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To cite this article: Abigail Claire Watson & David Ian Watson (2025) Antireflux surgeries and hiatal repair: keys to success, Expert Review of Gastroenterology & Hepatology, 19:2, 181-195, DOI: [10.1080/17474124.2025.2464039](https://doi.org/10.1080/17474124.2025.2464039)

To link to this article: <https://doi.org/10.1080/17474124.2025.2464039>



Published online: 12 Feb 2025.



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REVIEW



## Antireflux surgeries and hiatal repair: keys to success

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### ABSTRACT

**Introduction:** Gastroesophageal reflux is common, and when medical therapy is ineffective, alternative treatments should be considered. Nissen fundoplication controls reflux but can be followed by side effects such as dysphagia and flatulence. To improve outcomes, modifications have been advocated.

**Areas covered:** Modifications to Nissen fundoplication and newer procedures for gastroesophageal reflux aim to improve overall outcome. Randomized controlled trials (RCTs) and long-term outcomes from large cohorts are prioritized to consider the optimal procedure for reflux and hiatus hernia.

**Expert opinion:** Fundoplication is an effective treatment for gastroesophageal reflux, with success rates of >80% reported at 18–20-year follow-up. RCTs confirm that Nissen fundoplication delivers better reflux control than medication. However, some patients are troubled by side effects. Anterior and posterior partial fundoplication variants have been proposed as procedures that offer equally good reflux control, but fewer side effects, and RCTs have confirmed this with follow-up to 20 years. Which partial fundoplication is better is debated. Alternative laparoscopic or endoscopic approaches require expensive implants or equipment and deliver less reliable reflux control than partial fundoplication. Currently, level I evidence confirms that laparoscopic partial fundoplication delivers the optimal outcome in fit patients with reflux that is not well controlled by medication.

### ARTICLE HISTORY

Received 19 November 2024  
Accepted 4 February 2025

### KEYWORDS

Fundoplication;  
gastroesophageal reflux;  
laparoscopic surgery; hiatus  
hernia; surgery

## 1. Introduction

Surgery for gastroesophageal reflux disease was popularized after Nissen's original report in 1956 of a 360-degree fundoplication [1]. Whilst effectively stopping the reflux of gastric content into the esophagus, it was followed by troublesome side effects such as dysphagia, flatulence, and inability to belch in some patients [2,3]. Awareness of this problem, as well as the morbidity associated with major abdominal or thoracic surgery required for access, led to a reluctance to consider and refer for surgery. Awareness of this has driven surgeons to modify and develop alternative procedures which aim to deliver reflux control without the side effect profile of Nissen's original fundoplication.

Alternatives to Nissen's procedure have included partial fundoplications where the gastric fundus is wrapped only part way around the distal esophagus and positioned either in front or behind the esophagus. These modifications were first described by Dor [4] and Toupet [5], respectively. An alternative approach described by Allison focused on the hiatus hernia, which is often associated with reflux [6,7]. Allison's procedure entailed transthoracic repair of the hiatus hernia and accentuation of the angle of His, rather than a true fundoplication. All approaches have had proponents, and success rates of 85% to 90% have generally been reported at short to medium term follow-up [2,8]. At longer term follow-up of up to 20 years, lower but still significant success rates of 70% to 80% are reported following Nissen, posterior partial, anterior partial fundoplication and Allison's procedure [7,9,10].

Before the 1990s, surgical access for these procedures was via an open thoracotomy approach and then an open abdominal approach. As open access was associated with major wound-related morbidity, and the most popular procedure, Nissen's fundoplication, was associated with a significant risk of persistent side effects, physicians were reluctant to refer for surgery and patients were understandably reluctant to agree to undergo an operation for gastroesophageal reflux.

Laparoscopic techniques changed this! These approaches were first described in 1991 by Dallemagne et al. [11] and Geagea [12]. Larger series reported in 1994 by Jamieson et al. [8] and Hinder et al. [13] demonstrated excellent short-term outcomes for most patients. Laparoscopic approaches reduced wound-related pain and morbidity, required a shorter hospital stay, and delivered better cosmesis and a lower risk of a post-procedure incisional hernia. Patients and referring physicians perceived laparoscopic fundoplication to be a much more acceptable treatment for gastroesophageal reflux, and this drove a rapid increase in surgical rates in the 1990s, particularly in Australia and Belgium where restrictions on the prescription of proton pump inhibitors (PPIs) turbo-charged the rapid uptake in surgery. Consequently, most large case cohorts were reported from these countries [8,14,15].

However, these early large case series also highlighted the problem of post-fundoplication side effects as well as the technical challenges associated with adequately repairing large hiatal hernias. Recognition of these issues drove efforts

**Article highlights**

- Randomized trials of Nissen fundoplication vs proton pump inhibitor therapy consistently show better reflux control and outcomes following surgery.
- Long term (18–20 years) follow-up studies after fundoplication report successful outcomes in approximately 80% of patients.
- Some patients are troubled by persistent side effects (e.g. dysphagia, flatulence, inability to belch) after Nissen fundoplication.
- Modifications and alternative procedures have been advocated as procedures that control reflux effectively but with fewer side effects than Nissen fundoplication.
- Randomized trials show that anterior and posterior partial fundoplication variants achieve equivalent reflux control, with fewer side effects, at follow-up to 20 years in some trials.
- Which is better – anterior vs posterior partial fundoplication is less certain. Both control reflux and reduce side effects. Reflux control might be better after posterior fundoplication, and side effects are likely less after anterior fundoplication. Satisfaction with the overall outcome is similar.
- Alternative laparoscopic or endoscopic approaches require either an implant or specific equipment which adds expense. Follow-up after these procedures is generally shorter term, and studies show reflux control is less reliably achieved, when compared to partial fundoplication. Stronger evidence from randomized trials and longer follow-up of large cohorts is needed before advocating alternative approaches.
- Hiatus hernias can be repaired with sutures. Meta-analyses of randomized trials show that the use of mesh for hiatal repair does not reduce the risk of recurrence.
- Level I evidence from meta-analyses of multiple randomized trials shows laparoscopic partial fundoplication (anterior or posterior) delivers an optimal outcome for patients with gastroesophageal reflux symptoms that are not controlled by medication.

to improve short- and long-term outcomes, and in some centers, particularly in Australia and Sweden, randomized trials were undertaken to refine surgical techniques for fundoplication and hiatus hernia repair, aiming to achieve long-term reflux control, with few side effects and effective repair of the esophageal hiatus [16,17].

When considering surgery for the control of gastroesophageal reflux, it is important to consider case selection and which procedure to perform. In the context of surgery for gastroesophageal reflux, symptoms drive decision-making and any hiatus hernia in these patients is repaired as part of the antireflux operation. Very large hiatus hernias can require repair even in the absence of a reflux issue. Such hernias generally contain at least 50%, and up to 100% of the stomach, and they often present with ‘mechanical issues’ when the stomach twists upside down and rotates into the chest resulting in obstruction, strangulation, or volvulus. For these patients, the aim of surgery is to prevent further episodes of volvulus by repairing the hernia. Reflux is often a secondary concern with this presentation. Considerations pertinent to surgery for gastroesophageal reflux and hiatus hernia often require different approaches.

Whilst there are many areas of controversy and disagreement, there are some views about surgery for reflux and hiatus hernia that are no longer controversial, and it is assumed that the reader will agree with the authors’ views about these aspects. Specifically, there is broad consensus that a fundoplication of some sort is an appropriate option that can be considered for patients with moderate-to-severe

symptoms of gastroesophageal reflux that are not adequately controlled by medication. There is also broad agreement that hiatus hernia repair is appropriate for fit people with symptomatic very large hiatus hernias. Finally, a laparoscopic approach is now the standard of care, with open surgical approaches no longer considered for primary antireflux surgery.

Areas of uncertainty include;

- Which patients should have surgery for gastroesophageal reflux?
  - Typical vs atypical reflux symptoms, including laryngopharyngeal reflux?
  - Patients with poor esophageal motility, including aperistalsis?
- Do we operate on patients in whom PPIs achieve excellent reflux control?
  - What do the randomized controlled trials (RCTs) of surgery vs PPIs tell us?
- Which operation?
  - Nissen vs partial fundoplication? Which partial fundoplication?
  - Novel interventions including Linx and transoral incisionless fundoplication (TIF)?
  - Is there a role for robotic surgery for reflux and hiatus hernia?
- When repairing a hiatus hernia, should surgeons prioritize symptom control or restoration of normal anatomy?
  - Should mesh be used to repair the esophageal hiatus?

To achieve success after surgery, these issues need to be considered, and the evidence appraised as success always depends on performing the right operation on the right patient!

## 2. Aims of therapies for gastroesophageal reflux

Gastroesophageal reflux is common, and its symptoms can usually be effectively controlled by PPI medication. However, when PPIs fail to adequately control reflux symptoms, individuals can be considered for surgery. Surgeons generally agree that a fundoplication should be considered for fit individuals with typical reflux symptoms (heartburn and/or regurgitation) in whom PPIs are not adequately controlling symptoms. Controversy exists with how to manage patients with atypical presentations.

Many of the reports of outcomes following surgery for gastroesophageal reflux focus on objective outcomes such as normalization of ambulatory pH monitoring outcomes and esophageal manometry pressures. For patients undergoing surgery for hiatus hernia repair, stable restoration of normal anatomy demonstrated by radiology or endoscopy is also prioritized. These objective outcomes are easy to quantify and report. However, they might not be what individual patients are seeking from their surgery. From a patient’s perspective, they are seeking help for their symptoms, and they are less concerned about anatomy. Fixing symptoms is what they seek, and they do not want to be left with a new problem after a surgical procedure. On the other hand, as surgery is

about modifying anatomy surgeons might prioritize anatomy. It might seem logical that symptom control and restoration of normal anatomy and function are the same aim, but this is not always true.

Overall success rates following partial fundoplication procedures are similar to those reported after Nissen fundoplication, yet the physiology after these procedures is different, with higher pressures in the region of the lower esophageal sphincter seen at esophageal manometry after Nissen compared to partial fundoplications, especially anterior fundoplication, as well as differences in 24 pH study outcomes [17,18]. Mean pressures of 19.2 mmHg were reported after Nissen fundoplication by Broeders et al. [19], compared to 16.5 mmHg after anterior 180-degree partial fundoplication, and clinical success rates were similar. In a randomized trial from Watson et al. [17] mean esophageal acid exposure, defined as % time pH <4, was reported to be 1.1% following Nissen fundoplication vs 2.5% following Anterior 180-degree partial fundoplication. Both procedures were effective, but the Nissen procedure appeared to produce an over-competent valve compared to the partial fundoplication. Patients with significant and persistent side effects after Nissen fundoplication can report dissatisfaction despite excellent objective reflux control [17].

In the context of repair of very large hiatus hernia, small radiological recurrences are seen in 25–42% of patients at to 3–5 years follow-up, yet surgical revision rates are <5% [20,21]. Wang et al. [22] showed most patients with a small recurrent hiatus hernia are not symptomatic and do not develop a clinical problem across 5 years follow-up.

In both of these contexts, clinical outcomes from the patient's perspective reflect a balance between reflux control, hernia repair integrity, and side effects. Success requires correcting the presenting problem and not trading this off against troublesome side effects which adversely impact quality of life. Success after surgery for gastroesophageal reflux can be defined as control of reflux symptoms, normalization of objective outcomes such as esophageal acid exposure or anatomy, absence of side effects or adverse outcomes, or the patient's overall satisfaction with the procedure's outcome. From the patient's perspective, we consider overall satisfaction to be the key outcome as it integrates all other measures of success. In this review, the impact of different procedures on satisfaction will be prioritized.

### 3. Investigations and evaluation of gastroesophageal reflux in patients considered for surgery

Antireflux surgery has a high chance of success in appropriately selected patients with proven gastroesophageal reflux disease, typical symptoms, and at least a partial response to medical therapy with PPIs. Success depends on appropriate preoperative assessment and workup, as well as recognition that not all symptoms in patients with reflux are due to reflux. For patients with atypical symptoms and presentation success is not guaranteed. In patients with throat symptoms diagnosed as laryngopharyngeal reflux, no typical reflux symptoms, but objective evidence of reflux, fundoplication

achieves a good outcome in only 65–70% of patients [23,24]. This demonstrates the difficulty which can occur with linking symptoms to the outcomes of objective investigations for gastroesophageal reflux.

In the authors' practice, all patients considered for fundoplication are investigated with gastroscopy and esophageal manometry. pH monitoring is used to confirm excessive esophageal acidification and symptom correlation in patients with no esophagitis at gastroscopy, and also in those with esophagitis but less typical symptom presentations. Impedance is also considered when a workup has failed to support or refute progressing to surgery. Radiology (CT or contrast swallow radiology) is only needed to clarify anatomy in patients with a very large hiatus hernia. The Lyon consensus 2.0 details the nuances associated with the diagnosis of gastroesophageal reflux and provides a framework for reflux diagnosis before considering surgery [25].

Esophageal manometry is used to assess esophageal body peristalsis and exclude achalasia. The recently published Padova consensus provides a framework for assessing the adequacy of esophageal body peristalsis before constructing a Nissen fundoplication [26]. If peristalsis is satisfactory either a Nissen or a partial fundoplication can be offered. If deficient, however, the authors' choice is to always construct a partial fundoplication. In patients with absent esophageal peristalsis or even scleroderma, a good outcome can still be achieved. Hii et al. [27] evaluated 17 patients with scleroderma who underwent an anterior partial fundoplication and showed equivalent outcomes at 1–3 years, when compared with 526 matched controls without scleroderma. Similarly, Tran et al. [28] evaluated 40 patients with reflux and completely absent esophageal motility at esophageal manometry who underwent an anterior partial fundoplication and showed similar outcomes at up to 10 years follow-up, compared to 708 matched controls.

### 4. Outcomes following Nissen fundoplication

Nissen fundoplication, where the gastric fundus is wrapped fully around the distal esophagus, is considered by many to be the gold standard for surgery for gastroesophageal reflux. It has been reported to control reflux in 85% to 90% of patients at 5 years follow-up [29]. Longer term outcomes at 18 years have been reported by Mardani et al. [30], at 20 years by Salvador et al. [31], and at 20 years by Kinsey-Trotman et al. [9] with reflux symptom control achieved in 80–84% in these studies.

Excellent reflux control, however, can be offset by troublesome side effects in some patients. These include dysphagia, flatulence, inability to belch, and abdominal bloating. Side effects are particularly prevalent in the first 3–6 months after surgery, when rates of dysphagia requiring dietary modification of up to 20% are reported [32]. Whilst side effects reduce in frequency and severity with time, Lafullarde et al. [29] reported that 11% of patients who underwent a Nissen fundoplication continued to report dysphagia requiring dietary modification 5 years after surgery. These issues have driven

a search for alternatives that minimize the risk of side effects, yet still control reflux.

Recurrent reflux also occurs after Nissen fundoplication, with the rate of recurrence increasing as follow-up lengthens. At 6–12 months recurrent reflux is uncommon. At 5-year follow-up, Lafullarde et al. [29] reported that 13% of patients described some symptoms consistent with recurrent reflux, with most of these individuals managed with PPIs, and a much lower reoperation rate for recurrent reflux after Nissen fundoplication of 1.7% in that study. In a long-term outcome study reporting experience with 2261 patients undergoing surgery for reflux across 20 years, Engstrom et al. [33] reported a revision rate of 1.7% for recurrent reflux after Nissen fundoplication, with the majority of revision procedures undertaken within the first 5 years after the original surgery.

Funduplications can be considered to have failed when patients are unhappy with the outcome. In addition to recurrent reflux, other reasons for failure include post-operative hiatus hernia and troublesome side effects [33]. Post-operative hiatus hernias are not always symptomatic and should only be considered for further intervention when troublesome symptoms are present [22]. Small hernias can be associated with recurrent reflux due to slippage of the gastroesophageal junction into the mediastinum which results in displacement of the fundus from the intra-abdominal esophagus with loss of the fundoplication's antireflux mechanism. Larger hernias can also be associated with pain due to obstruction or trapping of stomach. Of the post-fundoplication side effects, dysphagia is the problem most likely to require further intervention. This is common early after surgery and settles in most individuals. However, in a few cases, the dysphagia is related to a tight closure of the diaphragmatic hiatus or a tight Nissen fundoplication. These issues will usually require surgical correction [34,35].

Overall reoperation rates of 5–10% are reported after fundoplication, but the indications vary according to the type of fundoplication constructed [36]. Reoperation for dysphagia is commonest in patients who have undergone a Nissen fundoplication with rates of 2% to 4% reported [29,37]. Reoperation for dysphagia is rare after partial fundoplication, but more common for recurrent reflux [30]. Reoperation rates of up to 7% for hiatus hernia have been reported after Nissen fundoplication [38].

## 5. Proton pump inhibitors vs fundoplication

Medical and surgical therapies for reflux are usually considered to be complementary, and there is consensus that all patients should undergo an adequate trial of PPI treatment before being considered for surgery. Additional information to inform decision-making is available from RCTs addressing medical vs surgical therapy. Eleven published RCTs have investigated this question [39–49], although only six commenced after PPIs became available [42–47,49]. All of these RCTs enrolled patients who had reflux symptoms that were well controlled by PPIs at enrollment. It is important to understand that patients with uncontrolled reflux were excluded, even though these patients are typically the patients referred for

surgery. Hence, the patient selection in the RCTs only informs the management of individuals with reflux in whom PPIs are effective. The RCTs did not address the management of patients in whom PPIs were not completely effective.

In 2000, Lundell et al. [44] reported a trial of PPIs versus open Nissen fundoplication, with 310 patients randomized. Fundoplication achieved better reflux control at 3 years follow-up [44], and also in subsequent reports at 7 years [49] and then 12 years follow-up [38]. Offsetting this, dysphagia and flatulence were more common after surgery. Mahon et al. [42] reported 217 patients randomized to PPIs vs laparoscopic Nissen fundoplication. Reflux control was better, with less esophageal acidification measured by pH monitoring, 3 months after treatment, and symptom control was better at 1 year. Anvari et al. [43] randomized 104 patients and reported follow-up at up to 3 years, with better reflux control and quality of life seen after Nissen fundoplication. In 2009, Lundell et al. [45] reported a multicenter RCT of laparoscopic Nissen fundoplication versus esomeprazole (20–40 mg per day), which enrolled 554 patients. Success rates of approximately 90% were reported for each group at 3 years follow-up. Grant et al. [46] utilized a pragmatic design to randomize 357 patients to PPI versus fundoplication (Nissen or partial). At 5 years fundoplication achieved better symptom control, and a better overall outcome. Spechler et al. [47] randomized 78 patients with PPI refractory reflux symptoms to fundoplication vs ongoing PPI use vs escalating PPI dosing. Fundoplication provided the best symptom control.

However, both fundoplication and PPIs are associated with risks that should be balanced against potential benefits. The risks of Nissen fundoplication are considered above. Long-term PPI use has also been associated with potential side effects and risks, with concerns emerging intermittently over the past decade [50]. A full discussion of these issues is beyond the scope of this review. However, concerns raised include increased susceptibility to pneumonia, increased gastrointestinal infections due to the reduction in the gastric acid barrier to pathogens, a potential impact on the absorption of vitamins and minerals leading to deficiencies in certain micronutrients, an increased risk of osteoporosis and hip and other bone fractures, and a possible association with renal failure [50]. However, definitive causal relationships are not well established, and the overall safety profile of PPIs is considered to be acceptable, and arguably better than the risk profile for surgery! Hence, when balancing any potential risks of PPIs with surgery, the authors consider PPIs to have a good safety profile, and that avoiding any risks associated with PPIs is generally not a reason to recommend surgery for reflux.

Nevertheless, the outcomes from the RCTs comparing PPIs with fundoplication have consistently confirmed that surgery delivers better overall control of reflux than PPIs, and a reasonable interpretation of the data from these RCTs is that there is high-level evidence to support fundoplication in individuals with reflux in whom medical therapy has failed to control typical reflux symptoms [42–45,49]. More controversially, these RCTs also provide high-level evidence to support offering a fundoplication to any individual with gastroesophageal reflux which requires ongoing treatment with a PPI, even when symptoms are well controlled by the PPI. However, this

conclusion is not consistent with common clinical practice where most people undergoing surgery for reflux are only referred when PPI therapy is failing. This highlights a discrepancy between evidence, opinion, and practice.

## 6. Optimizing outcome by minimizing side effects and still controlling reflux

### 6.1. Partial fundoplication alternatives to Nissen fundoplication

In response to the problem of side effects after Nissen fundoplication, modifications to Nissen's original procedures have been advocated. Routine division of the short gastric blood vessels to enable better mobilization of the gastric fundus to facilitate the construction of a loose 360-degree wrap was advocated by Donahue in 1977 [51], and then DeMeester in 1986 [2]. This is probably the most common modification used when constructing a 360-degree fundoplication. Short gastric vessel division during Nissen fundoplication was the source of considerable disagreement between surgeons since the 1990s. However, multiple RCTs have now shown no benefit following the division of these vessels, and larger trials and meta-analyses have actually found that vessel division increases the risk of gas-related side effects such as flatulence and inability to belch [9,52,53].

To reduce side effects, yet still control reflux, partial fundoplication variants were developed and arguably have the greatest potential to address this issue. A posterior partial fundoplication was described by Toupet in 1963 [5], and anterior partial fundoplication was described by Dor, also in 1963 [4]. Posterior partial fundoplication variants place the gastric fundus behind the esophagus, and it is then sutured to both sides of the esophagus, leaving a portion of the anterior esophageal wall uncovered. Variations within this approach are to what extent the wrap covers the esophagus within a range of 180 to 270 degrees. Anterior partial fundoplications involve placing the fundus over the front of the esophagus and then suturing it to the esophagus and the hiatal rim. Variations from 90 to 180 degrees are described, with the 180-degree partial fundoplication anchored to the right hiatal pillar and the apex of the hiatus, and the lesser degrees not anchored to the right pillar, thereby leaving

a segment of uncovered esophageal wall on its right antero-lateral aspect [54,55].

All partial fundoplication variants aim to 1) stabilize a segment of intra-abdominal esophagus and 2) fashion a flap valve to control reflux. Cohort studies suggest reflux control is achieved with less side effects following these variants [54,56]. The areas of debate between anterior vs posterior partial fundoplication are around the extent of any reduction in side effects, and to what extent adequate reflux control is achieved. Key to long-term success is stabilizing the gastroesophageal junction below the diaphragm, with the gastric fundus sitting adjacent to the intra-abdominal esophagus to form a flap valve [57]. This anatomy needs to remain intact for the duration of the patient's life.

### 6.2. Randomized trials of Nissen vs posterior partial fundoplication

Over the last 3–4 decades many RCTs comparing Nissen with posterior partial fundoplication have been published. Many of the earlier trials were underpowered or only reported short-term outcomes, and now only contribute to meta-analyses. However, several RCTs have enrolled large cohorts and report long-term follow-up [30,58–69]. Table 1 summarizes the RCTs that enrolled more than 50 patients and followed patients for at least 1 year.

Lundell et al. [16] reported a trial of Nissen versus Toupet posterior partial fundoplication, which enrolled 137 patients. At 5-year follow-up reflux control and dysphagia were similar, whilst flatulence was more common after Nissen fundoplication at 2- and 3-year follow-up, and revision surgery was performed more often after Nissen fundoplication [70]. A later paper reported minimum 18-year follow-up from this RCT with success rates of more than 80% after both procedures, and no significant differences in side-effects at very late follow-up [30].

Zornig et al. [63] reported a RCT enrolling 200 patients. A good early outcome was reported in 90% in each group, and in 85% at 2 years. Reflux symptom control was similar. Guérin et al. enrolled 140 patients and reported similar outcomes at 3 years follow-up [65]. Booth et al. [66], Khan et al. [67], and Shaw et al. [68] enrolled 127, 121, and 100 patients, respectively, and all reported similar reflux control at 1-year.

**Table 1.** Randomized controlled trials of Nissen vs posterior partial fundoplication.

Trial author and year published	Number of patients	Maximum follow-up	Reflux symptoms controlled	Dysphagia	Able to belch	Satisfied with overall outcome
Lundell [16,30,70]	137	18 yrs	82% vs 90%	Mean score – 4.6 vs 3.3 (Maximum 45)	62% vs 82%	n/a
Zornig [63,64]	200	2 yrs	75% vs 83%	19% vs 8%	75% vs 87%	85% vs 85%
Guerin [65]	140	3 yrs	93% vs 95%	3% vs 0%	100% vs 97%	91% vs 89%
Booth [66]	127	1 yr	76% vs 76%	27% vs 9%	87% vs 95%	92% vs 91%
Khan [67]	121	1 yr	97% vs 87%	15% vs 3%	100% vs 100%	97% vs 100%
Shaw [68]	100	1 yr	83% vs 83%	6% vs 2%	n/a	89% vs 86%
Hakanson [69]	456	5 yrs	Mean score– 0.8 vs 0.5 (Maximum 7)	Mean score for solids – 1.5 vs 1.7 (Maximum 7)	n/a	n/a
Walker [60]	52	1 yr	100% vs 85%	8% vs 15%	n/a	n/a

Outcomes reported are from the most recent follow-up.

All comparisons are Nissen vs posterior partial fundoplication.

Only trials enrolling more than 50 patients and followed for at least 1 yr included in the table.

n/a = not available.

Dysphagia was more common following Nissen fundoplication in Booth's RCT. Hakanson et al. [69] reported the largest trial of Nissen vs posterior partial fundoplication, enrolling 456 patients. Less dysphagia was seen after posterior fundoplication at 12 months, but at longer term follow-up, this difference disappeared.

Meta-analyses of the Nissen versus posterior partial fundoplication RCTs have been reported and all conclude similar reflux control but less side effects after posterior partial fundoplication [71–73]. The evidence for less side effects in the meta-analyses is strongest for excessive flatulence and inability to belch. Dysphagia differences are less clear, likely less following posterior partial fundoplication at early follow-up, but with differences in dysphagia rates largely disappearing at follow-up beyond 5 years. Of note, a statistically significant reduction in dysphagia following posterior partial fundoplication has only been demonstrated in three of the published RCTs.

### 6.3. Randomized trials of nissen vs anterior partial fundoplication

Randomized trials have also compared anterior partial fundoplications with Nissen fundoplication. Table 2 summarizes the key RCTs. In 1999, Watson et al. [17] reported a RCT which enrolled 107 patients comparing Nissen vs anterior 180-degree partial fundoplication. At 6 months follow-up patients who underwent anterior fundoplication reported less dysphagia for solid food (15% vs 40%), were less troubled by flatulence (28% vs 49%), were more likely to be able to belch to relieve bloating (83% vs 68%) and reported a better overall outcome (94% vs 83%). Outcomes at 5 years showed similar reflux symptom control, with less dysphagia for solids (18% vs 27%), less bloating (44% vs 75%), and better preservation of belching (80% vs 57%) [36]. The proportion of patients reporting a good or excellent overall outcome at 5 years was higher after anterior fundoplication (94% vs 86%). Analysis of 10 years follow-up from this RCT found no difference for the two procedures for reflux symptoms and side-effects [74]. Most recently, good or excellent overall satisfaction outcome was reported in 94.7% after anterior fundoplication vs 85.4% after

Nissen fundoplication at 20 years follow-up [10]. However, there was a trade-off between reflux control and side effects, with the anterior 180-degree partial fundoplication associated with more reflux symptoms but less side effects (dysphagia, bloating, and flatulence) at 20 years. Of importance, when considering patient satisfaction outcomes, both procedures had high rates of overall success at very long-term follow-up, supporting the view that fundoplication is an excellent procedure for the long-term control of symptomatic gastroesophageal reflux.

In a similar RCT, Baigrie et al. [75] reported 2-year follow-up from 161 patients randomized to Nissen vs anterior 180° partial fundoplication and also found similar reflux symptom control, with less dysphagia following anterior fundoplication. A follow-up report of 12 years of follow-up showed similar outcomes, although re-operation for recurrent reflux was required more often after anterior fundoplication [76]. Cao et al. [77] reported similar reflux symptom control at 5-years and less flatulence after anterior fundoplication in a RCT, which enrolled 100 patients. Raue et al. [78] also reported similar outcomes at 18 months in a RCT of 64 patients.

Trials of lesser degrees of anterior partial fundoplication have also been reported. Djerf et al. [79] reported a RCT with 10-years follow-up following randomization of 72 patients to anterior 120 degrees vs Nissen fundoplication. Again, anterior fundoplication provided good control of reflux symptoms, with less dysphagia and less wind-related side effects. Other RCTs have compared a laparoscopic anterior 90-degree partial with Nissen fundoplication. A total of 112 patients were enrolled in a multicentre Australia and New Zealand RCT [80]. Early side-effects at 6 months were lower following anterior 90-degree fundoplication, but this was traded off against a slightly higher incidence of recurrent reflux. At 5 years, the outcomes in this RCT were similar for side-effects, but recurrent reflux was again more common after anterior 90-degree partial fundoplication [81]. Fewer side-effects, but more reflux, were also seen following anterior 90-degree partial fundoplication in a single-center trial which enrolled 79 patients [82]. After combining the data from both trials to deliver a cohort of 191 patients with 10 years follow-up, similar long-term success was seen for both procedures, but again with a trade-

Table 2. Randomized controlled trials of Nissen vs anterior partial fundoplication.

Trial author and year 1st published	Fundoplication types compared	Number of patients	Maximum follow-up	Reflux symptoms (heartburn score)	Dysphagia	Able to belch	Satisfied with overall outcome
Watson 1999 [10,17,36]	Nissen vs Anterior 180 degree partial	107	20 yrs	Score – 1.4 vs 3.2 (Maximum 10)	Score – 1.5 vs 1.0 (Maximum 10)	66% vs 84%	85% vs 95%
Baigrie 2005 [75,76]	Nissen vs Anterior 180 degree partial	161	12 yrs	Score – 0.0 vs 1.0 (Maximum 10)	Score – 1.5 vs 0.0 (Maximum 10)	79% vs 79%	90% vs 82%
Cao 2012 [77]	Nissen vs Anterior 180 degree partial	100	5 yrs	Score – 1.4 vs 1.5 (Maximum 10)	Score – 7.2 vs 5.3 (Maximum 45)	n/a	89% vs 92%
Raue 2011 [78]	Nissen vs Anterior 180 degree partial	64	1.5 yrs	4% vs 3%	7% vs 10%	n/a	92% vs 70%
Djerf 2016 [79]	Nissen vs Anterior 120 degree partial	72	10 yrs	Score – 2.0 vs 1.0 (Maximum 7)	Score – 1.0 vs 0.0 (Maximum 7)	66% vs 93%	n/a
Watson 2004 [80,81,83]	Nissen vs Anterior 90 degree partial	112	5 yrs	Score – 0.9 vs 2.2 (Maximum 10)	Score – 2.1 vs 1.5 (Maximum 10)	68% vs 91%	91% vs 84%
Spence 2005 [82,83]	Nissen vs Anterior 90 degree partial	79	10 yrs	Score – 2.0 vs 1.7 (Maximum 10)	Score – 3.7 vs 1.6 (Maximum 10)	60% vs 78%	76% vs 84%

Outcomes reported are from the most recent follow-up. All comparisons are Nissen vs anterior partial fundoplication. Scores are all means. n/a = not available.

off between reflux symptom control vs less side effects [83]. These outcomes were similar to the 20-year follow-up outcomes for the anterior 180° vs Nissen fundoplication RCT [10].

#### 6.4. Anterior vs posterior randomized trials and network meta-analyses

As both types of partial fundoplication offer acceptable reflux symptom control but with fewer side effects than Nissen fundoplication, a direct comparison of anterior vs posterior partial fundoplication is needed. Four RCTs have addressed this. Hagedorn et al. [84] enrolled 95 patients and showed better reflux control, but more side-effects following posterior partial fundoplication at up to 5 years. These outcomes were similar to the anterior partial vs Nissen fundoplication RCTs described above. Khan et al. [85], Roks et al. [86], and Daud et al. [87] all reported short term (up to 12 months) outcomes from RCTs enrolling 103 patients, 94 and 47 patients, respectively, with posterior fundoplication delivering somewhat better reflux symptom control but offset by more side-effects. These RCTs showed similar trade-offs to those seen in the Nissen vs anterior partial fundoplication trials.

Network meta-analyses have compared anterior vs posterior vs Nissen fundoplication, with a 3-way comparison achieved by combining data from multiple trials that compared 2 of the 3 procedures [71,72,88]. Each showed fewer side effects after partial fundoplications, and satisfactory reflux control after posterior partial fundoplication. Anterior partial fundoplication also achieved a good outcome in these analyses. The network meta-analysis from Andreou et al. [71] of 29 randomized trials identified fewer side effects after all partial fundoplication variants, as well as similar reflux control for Nissen vs posterior vs anterior fundoplication. They concluded that a posterior partial fundoplication is superior to Nissen fundoplication based on a large cohort of RCTs that could be included in their analysis. They also concluded that anterior partial fundoplications 'might be equally effective,' but with this statement considered conditional as a smaller number of RCTs including an anterior fundoplication were available for their network meta-analysis. Figure 1 summarizes the spectrum of outcomes that are delivered by the different fundoplication subtypes and highlights trade-offs.

#### 6.5. Alternatives to fundoplication

To address concerns about side effects following Nissen fundoplication, alternative approaches based on novel devices have been advocated. As these require the use of an expensive consumable, uptake has been limited in many countries. The common aim of these novel technology-driven approaches has been to control reflux but with fewer side effects. The evidence from the long-term outcomes of the RCTs discussed above suggests that this aim is met by the partial fundoplication options, which can be delivered cost-effectively using widely available conventional laparoscopic instrumentation. Uptake of alternative approaches is yet to be supported by studies that demonstrate either advantages or cost-effectiveness, when compared to laparoscopic approaches such as partial fundoplication.

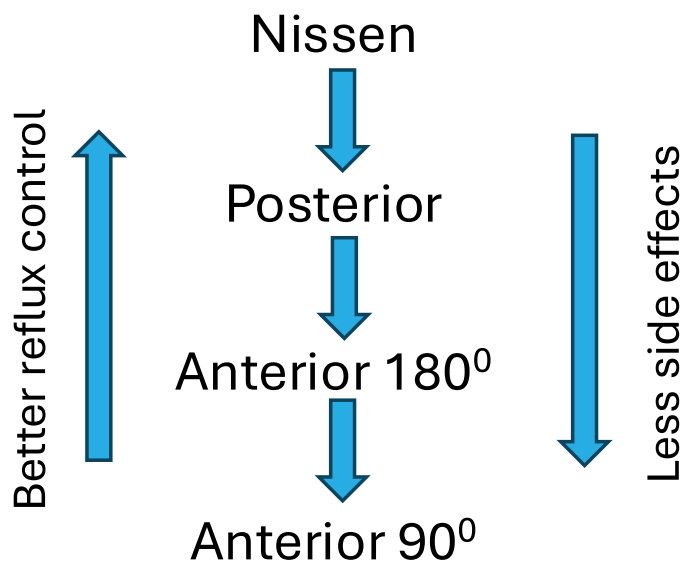


Figure 1. Trade-offs between reflux control vs side effects across the different fundoplication types.

One modification to the laparoscopic approach is the augmentation of the lower esophageal sphincter with an encircling implantable string of titanium beads with magnetic cores – the Linx™ Reflux Management System (Torax Medical, Shoreview, MN). This device is placed around the distal esophagus and aims to control reflux, without impacting swallowing or belching. Similar to fundoplication, success rates of approximately 90% are reported at short-term follow-up [89]. No randomized trials comparing this procedure to any fundoplication variant are reported. Although now performed in many centers in the U.S.A., it is not widely used elsewhere in the world, and convincing advantages over fundoplication, particularly partial fundoplication, are yet to be reported. Significant improvements in GERD Health-Related Quality of Life scores are reported in 85–90% of patients at 1–2 years follow-up [89], and Louie et al. [90] showed esophageal acid exposure time was normalized in 74.4% of patients after 1 year. Some have reported that 86–90% of patients could stop PPI use at 1–2 years [89], with others finding an 84.7% decrease in PPI use after 5 years [91]. These outcomes are no better than those reported following fundoplication, and longer-term outcomes from large cohort studies are lacking. Problematically, the magnetic sphincter augmentation device is a foreign body placed around the distal esophagus, and erosion of the device into the esophageal lumen has been reported in 0.3% of patients at up to 4 years follow-up [92]. This is a risk which is not inherent with fundoplication approaches.

Another alternative laparoscopic procedure advocated to reduce side effects is the RefluxStop device [93]. This entails accentuating the angle of His with sutures and then suturing a plastic ball-shaped device into the gastric fundus to stabilize the reconstruction. Short-term outcomes suggest good reflux control, but longer-term outcomes are awaited [93]. Again, this procedure involves implanting a foreign body which is likely to have a risk of erosion. Personal communication with a surgeon who has implanted this device confirms an

incidence of erosion resulting in gastro-gastric fistulas which allow the device to migrate into the gastric lumen in a subset of patients. Currently, this device is only available in Europe, and more robust data is required before it should be considered for routine use. Further, as the reconstruction has similarities to an anterior partial fundoplication minus the implant, it is not certain that the device adds to the antireflux barrier which is created by the partial fundoplication.

### 6.6. Novel endoscopic approaches

Since the 1990s, transoral endoscopic approaches have also been applied, although many have also since been abandoned. A full review of the earlier procedures is beyond the scope of this review. Effective antireflux procedures have been shown to work by fashioning a loose flap valve which accentuates and stabilizes the angle of His [57] and also stabilizes the gastroesophageal junction below the diaphragm. Apart from the Linx™ Reflux Management System, which encircles the esophagus with magnetic beads, no other effective procedure relies on encircling or tightening the gastroesophageal junction. The early endoscopic approaches all aimed to tighten the gastroesophageal junction using either endoscopic sutures or a tissue remodeling approach [94,95], and they predictably failed as the stenosis created did not control reflux adequately, and any impact was not durable. Endoscopic submucosal resection at the gastroesophageal junction to control reflux has also been described and relies on post-resection fibrosis to create a stenosis [96]. This procedure has also failed to go mainstream.

There are two endoscopic approaches that do try to replicate the principles of an anterior partial fundoplication. Transoral Incisionless Fundoplication (TIF) using the EsophyX device (Endogastric Solutions, Washington) is the more widely applied procedure [97,98]. It uses a standard endoscope for vision, combined with a proprietary device to retract the esophagogastric junction while compressing the gastric fundus against the esophagus and concurrently passing polypropylene fasteners between the esophagus and the fundus to create the anterior fundoplication. Good early clinical success rates of 55–80% at up to a 2-year follow-up were reported by Cadriere et al. [97]. However, normalization of esophageal acid exposure was seen in less than half of the treated patients in that series, an outcome which indicated that an effective fundoplication was not consistently achieved. A meta-analysis of five studies from Testoni et al. evaluated mean 5.3-year outcomes following TIF in 418 patients [99]. Satisfaction with the outcome was reported to be 70.6%, with only 24.2% abstaining from PPIs at 5 years follow-up.

Small RCTs of TIF vs PPIs have also been reported. Witterman et al. randomized 40 patients to TIF vs 20 to ongoing PPI treatment and reported reflux symptom improvement but no improvement in esophageal acid exposure or long-term objective reflux control [100]. Normalization of esophageal pH was only achieved in 29% in this study. Hakansson et al. enrolled 44 patients to a RCT of TIF vs sham endoscopy [101]. In this RCT, TIF outperformed sham, with pH normalized in 69% at 6 months, and reflux symptoms controlled in 59% of patients at 6 months follow-up. The results for TIF in these RCTs are inferior to those achieved by fundoplication.

It should also be recognized that TIF is unable to fix a hiatus hernia. This means it is not suitable in patients with a significant hiatus hernia that is usually defined as more than 2 cm in length. Hence, it is not applicable for the majority of the patients currently presenting for surgery for reflux, so for now its role remains limited.

A similar approach to TIF is the MUSE procedure (Medigus, Omer, Israel), which uses a dedicated stapling endoscope to also construct an anterior partial fundoplication. Outcomes appear similar to those following TIF. Kim et al. [102] reported outcomes from a cohort of 37 patients who underwent the MUSE procedure. Reflux symptoms were improved, and 69% of patients were able to cease PPI medication at 4 years follow-up, although pH monitoring only demonstrated normalization of acid exposure in 37%. The reported reflux control outcomes following both the TIF and MUSE procedures remain inferior to laparoscopic fundoplication approaches, and a durable partial fundoplication is achieved in less than half the patients who undergo one of these procedures.

## 7. Hiatus hernia

Hiatal hernias are common and often associated with gastroesophageal reflux. However, not all patients with reflux have a hiatus hernia, and not all patients with a hiatus hernia have reflux. When considering the implications of a hiatus hernia and how to manage it, it is important to consider the size of the hernia and the symptom presentation. When small hernias are present in patients undergoing surgery for reflux, the reflux presentation takes priority and drives decision-making, and the hernia is repaired as a routine component of a laparoscopic fundoplication. A small hiatus hernia in someone who does not have reflux or in someone in whom the reflux symptoms are well controlled by PPIs does not require repair.

Very large hiatus hernias are increasingly common in aging populations and represent an increasing component of the reflux/hiatus hernia surgical workload [103]. Hernias containing at least 50% of the stomach can present with either reflux or mechanical issues related to rotation of the stomach or volvulus. If reflux is the dominant issue, then this drives the decision making for or against surgery. If mechanical problems are the major issue, then even in the absence of reflux this is an indication for surgical repair.

Fit patients with a symptomatic large hiatus hernia containing more than 50% of the stomach should undergo repair, irrespective of age. For asymptomatic patients in whom a very large hiatus hernia has been identified, the decision-making is less clear. In 2002, Stylopoulos et al. [104] reported a modeling study that considered the risk vs benefit of repairing a very large hiatus hernia in patients without symptoms and concluded that anyone less than 65 years old should undergo repair, but if older than 65, then the risks likely exceeded any benefit. However, this study modeled data from the open surgery era, and it assumed that surgical repair was associated with a 1.4% mortality rate. These assumptions are not consistent with current laparoscopic outcomes. A recent laparoscopic case series analyzed outcomes from 12,422 patients using the NSQIP database and identified a much

lower mortality risk of 0.4% in patients up to the age of 80 [105]. Markov modeling from DeMeester et al. [106], which used recent data relevant to laparoscopic approaches, suggests that the age threshold for surgery in asymptomatic patients should be raised to at least 80 years. They also demonstrated the advantages of surgical repair in symptomatic patients aged up to 90.

In the early 2000's cohort studies reported objective follow-up from barium meal radiology studies after laparoscopic sutured repair of large hiatus hernias. Hashemi et al. [107] reported a 42% recurrence rate in 21 patients. Aly et al. reported a 30% recurrence rate in a larger series of 100 patients [21], and Smith et al. reported a 21% recurrence rate [20]. Although most hernias identified in these studies were not symptomatic and did not require surgical revision, concerns were raised that this might become a significant problem with longer follow-up.

### 7.1. Mesh for repair of hiatus hernia

Mesh reinforced surgical repair was advocated in response to concerns about high rates of radiological recurrence. An early RCT reported by Frantzides et al. [108] enrolling 72 patients to sutured vs polytetrafluoroethylene mesh repair demonstrated a reduction in hernia recurrence from 22% to 0% at early follow-up. Early outcomes from another RCT added further support for the use of mesh. Using an absorbable porcine-derived mesh material, Oelschlager et al. [109] reported a reduction in hernia recurrence from 24% to 9% at 6 months follow-up. However, when longer term follow-up outcomes were reported, the earlier mesh advantages disappeared, with small recurrent hernias seen in 59% vs 54% at 5 years [110].

Subsequent RCTs have failed to demonstrate any early or later advantages for mesh repair. A multicenter RCT from Watson et al. [111,112], which enrolled 126 patients, identified no advantages for either absorbable or non-absorbable mesh at early and then 5-year follow-up. Similarly, Anastos et al. reported 13-year follow-up of 145 patients in a randomized trial of sutured vs polytetrafluoroethylene mesh repair of hiatus hernia [113]. They also found no difference in hernia recurrence rates (31% vs 38%) but importantly found higher dysphagia scores after mesh repair at 13-year follow-up, concluding that mesh repair yielded a poorer clinical outcome. A recent meta-analysis of the seven published RCTs of mesh vs sutured repair of large hiatus hernias by Petric et al. [114] also showed no advantages for mesh repair at either early or late follow-up. As clinically significant recurrent hiatus hernias are relatively uncommon, all of these RCTs have used radiological or endoscopic hernia recurrence as a surrogate outcome of interest. RCTs powered to address clinically significant recurrences would require an impractically large number of patients.

Of concern, mesh repair of a large hiatus hernia has been followed by erosion of mesh into the esophageal lumen [115]. This can be difficult to deal with. Mesh, even if not eroded, makes any future revision operation significantly more difficult. Advocates for mesh repair suggest that a small recurrent

hernia might become a symptomatic clinical problem and then require later revision surgery, and that mesh will prevent this problem. The significance of small recurrent hernias was addressed by Wang et al. [22] in a study which identified 74 patients with a radiologically identified recurrent but asymptomatic hiatus hernia and then followed these patients for 5+ years. Clinical outcomes remained excellent in 94.6% of these patients, and only 2 patients required surgical revision during follow-up, refuting concerns about the progression of small recurrent hernias.

As randomized trials have failed to show benefits for repair with either non-absorbable or absorbable biological meshes, some surgeons have looked for alternatives and now advocate biosynthetic mesh to deliver a better outcome. Cohort studies with clinical follow-up following biosynthetic mesh repair have been reported and generally report good clinical outcomes but are limited to short-term follow-up and lack matched control groups [116,117]. Hernia recurrence rates are variable, reflecting different definitions of recurrence and variable objective follow-up. No RCT data are available to assess the value of biosynthetic meshes. At present, there is no logical reason to suggest that a biosynthetic mesh will result in fewer hernia recurrences than those following non-absorbable mesh repair. Before advocating for yet another mesh type, RCT evidence of better outcomes is needed.

### 7.2. Other approaches to repair of hiatus hernia

#### 7.2.1. Collis gastroplasty

It is likely that some patients acquire a shortened esophagus following damage from chronic gastroesophageal reflux, and when this is associated with a large hiatus hernia it is proposed that this might lead to difficulty returning the stomach fully below the diaphragm. Tension from this has been proposed as a risk factor for hernia recurrence. In 1957, the Collis gastroplasty was proposed as a solution for this [118]. This entails 'lengthening' the esophagus using stapling devices to fashion a gastric tube beyond the esophagus along the less curve aspect of the stomach and then creating a fundoplication around the 'neo-esophagus.' Proponents report good short-term outcomes [119,120], whereas skeptics point to the creation of an amotile tube of acid secreting stomach above a fundoplication and worry also about the risk of postoperative leakage from the gastric staple line [121]. The actual prevalence of a shortened esophagus is debated, with some surgeons performing a Collis procedure on up to 40–53% of the patients who undergo hiatus hernia repair [122,123], and others virtually never using this procedure. For now, most surgeons avoid this procedure [112].

#### 7.2.2. 'Relaxing' incisions

Another approach to repair hiatus hernias is a diaphragmatic relaxing incision. This entails extensively incising the lateral left hemidiaphragm to allow the left hiatal pillar to be sutured to the right hiatal pillar without tension, and then patching the surgically created left lateral diaphragmatic defect with mesh. The rationale for this is to reduce tension on the hiatal repair and to allow mesh to be placed well away from the esophagus to avoid any risk of mesh erosion into the

esophagus. Variable short-term outcomes have been reported [124,125]. Crespin et al. reported hernia recurrences in 56% at 6 months, whereas Mackay et al. reported recurrences in only 3.9%. Relaxing incisions are currently only performed in a few centers, and their complexity has discouraged wide use. Concerns also exist about complications following the division of the left hemi diaphragm, and herniation via the surgically created diaphragmatic defect has been reported [124]. As there is a lack of longer-term follow-up data or clinical trial evidence to support this procedure, most surgeons are reluctant to consider it.

### 7.3. The authors' approach to hiatus hernia

For the repair of a large hiatus hernia, the authors' preference is to 'keep it simple' by using a sutured repair, not placing mesh at the esophageal hiatus, and not complicating the procedure with either a diaphragmatic relaxing incision or a Collis procedure. This view is based on the lack of advantages for mesh or any other options in the RCTs. Further, it has been shown that a revision operation is only required in a small proportion of patients following sutured repair [110,112]. If further surgery is required, the authors would prefer not to encounter the additional difficulties of reoperating on the esophageal hiatus after mesh placement.

## 8. Robotic surgery

With the wider availability of robotic platforms for laparoscopic surgery in some parts of the world, robotic approaches have been advocated for fundoplication and hiatus hernia repair. Suggested advantages include high-definition 3-dimensional imaging and more flexible instruments to enable easier suturing [126]. Case series with similar short-term outcomes to those delivered by conventional laparoscopic approaches are reported. However, comparative studies suggest no advantages over laparoscopic approaches [127]. In a case-control study, Jensen et al. reported similar clinical outcomes for 39 patients undergoing a robotic fundoplication, compared to 64 who underwent conventional laparoscopic surgery, but operating times were increased by 49 min (135 vs 49) for the robotic fundoplication [128].

Using American health costings, Panse et al. reported a cost-utility analysis of robotic vs laparoscopic paraesophageal hiatus hernia repair [129]. They concluded that laparoscopic approaches were more cost-effective (US\$35,843 vs \$36,342 per quality adjusted life year gained), with the difference due to the additional equipment costs for robotic surgery. Ward et al. analyzed outcomes following laparoscopic vs robotic paraesophageal hiatus hernia repair using a large American population database and showed that the robotic approach was associated with more complications (odds ratio 1.17), and the risk of esophageal perforation was more than doubled (odds ratio 2.19) [130].

As conventional laparoscopic approaches are well established, and robotic approaches take longer to perform and require more expensive equipment and consumables [131], it is hard to see how a robotic platform, which requires virtually identical surgical wounds for access, will be able to offer

demonstrable advantages over established laparoscopic techniques. Unless future longer term outcome studies, RCTs and health economic analyses demonstrate clear advantages, robotic hiatus hernia repair should not be considered to offer any advantage over established laparoscopic approaches.

## 9. Conclusion

Surgery for gastroesophageal reflux and hiatus hernia is well established. Large cohort studies and RCTs provide excellent outcome data at up to 20 years follow-up and confirm the effectiveness of all fundoplication types. Few other areas of medical practice are informed and supported by this level of evidence. For fit patients with symptoms of gastroesophageal reflux that are not well controlled by PPI medication, and also those with a very large hiatus hernia, laparoscopic surgery offers an effective solution that delivers a good long-term outcome in most individuals. As multiple RCTs provide high-level evidence which confirms better reflux control after fundoplication, a discussion with a surgeon should be facilitated for patients with troublesome gastroesophageal reflux and/or hiatus hernia. Surgeons should have adequate experience with the assessment of patients for surgery for gastroesophageal reflux, and also a good understanding of the evidence supporting the different approaches to treatment and the ability to apply the evidence to the nuances of each patient's presentation.

Meta-analyses of RCTs comparing Nissen with posterior and anterior partial fundoplication variants support the construction of both types of partial fundoplication, and confirm that these approaches deliver good reflux control, but with a lower risk of side effects. Meta-analyses of RCTs comparing mesh with sutured repair for hiatus hernia show no benefit for adding mesh to hiatus hernia surgery. For now, the debate is whether to construct an anterior vs posterior partial fundoplication for patients undergoing surgery for gastroesophageal reflux.

Alternatives that require the use of proprietary equipment or devices are advocated as solutions to the problem of side effects after Nissen fundoplication. However, long-term outcomes of these approaches are unclear, reflux control is less certain, and the requirement for an expensive device or piece of equipment means these approaches are more expensive and less reliable than a partial fundoplication. Any new approach should be tested in RCTs which use an appropriate comparator, arguably a partial fundoplication.

For now, the weight of evidence confirms that laparoscopic fundoplication is the gold standard for the treatment of gastroesophageal reflux in individuals in whom PPIs are not delivering a good outcome. For the authors, a partial fundoplication is the preferred approach for reflux, and mesh is not used for hiatus hernia repair.

## 10. Expert opinion

Surgery for gastroesophageal reflux disease has been performed since the 1950s, with Nissen fundoplication the procedure of choice in most centers until the 1990s. Multiple RCTs

confirm the superior efficacy of Nissen fundoplication for reflux control compared to PPI medication, as well as better short-term outcomes with laparoscopic approaches, and advantages for partial funduplications. Both anterior and posterior partial funduplications deliver excellent reflux control and a lower incidence of post-fundoplication side effects than seen after Nissen fundoplication. For patients requiring surgery for reflux, disagreement exists about which type of partial fundoplication to construct.

Partial funduplications are potentially applicable for all patients requiring surgery for gastroesophageal reflux. Unlike Nissen fundoplication, anterior partial fundoplication achieves good outcomes in patients with poor esophageal peristalsis and has been shown to deliver excellent outcomes in patients with an aperistaltic esophagus, and in patients with scleroderma. Hence, this option can be considered in all patients with gastroesophageal reflux in whom PPIs are not effective, irrespective of concerns about esophageal peristalsis or hiatus hernia.

Alternative newer procedures that require the use of a proprietary device or implant and have been advocated as solutions to side effects after Nissen fundoplication. However, the requirement for a novel device or implant means they are more expensive than the established laparoscopic approaches, and case selection restrictions mean they are not suitable for all patients with reflux and/or hiatus hernia. Similarly, robotic platforms for hiatus hernia repair have not been shown to deliver any clinical advantages, and they are also likely to add cost due to the requirement for more expensive equipment and consumables. Before advocating the routine use of any new device, platform, or procedure, new options should be evaluated within appropriately designed randomized trials and cohort studies which follow a large enough cohort for sufficient time to demonstrate safety and efficacy. Currently, evidence from trials shows that concerns about post-Nissen fundoplication side effects can be addressed by constructing a partial fundoplication, and this can be delivered using widely available conventional laparoscopic equipment.

For repair of large hiatus hernia disagreement exists about the use of mesh to repair the diaphragmatic defect. Outcomes from early RCTs and cohort studies suggested fewer hernia recurrences in patients following mesh repair. However, subsequent larger RCTs failed to demonstrate any advantages for mesh repair, and recent meta-analyses of the published RCTs show no reduction in hernia recurrence following mesh repair. Level I evidence suggests that mesh should not be used routinely for hiatus hernia repair. Any alternative proposal should be supported by evidence from new randomized trials.

For now, excellent outcomes following surgery can be achieved if patients with appropriate symptoms undergo appropriate workup, are well selected, and undergo surgery with an experienced surgical team. Case selection is facilitated by collaboration between surgeons, gastroenterologists, and others involved in the care and workup of patients with gastroesophageal reflux. Multidisciplinary team (MDT) meetings have become the standard of care for cancer management, and benign disease upper gastrointestinal MDTs are now emerging for the management of patients in whom decision-making is not clear. As case selection is critical for

good outcomes for patients with gastroesophageal reflux and hiatus hernia, and surgical techniques are now well established and understood, improved case selection is likely a key area for future development.

## Funding

This paper was not funded.

## Declaration of interests

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

## Reviewer disclosures

Peer reviewers on this manuscript have no relevant financial or other relationships to disclose.

## Author contributions

We adhere to the definitions of authorship set out by the International Committee of Medical Journal Editors (ICMJE). Both authors have made substantial contributions to the conception and design of the work review of the literature, drafting the work or reviewing it critically for important intellectual content, and give approval of the final version to be published.

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