and symptomatic outcomes. In terms of esophageal manometry, 24-hour pH monitoring and symptom scores, patients in both groups exhibited comparable preoperative values. At the three-month and one-year follow-up points, the functional outcome variables (lower esophageal sphincter pressure and DeMeester score) demonstrated significant improvement compared to the preoperative values. A higher incidence of postoperative dysphagia was observed in group 2. Intrathoracic band migration occurred in 13 patients (26%) in group 1 compared to 4 (8%) in group 2 ($P < 0.001$). The results demonstrate that laparoscopic Nissen fundoplication with sacral prosthetics is an effective method for reducing the rate of recurrent HH and band migration into the thoracic cavity [1].

In a prospective, randomized clinical trial conducted by Zornig et al. (2002), 200 patients with GERD underwent either laparoscopic Nissen or Toupet fundoplication, stratified equally according to the presence or absence of preoperative esophageal motility disorders. The procedures were performed between May 1999 and May 2000. Each surgical group—Nissen and Toupet—included 100 patients, with 50 patients exhibiting normal esophageal motility and 50 presenting with motility disorders. The primary objective of the study was to evaluate the impact of tailoring the surgical technique to esophageal motility status on clinical outcomes, with a particular focus on the incidence of postoperative dysphagia and reflux control. Preoperative and postoperative assessments included structured clinical interviews, endoscopy, 24-hour pH monitoring, and esophageal manometry, with follow-up evaluations conducted four months after surgery. The findings indicated that both procedures exhibited comparable efficacy in terms of acid reflux control, with 88% of patients undergoing Nissen and 90% of patients undergoing Toupet reporting satisfaction. However, postoperative dysphagia occurred significantly more often following Nissen fundoplication (30 vs. 11 cases, $p < 0.001$), regardless of preoperative motility. Furthermore, new-onset dysphagia and a higher need for endoscopic dilatation were observed more frequently in the Nissen

group. The authors concluded that tailoring anti-reflux surgery to esophageal motility is not supported by current evidence. Instead, the findings suggest that the Toupet procedure may be preferable due to its lower incidence of dysphagia while maintaining equivalent effectiveness in symptom control [20].

In a study conducted in a span of 10 years (from 2001 to 2011) by Qin et al. Toupet fundoplication was compared to Nissen fundoplication. A total of 383 patients were randomized into two groups, 215 of them underwent Nissen fundoplication and Toupet procedure was performed on 168 patients. The average follow up was reported to be 5.6 years. The recurrence of symptoms did not arise in patients who underwent Nissen procedure, eighteen patients from the Toupet group reported such problems, which were later addressed by means of pharmacotherapy. Four months after the procedure, acid reflux testing and esophageal manometry were performed in both groups, their results were within the normal range. Esophageal inflammation was reported as cured in 88.4% patients who underwent Nissen procedure, which was higher than the cure rate in the Toupet group – 67.7%. Four days after the operation incidence rate of dysphagia and abdominal distension was measured in each group; it was significantly higher in the Nissen group when compared to the Toupet group (28.4% and 16.7%, respectively). This difference however decreased in a span of 1 year, and then incidence rates were reported as 1.5% in the Nissen group and 0.8% in the Toupet group. The authors conclude that although in a short term the incidence of dysphagia was much lower in patients who underwent Toupet fundoplication, the difference between the two groups decreased as the recovery period extended. Qin et al. propose that Nissen procedure may be optimal for patient with moderate to severe GERD, while the Toupet procedure may be beneficial for elderly patients or individuals with impaired esophageal peristalsis [3].

LINX System

The LINX Reflux Management System is a minimally invasive treatment method that is designed to strengthen the lower esophageal sphincter and restore its barrier function in patients with GERD. The device is composed of a series of interconnected titanium beads, each containing a hermetically sealed magnetic core (Fig.4). These beads are connected by independent titanium wires, forming a flexible and stretchable ring that is surgically placed around the outer part of the esophagus at the junction of the esophagus and stomach (GEJ).

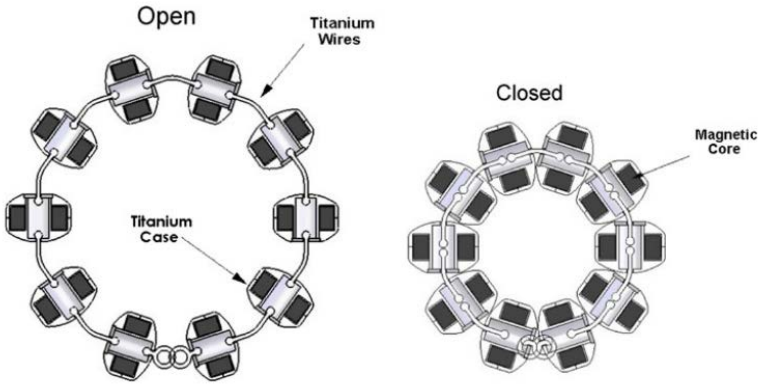

Figure 4. Cross section of the LINX device in open and closed positions. Lipham, J. C., DeMeester, T. R., Ganz, R. A., Bonavina, L., Saino, G., Dunn, D. H., Fockens, P., & Bemelman, W. (2012). The LINX reflux management system: Confirmed safety and efficacy now at 4 years. Surgical Endoscopy, 26(10), 2944–2949.

The magnetic attraction between adjacent beads prevents the LES from opening abnormally under gastric pressure, while allowing normal physiological functions such as swallowing, belching, or vomiting. During the act of swallowing, peristaltic pressure temporarily overcomes the magnetic bonds, allowing the device to expand and food to pass through. Once the food has passed, the magnetic force closes the device again (Fig.5).

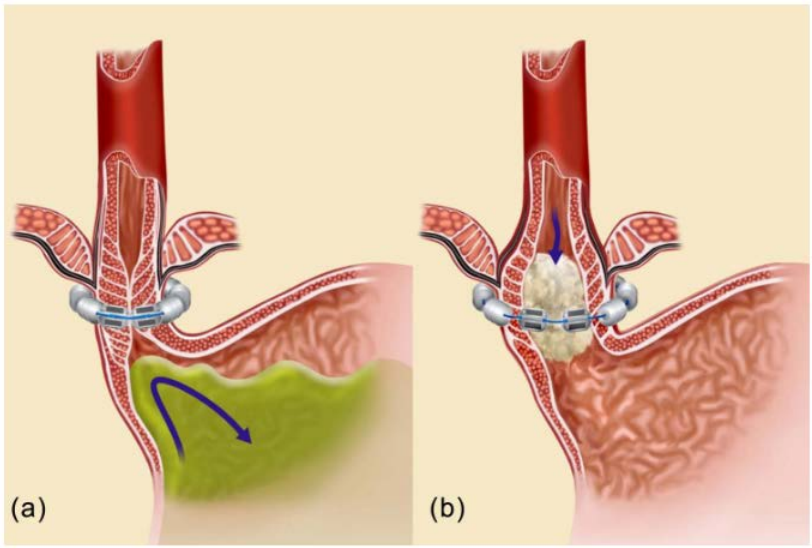

Figure 5. The LINX System encircling the distal esophagus in closed position (a) and in the open position (b). Bonavina, L., Saino, G., Lipham, J. C., & DeMeester, T. R. (2013). LINX® Reflux Management System in chronic gastroesophageal reflux: A novel effective technology for restoring the natural barrier to reflux. Therapeutic Advances in Gastroenterology, 6(4), 261–268.

The system is dynamic, with each bead moving independently, mimicking the natural movement of the esophagus and maintaining a "Roman arch" configuration without compressing the esophageal wall. The reinforcing force is constant and independent of the number of beads used, which can range from 10 to 18, depending on the circumference of the esophagus. The LINX device is implanted laparoscopically under general anesthesia. The esophagogastric junction is exposed, and a tunnel is created behind the esophagus to allow placement of the device. The esophagus is then gently surrounded, and its circumference is measured using a special sizing tool. The selection and placement of a LINX device is determined by this measurement. The device is positioned around the lower part of the esophagus, specifically just above the hepatic branch of the vagus nerve. The ends of the device are connected without the need for suturing to the wall of the esophagus (Fig.6). The procedure generally takes approximately 30 minutes, and the majority of patients are discharged from hospital within 24 hours [5, 9, 16].

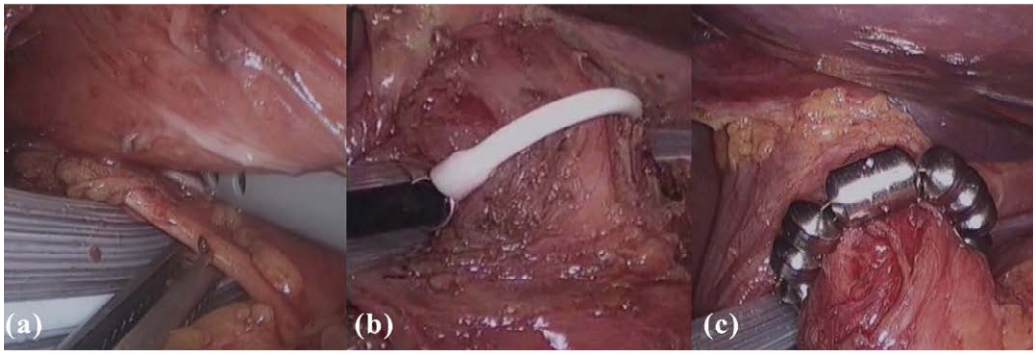

Figure 6. Tunneling between the posterior vagus nerve and the esophageal wall (a), the sizing device in place to measure the esophageal circumference (b), the LINX device positioned at the gastroesophageal junction (c). Bonavina, L., Saino, G., Lipham, J. C., & DeMeester, T. R. (2013). LINX® Reflux Management System in chronic gastroesophageal reflux: A novel effective technology for restoring the natural barrier to reflux. Therapeutic Advances in Gastroenterology, 6(4), 261–268.

In a study conducted by Schwameis et al. (2014), 23 patients diagnosed with GERD underwent minimally invasive implantation of the LINX™ Reflux Management System. The parameters under investigation were the overall feasibility of the procedure, the short-term safety of the procedure, and the efficacy of the procedure. Furthermore, the quality of life of the patients was evaluated. All procedures were completed without any significant adverse effects. The prevalence of GERD-related symptoms was significantly reduced, with a notable decrease observed in heartburn (96%-22%, $p < 0.001$) and flatulence. The results demonstrated a 70% to 30% reduction in respiratory complaints ($p=0.006$). The results demonstrated a statistically significant reduction in sleep disturbances ($p=0.039$).

A reduction of 65% to 4% was observed ($p < 0.001$). A four-week reduction of ≥50% in proton pump inhibitor (PPI) dosage was achieved in over 80% of patients. Self-limiting dysphagia was observed in 70% of patients at four weeks. One patient required endoscopic dilation. Patients' quality of life related to GERD improved significantly. Based on the above results, we conclude that LINX™ implantation is a standardized, technically simple, safe and well-tolerated procedure [4].

In a multicenter study published by Lipham et al. (2012), 44 patients underwent laparoscopic placement of the LINX system for the purpose of assessing the safety and efficacy of the procedure after a period of four years. The baseline GERD status of each patient served as a control for subsequent assessment following implantation. To assess long-term efficacy, parameters such as esophageal acid exposure, GERD quality of life and PPI use were measured. Adverse events and long-term complications were monitored closely. It was demonstrated that the mean total time of esophageal acid exposure at pH below 4 was reduced from 11.9% at the commencement of the study to 3.8% after three years ($p < 0.001$), with 80% (18/20) of patients achieving pH normalization (5.3%). After four years, 100% (23/23) of patients exhibited an enhanced quality of life for GERD, and 80% (20/25) had eliminated the use of PPIs entirely. No deaths, instances of device migration or erosion were observed. The LINX system was found to provide clinical benefit without any safety issues, as evidenced by a reduction in esophageal exposure to gastric acid, an improvement in quality of life associated with GERD and a cessation of PPI use, with minimal side effects. It is possible that patients who are unable to achieve adequate symptom control with acid suppression therapy may find benefit in sphincter augmentation therapy [5].

In a study conducted by Bonavina et al. (2010) safety and efficacy of LINX system for the treatment of GERD was evaluated. LINX system – a type of sphincter augmentation device – was implanted at the gastroesophageal junction in 44 patients by means of laparoscopy in order to prevent reflux resulting from abnormal function of lower esophageal sphincter. Before the procedure was carried out all patients suffered from typical GERD symptoms, and were treated without full success with proton pump inhibitors. Moreover, 24h pH monitoring revealed an abnormal esophageal acid exposure, also in each patient's case. After the surgery, evaluation of patients comprised of GERD-HRQL score, usage of PPIs, gastroscopy, 24h esophageal pH monitoring and esophageal manometry. Overall, GERD-HRQL score improved from a mean baseline value of 25.7 to 3.8 and 2.4 at 1- and 2-year follow-up, which represented an 85% and 90% reduction respectively. Phar-

macotherapy using PPIs was completely ceased in 90% of patients after the first year, and 86% after the second. Dysphagia occurred in 43% of patients, but it self-resolved within 90 days. One device had to be explanted, due to persistence of dysphagia. There were no device migrations, mucosal injuries or erosions. After first year 77% of patients showed normal acid exposure, which rose to 90% after the second year. The authors report that the mean percentage time pH was less than 4 decreased from 11.9% to 3.1% ($p < 0.0001$) after a year and to 2.4% ($p < 0.0001$) after two years. Patient satisfaction was reported to be at 87% at 1 year and at 86% at 2 year. Bonavina et al. conclude that the LINX system eradicates GERD symptoms successfully without generating side effects. This type of procedure proves to be still effective after one and two years of follow up [16].

A longitudinal observational cohort study conducted by Asti et al. (2016) compared two patient groups undergoing surgical treatment for early-stage GERD: those treated with laparoscopic Toupet fundoplication and those who received magnetic sphincter augmentation (MSA) using the LINX device. The primary objective was to evaluate and compare HRQL and secondary clinical outcomes following the two interventions. The study included a total of 238 patients, with 103 undergoing Toupet fundoplication (Group 1) and 135 receiving LINX implantation (Group 2). All patients were followed for at least one year postoperatively, with follow-up conducted between March 2007 and July 2014. Inclusion criteria required patients to be over 18 years of age, to report persistent GERD symptoms despite at least six months of PPI therapy, to exhibit abnormal esophageal acid exposure on pH monitoring, and to demonstrate normal esophageal motility confirmed via manometry. Exclusion criteria included the presence of a HH >3 cm, Los Angeles grade C or D esophagitis, (IEM), a body mass index (BMI) >35, or prior upper gastrointestinal surgery. Primary outcomes were assessed using the validated GERD-HRQL questionnaire. Secondary endpoints included PPI usage, dysphagia-related symptoms, gas-related complaints, and reoperation-free survival. To account for baseline differences, propensity score full matching was employed. Repeated measures were analyzed using generalized estimating equations. Both groups demonstrated significant and sustained improvements in GERD-HRQL scores over time. No statistically significant differences were observed between the groups in terms of HRQL improvement (odds ratio [OR] 1.04; confidence interval [CI] 0.89–1.27; $p = 0.578$), PPI use (OR 1.18; CI 0.81–1.70; $p = 0.388$), gas-related symptoms (OR 0.69; CI 0.21–2.28; $p = 0.542$), incidence of dysphagia (OR 0.62; CI 0.26–1.30; $p = 0.241$), or reoperation-free survival (stratified log-rank test = 0.556). In this propensity score–matched cohort of patients with early-stage GERD, both LTF and LINX procedures resulted in comparable and sustained improvements in disease-specif-

ic quality of life over a 7-year follow-up. These findings suggest that both surgical techniques offer equivalent long-term clinical efficacy [14].

REFLUX STOP™

The RefluxStop™ device is a sterile, single-use, non-active implant composed of medical-grade silicone, consisting of five small interconnected parts bound by an absorbable suture [9] (Fig.7).

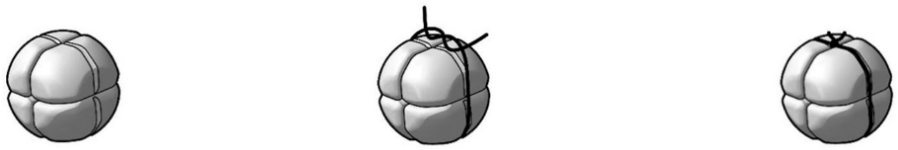

Figure 7. RefluxStop™ implant- illustration without suture, followed by assembly and suture placement. Bjelović, M., Harsányi, L., Altorjay, Á., Kincses, Z., Forsell, P., & Investigators of the RefluxStop™ Clinical Investigation Study Group. (2020). Non-active implantable device treating acid reflux with a new dynamic treatment approach: 1-year results. RefluxStop™ device; a new method in acid reflux surgery obtaining CE mark. BMC Surgery, 20, Article 179

Unlike traditional fundoplication, this approach does not involve the encircling of the esophagus [7]. Instead, the device is placed in a pouch created from the gastric fundus wall, externally to the stomach and near the esophagus, ensuring the LES stays within the abdominal cavity during body movement [12].

The surgical procedure is performed laparoscopically under general anesthesia, with the patient in a reverse Trendelenburg position [11]. The standard Laparoscopic Antireflux Surgery (LARS) trocar placement technique is used [8, 10]. Following the opening of the pars flaccida, the esophagus is dissected in the mediastinum, a process which preserves the vagus nerves and mobilizes a minimum of 4–5 cm of intra-abdominal esophagus [6, 12]. In cases where a HH is present, it is reduced and the hernia sac removed [6].

The hiatus is closed with figure-of-eight sutures, ensuring no compression on the esophagus to prevent dysphagia [6, 8, 10]. Subsequent to this procedure, an esophagogastric plication is then performed to restore the angle of His, using resorbable sutures extending approximately 4 centimeters along the distal esophagus. This process helps to secure the LES below the diaphragm, thereby reinforcing the anti-reflux barrier.

After completing the plication, the RefluxStop™ device is introduced with a deployment tool [11] (Fig.8).

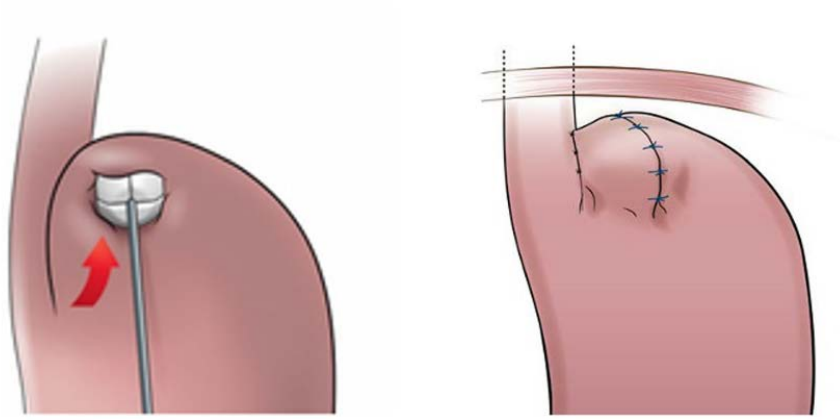

Figure 8. The device is positioned using RefluxStop™ deployment tool. Bjelović, M., Harsányi, L., Altorjay, Á., Kincses, Z., Forsell, P., & Investigators of the RefluxStop™ Clinical Investigation Study Group. (2020). Non-active implantable device treating acid reflux with a new dynamic treatment approach: 1-year results. RefluxStop™ device; a new method in acid reflux surgery obtaining CE mark. BMC Surgery, 20, Article 179

It is located high on the stomach's outer wall, in a fundic pouch close and parallel to the esophagus, ideally with its top more than one device-length above the LES [6] (Fig.9).

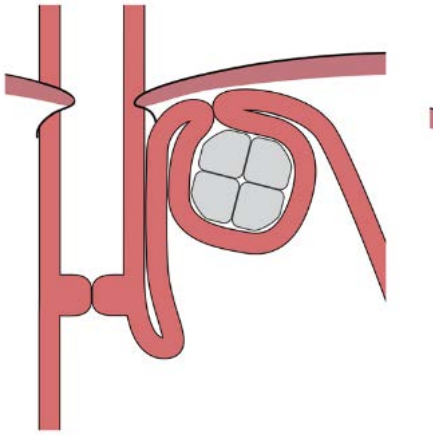

Figure 9. Optimal device placement. Top of the device placed >1 time the device size above the upper edge of the LES. Bjelović, M., Harsányi, L., Altorjay, Á., Kincses, Z., Forsell, P., & Investigators of the RefluxStop™ Clinical Investigation Study Group. (2020). Non-active implantable device treating acid reflux with a new dynamic treatment approach: 1-year results. RefluxStop™ device; a new method in acid reflux surgery obtaining CE mark. BMC Surgery, 20, Article 179

The pouch is closed—typically with purse-string sutures—to invaginate and fix the device in place [12] (Fig.10) (Fig.11).

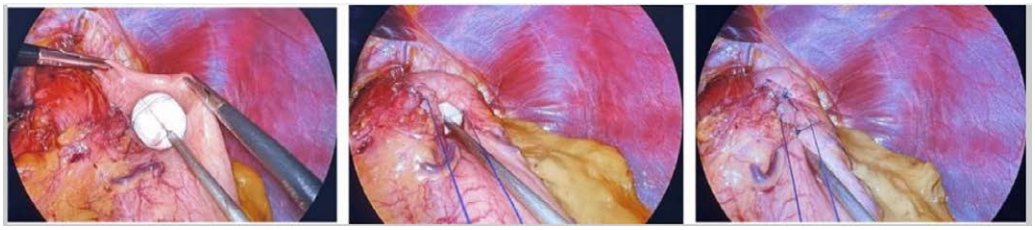

Figure 10. Intraoperative placement and fixation of the RefluxStop™ device. Feka, J., Saad, M., Boyle, N., Paireder, M., Kristo, I., Rieder, E., Asari, R., & Schoppmann, S. F. (2024). Multicentric short term and safety study of ineffective esophageal motility patients treated with RefluxStop device. Scientific Reports.

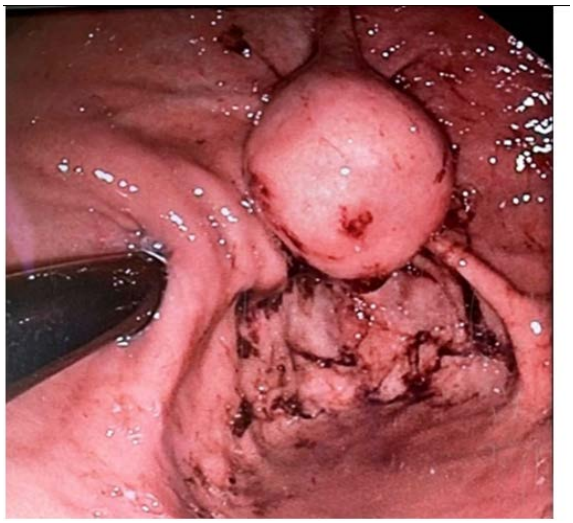

Figure 11. Endoscopic view of RefluxStop™ placed in a fundic pouch (from the outside). Harsányi, L., Kincses, Z., Zehetner, J., & Altorjay, Á. (2024). Treating acid reflux without compressing the food passageway: 4-year safety and clinical outcomes with the RefluxStop device in a prospective multicenter study. Surgical Endoscopy.

In a study conducted by Bjelović et al. (2020), 50 patients underwent surgical implantation of the RefluxStop™ device for the purpose of analyzing the device's safety and efficacy. The procedures were conducted between December 2016 and September 2017, with patients undergoing follow-up for a period of one year (CE-mark study: six months). As a primary indicator of safety, the occurrence of device-related serious adverse events was evaluated. To assess efficacy, the reduction of GERD symptoms based on the GERD-HRQL score was considered. Further exponents investigated included the incidence of adverse events, the reduction in total acid exposure time as observed in 24-hour pH monitoring, and the reduction in average daily PPI use. Additionally, patient satisfaction was considered.

A reduction in the percentage of time with pH < 4 was observed in the 24-hour pH monitoring, from 16.35% to 0.80% six months after surgery ($p < 0.001$) in comparison to the baseline. A total of 98% of subjects exhibited a normal 24-hour pH. One year after the procedure, no new cases of dysphagia were observed in the two subjects who had been experiencing this symptom since the study's inception. Of the total cohort of 50 patients who were taking PPIs prior to the procedure, only one was required to maintain a daily intake post-procedure. This was due to the device being placed in an incorrect position during surgery, resulting in it being unable to perform its intended function. In terms of symptoms, 97.8% of participants experienced either no or minimal episodes of regurgitation. Additionally, 30 patients reported an improvement in their gas bloating, while seven patients observed a resolution [6].

A study by Harsányi et al. (2024) reported the clinical results of RefluxStop™ use 4 years after device implantation. The study included 50 patients with chronic GERD. At the 4-year mark, data were available for 44 patients. Additionally, follow-up data from three patients at the 3-year time point were carried forward and included in the full analysis set, making a total of 47 patients evaluated at long-term follow-up. After 4 years, the median GERD-HRQL score had decreased by 90% compared with the initial value. Two patients (2/44) were using PPIs regularly, although subsequent 24-hour pH monitoring yielded normal results. No device-related adverse events (esophageal dilatations, migrations and device explants) were reported throughout the study period. Between 1 and 4 years, one patient reported heartburn and had an abnormal pH result as a result of the device being placed too low during surgery and one patient reported dysphagia. Thus, 46/47 patients had no adverse events related to dysphagia. Two patients (2/47) reported dissatisfaction with the treatment despite proper 24-hour pH monitoring. One patient developed dysmotility 6 months after treatment, confirmed by manometric testing, indicating dissatisfaction for reasons other than acid reflux. These results confirm the safety and efficacy of RefluxStop™ in the treatment of GERD over 4 years. The GERD-HRQL score, pH-metric testing and use of PPIs indicate the efficacy of the therapy without dysphagia or bloating, and other adverse events occurred in minimal frequency. This study showed that the RefluxStop™ method has a low rate of adverse events which can probably be attributed to the more physiological effect and its non-aggressive nature [7].

The aim of the study reported by Fringeli et al. (2024) was to evaluate the safety and feasibility of laparoscopic HH repair with the RefluxStop™ device in patients with GERD and a coexisting large HH (≥ 4 cm). Over the course of two years, between May 2020

and April 2022, 30 patients with large HH underwent surgery to repair the hiatus with the RefluxStop™ device. The surgical technique and results of the operation were evaluated in order to determine safety, efficacy, incidence of hernia recurrence, incidence of dysphagia, and postoperative patient satisfaction. All patients demonstrated the typical symptoms of GERD, including heartburn and regurgitation. Preoperatively, dysphagia was present in 15 patients (50%). The median HH size was 5 cm (interquartile range 4 to 5). The median operating time was 56 minutes (interquartile range 52 to 63), with no device-related intra- or postoperative complications. One patient experienced adhesion-related bleeding during the attempted abdominal access and therefore required laparotomy. To confirm the proper positioning of the RefluxStop™ device, all patients underwent videofluoroscopy on the first postoperative day and at three months. One patient (3.3%) required balloon dilatation due to the occurrence of severe postoperative dysphagia. The incidence of heartburn and acid regurgitation was significantly reduced in all patients at the six-month follow-up ($p < 0.001$). One case of HH recurrence was observed during the follow-up period (3.3%). The results of this study demonstrate that laparoscopic HH treatment with the RefluxStop™ device is safe and effective in patients with severe HH. It is associated with a low rate of postoperative dysphagia and improvement or resolution of reflux symptoms in all patients [8].

Conclusions

Comparative analysis of GERD surgical treatment methods, such as Nissen fundoplication, Toupet fundoplication, LINX system and RefluxStop™, in patients with HH, showed that each technique is effective in reducing symptoms and improving quality of life. However, there are significant differences regarding effectiveness, complication incidence and invasiveness of procedures, which should be taken into account while choosing the optimal treatment method.

Nissen fundoplication appears to offer the most durable symptom control, particularly in patients with large HH. However, this advantage is offset by a higher incidence of complications, such as dysphagia and gas-bloat syndrome, which may negatively impact postoperative quality of life [13].

Toupet fundoplication, as a partial posterior wrap, is associated with a lower risk of adverse effects and is therefore preferable in patients with IEM. While it may offer slightly reduced reflux control compared to the Nissen technique, its overall safety profile makes it a valuable alternative [20].

The LINX system represents a less invasive approach that maintains reflux symptoms control while preserving physiological functions such as belching and vomiting. Its advantages include a lower risk of gas-related symptoms and ease of device removal. However, it is less suitable for patients with large HHs [15].

The RefluxStop™ device is a recent innovation that has shown promising outcomes in reducing GERD symptoms and controlling acid reflux, particularly in patients with HH. This method is less invasive than conventional fundoplications while offering comparable efficacy in symptom relief. Notably, recent evidence indicates that RefluxStop™ may be especially beneficial in patients with (IEM), a population typically at increased risk for postoperative dysphagia with other surgical methods. In these patients, RefluxStop™ achieved excellent symptoms control with a low rate of complications [10,11]. Furthermore, 4-year follow-up data from a prospective multicenter study support the long-term safety and durability of this procedure. No device-related adverse events, esophageal dilations, or migrations were observed during the entire study period [9].

In conclusion, the choice of surgical technique should be individualized based on HH size, esophageal motility, symptom severity, and patient preference. While all discussed procedures offer substantial symptom relief and quality-of-life improvement, the decision must be guided by a comprehensive evaluation of risks, benefits, and patient-specific factors. The growing body of evidence–particularly regarding RefluxStop's™ performance in challenging patient populations–suggests an expanding role for tailored, less invasive anti-reflux solutions in modern surgical practice.

Summary

Surgical treatment of GERD in patients with concomitant hiatal hernia may significantly improve the quality of life, offering an effective management of reflux symptoms and lowering the risk associated with chronic exposition of esophagus to stomach acid. In this review four surgical treatment methods were compared: Nissen fundoplication, Toupet fundoplication, LINX system and RefluxStop™.

Main conclusions from the analysis show that each method has its specific advantages and limitations. Nissen fundoplication offers the highest effectiveness in symptoms control, especially in patients with sizeable HH, but is associated with higher postoperative complication incidence. Toupet fundoplication, although less effective in reflux reduction, has a lower risk associated with esophageal motility disruption, which makes it a preferred method in patients with preexisting motility problems.

Newer methods, such as LINX system and RefluxStop™, make up a less invasive alternative, offering good clinical results with lower complication incidence. LINX allows preserving the ability to eructate and vomit, which is a significant factor impacting patients' quality of life. RefluxStop™ shows promising results, especially in patients with HH, but further studies are required to fully assess its long-term effectiveness.

Choice of an optimal surgical method should be tailored to the individual patient characteristics, such as symptom severity, HH size and preference concerning risk of complications. Surgical treatment of GERD, especially in patients with hiatal hernia, remains a relevant therapy element, particularly when pharmacotherapy proves ineffective.

Conflict of interest: The authors do not declare any conflict of interest.

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