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ORIGINAL ARTICLE

Long-term results after laparoscopic revision fundoplication: a retrospective, single-center analysis in 194 patients with recurrent hiatal hernia

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Abstract

Background After laparoscopic fundoplication, 10–20% of patients experience symptom recurrence—often due to resurgence of the hiatal hernia. The standard surgical treatment for such cases remains laparoscopic revision fundoplication. However, there is little data on the time frame and anatomic patterns of failed fundoplications. Additionally, few large studies exist on the long-term efficacy and safety of laparoscopic revision fundoplication.

Methods In a single-center, retrospective analysis of 194 consecutive revision fundoplications for recurrent reflux disease due to hiatal hernia, we collected data on time to failure and patterns of failure of the primary operation, as well as on the efficacy and safety of the revision.

Results The median time to failure of the primary fundoplication was 3 years. Most hiatal defects were smaller than 5 cm and located anteriorly or concentric around the esophagus. Laparoscopic redo fundoplication was technically successful in all cases. The short-term complication rate was 9%, mainly dysphagia requiring endoscopic intervention. At a mean follow-up of 4.7 years, 77% of patients were symptom-free, 14% required daily PPI, and 9% underwent secondary revision. Cumulative failure rates were 9%, 23%, and 31% at 1, 5, and 10 years.

Conclusion The majority of failed fundoplications occur within 3 years of primary surgery, with most patients exhibiting anterior or concentric defects. For these patients, laparoscopic revision fundoplication is a safe procedure with a low rate of short-term complications and satisfactory long-term results.

Keywords Gastroesophageal reflux · Fundoplication · Hiatal hernia · Reoperation

Introduction

Primary fundoplication fails to resolve reflux symptoms sustainably in 10–20% of patients [1, 2]. Failure typically occurs when the hiatal crura detach and the fundoplication misaligns during the postoperative course [3, 4]. Most patients present with recurrent heartburn and acid regurgitation. Laparoscopic surgical revision remains the gold standard after failed primary fundoplication if medication proves ineffective.

During revision, most surgeons combine renewed suturing of the hiatal crura with a secondary 270′ (Toupet) or 360′ (Nissen) fundoplication [5]. Correction is often complicated by adhesions and anatomic variations, such as a large hiatal defect or short esophagus. Reoperation endangers adjacent mediastinal structures; the most common serious complications comprise injuries to the esophagogastric junction. Redo anti-reflux surgery is generally associated with higher perioperative mortality and morbidity and poorer outcomes than primary surgery [6, 7].

Consequently, laparoscopic revision fundoplication requires expertise to ensure patient safety and efficacy. Failure and complication rates decrease with surgeon experience

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[8]. However, there is little data from high-volume centers on the safety and effectiveness of revision and on patterns of failure of the primary fundoplication [9]. In a recent meta-analysis, only five studies included more than one hundred patients [10].

We thus conducted a retrospective analysis with patient data from one of the largest patient cohorts undergoing laparoscopic revision fundoplication across Europe.

The aim of this paper was twofold. Firstly, we wanted to determine when the primary fundoplication failed and why. For this purpose, we reviewed the time to failure between the initial and redo surgery and analyzed the anatomy of the hiatal hernia at the time of the revision concerning its size and type.

This paper's second and primary objective was to determine the long-term efficacy and safety of redo fundoplication. This analysis included postoperative complications and time-dependent failure rates, i.e., the proportion of patients who needed to re-uptake proton pump inhibitors, were diagnosed with recurrent hiatal hernia, or underwent a second revision operation for each year.

Methods

This was a retrospective single-center analysis of laparoscopic redo fundoplication cases in Berlin, Germany. Inclusion criteria included all patients (i) ≥ 18 years, (ii) who underwent laparoscopic revision of their primary fundoplication between January 2010 and December 2020, (iii) for recurrent gastroesophageal reflux disease, (iv) and underlying recurrent hiatal hernia. Exclusion criteria comprised alloplastic hiatal augmentation and revision due to a mechanical failure of the wrap without a corresponding hiatal hernia.

As part of our protocol after anti-reflux surgery, patients are given a standardized questionnaire at 1, 5-, and 10 years post-surgery. This questionnaire covers side effects like dysphagia and bloating/gas, recurrence of the disease, and subsequent treatments, including surgical revision and proton pump inhibitor (PPI) reuptake. For this research, we contacted patients for routine check-ups or phone calls to monitor any changes in their treatment or disease progression since their last scheduled contact. Records are updated automatically within our electronic database (ORBIS U, Leeds, United Kingdom), including intraoperative imaging for each surgery. The PPI reuptake rate was defined as daily medication usage. "Surgical redo" refers to any case where the initial surgery needed revision, regardless of the reason, including the recurrence of the disease or immediate operative complications and side effects.

The first part of the analysis included the time to failure since the primary fundoplication and the anatomical pattern of the hiatal defect. The recurrence of the hiatal hernia was confirmed pre- and intra-operatively. Hernia size was estimated in two ways: firstly, the size was categorized as small (I, 0–2 cm), moderate (II, 2–5 cm), large (III, > 5–10 cm), or massive (IV, > 10 cm) as proposed by Suppiah et al. [11]. Secondly, the hiatal hernia surface area (HSA) at the time of the primary fundoplication was compared relatively with the HSA at the time of revision for patients who received surgery at both times at our clinic, using the formula proposed by Granderath et al. [12]. The measurement of the hiatal defect sizes via digital imaging tools was conducted by a separate team, which was not involved in the analysis and writing of this manuscript. Finally, to analyze the anatomical patterns of failure, i.e., the location of the hernia to the esophagus, a modified version of the second categorization proposed by Suppiah et al. was used: defects were thus categorized as anterior, posterior, concentric, and lateral to the esophagus [11]. In the case of a concentric hernia, surgeons found a circular defect around the esophagus after preparation of the hiatus with varying width.

The second part of the analysis included the failure rate—defined as the combined rate of secondary redo fundoplication, recurrent hiatal hernia, or daily proton pump inhibitor re-uptake–and safety measures. Safety endpoints included perioperative complication (as measured by the Clavien Dindo classification) and conversion rates [13].

The distributions of continuous variables are expressed as mean ± standard deviation (SD), those of categorical variables as counts (percentage of total). For the subset of patients who received their primary fundoplication at our institution (n = 157), the time between primary surgery and primary revision was available. We calculated the median time to revision in this group. For analysis of the annual risk of primary revision failure, the second period, our approach was twofold. Initially, we employed the Kaplan–Meier estimator to ascertain the annual risk as described elsewhere [14]. Subsequently, to identify significant predictors of treatment failure, we applied serial uni- and multivariable Cox proportional hazard models [15]. Variables included age, BMI, surgical technique, as well as hernia size and type. Age and body mass index (BMI) were categorized based on their median values. Hernia size was treated as a continuous variable in cm, while hernia type (anterior, posterior, concentric, lateral) and surgical technique (Nissen, Toupet, Hemifundoplication) were considered categorical. We employed the least absolute shrinkage and selection operator (LASSO) method to evaluate multiple models, including interaction effects, ensuring robustness in identifying significant predictors [16]. A significance level (alpha) of 0.05 was used for all statistical tests. All statistical analysis was performed using R Statistical Software (version 4.3.1; R Foundation for Statistical Computing, Vienna, Austria).

In our surgical approach, the decision to perform Nissen versus Toupet fundoplication for primary surgeries and the choice of hemifundoplication for revisions, was primarily guided by intraoperative findings, especially the mobility of the gastric fundus. Nissen 360° fundoplication, combined with hiatoplasty, was our standard procedure. However, in cases where limited fundus mobility impeded the creation of a complete wrap without tension, a 270° Toupet fundoplication was performed. During revision surgeries, our primary concern is to mitigate complications related to the blood supply in the fundus/gastrointestinal junction area, such as ischemia and subsequent necrosis due to excessive tissue pressure. Therefore, when confronted with increased tissue tension, our preferred approach is to opt for less extensive cuffs, such as Toupet or hemifundoplication, combined with fundophrenicopexy (a single knot from the fundus to the diaphragm). This patient-specific decision-making process, underpinned by a commitment to tailoring the surgical technique to the observed anatomical and functional characteristics, aimed to optimize outcomes while minimizing potential complications.

Results

Characteristics of the study group

Three surgeons performed 194 laparoscopic revisional fundoplication procedures for recurrent reflux symptoms between July 2011 and November 2020. On average, patients were 61 years old at the time of surgery, and most were female (Table 1). All Surgeries were conducted laparoscopically within an average duration of 60 min. Most patients were discharged within 3 days, with the range of hospital stay being 2–6 days. The mean follow-up was 4.7 years (range 1–11).

Table 1 Descriptive characteristics of the study group, means ± SD or N (%)

Characteristic	
N	194
Age (years)	61 ± 12
Female	116 (60%)
Male	78 (40%)
Recurrent gastroesophageal reflux disease, hiatal hernia	194 (100%)
Surgery duration (min)	60 ± 21
Laparoscopy	194 (100%)
Hospital stay (days)	3 ± 1
Surgery type (primary fundoplication)	
Nissen	165 (85%)
Toupet	29 (15%)
Surgery type (revision fundoplication)	
Nissen	119 (61%)
Toupet	44 (23%)
Hemifundoplication	31 (16%)

The primary fundoplication procedures consisted of 165 (85%) Nissen and 29 (15%) Toupet cases. For revision fundoplication, the distribution was 119 Nissen (61%), 44 Toupet (23%), and 31 Hemifundoplications (16%), highlighting reduced tissue mobility during redos.

Patterns of failure of the primary fundoplication

Time to revision surgery

Time between primary and redo fundoplication was available for 157/194 (81%) patients who underwent their initial surgery at our institution. The median time between primary and redo fundoplication was 3 years (range 1–11), with 43% (n = 68/157) of patients requiring revision within 2 years and around one-third (n = 42/157, 27%) needing the second surgery 8 years or later (Fig. 1).

Hiatal defect anatomy at the time of revision

Hernia Size—Moderate defects (II, 2–5 cm) of the hiatus were the most common across all periods—comprising 63–82% (Fig. 2). Their incidence increased as patients presented later since their primary fundoplication. Larger hernias (III and IV, ≥ 5 cm) made up 25%, 28%, and 16% of cases at ≤ 2, 2–4, and ≥ 6 years, respectively. Minor defects (I, < 2 cm) were only relevant during the early years of treatment failure (12% at ≤ 2 years) and were uncommon (≤ 5%) as patients presented further from the initial intervention.

Hernia Type—Concentric hernias, i.e., hernias where the surgical site displayed a concentric hiatal defect and axial migration of the cardia, remained the most prevalent across all periods—comprising 44–70% of cases (Fig. 3). The second most common defect, hernias placed anteriorly, tended to occur in the earlier postoperative years (32% and

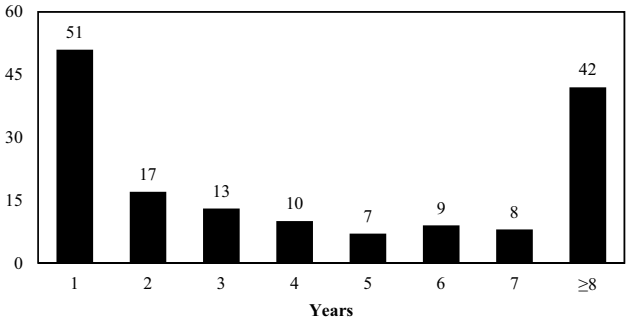

Fig. 1 Years since primary fundoplication. Number of patients who underwent initial surgery at our institution. N = 157

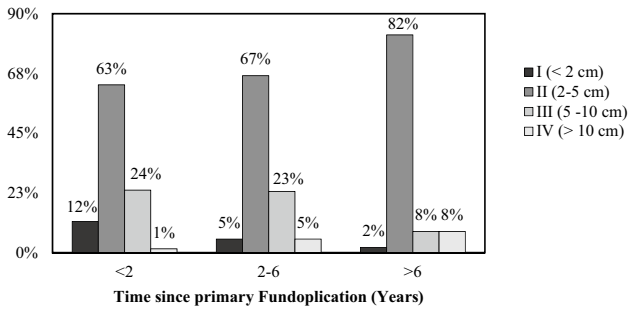

Fig. 2 Hernia size, N = 194

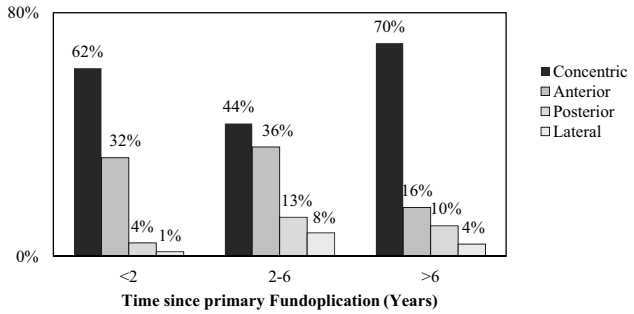

Fig. 3 Hernia type, N = 194

36% at ≤ 2 and 2–4 years) and became less frequent at year six and onward (16%). Predominantly posterior and lateral gaps occurred infrequently, with less than 10% of patients presenting with these defects at ≤ 2 years and around 15% past the 6-year mark.

The hiatal surface area (HSA) during primary surgery and revision—This section compares the hiatal hernia surface area at the time of re-fundoplication to the HSA at the time of primary surgery among a subset of patients who received prior anti-reflux surgery at our clinic (42%, n = 81/194 patients). At the time of the revision, surgeons noted a reduction in the hiatal hernia surface (defined as a reduction by a minimum of 25%) in 70% of this group (n = 57/81). However, in 25% (n = 20/81) and 5% (n = 4/81) of patients, the defect size remained relatively the same or increased (by more than 25% of the area) compared to presentation at the initial operation, respectively.

Efficacy and safety of revision fundoplication

Efficacy

At a mean follow-up of 4.7 years, 23% of patients (n = 44/194) had a recurrence of their conditions, defined as a return of the hiatal hernia or the need to use proton pump inhibitors. Of those, 41% (n = 18/44) underwent tertiary surgery. Primary redo fundoplication procedures failed predominantly during the first 3 years, with 65% of failures occurring during this period (Fig. 4, Table 2).

The failure-free probability was 91%, 77%, and 69% at 1, 5, and 10 years. 9% (18/194) underwent additional, secondary revision. We utilized serial uni- and multivariable Cox proportional hazard models to assess factors such as age, sex, surgical technique, BMI, hernia size, and type, as well as the interaction effects among these variables. Despite this comprehensive analysis, none of these factors emerged as statistically significant predictors of failure at the predefined alpha level of 0.05.

Safety

A minority of the patients (9%, n = 18) experienced postoperative complications, with a median Clavien-Dindo severity level of three (Table 3). No deaths occurred, and all complications were successfully managed. Most patients required endoscopy (n = 11, 6%): in six of these cases, patients underwent endoscopic intervention due to dysphagia. In four cases, injury to the esophageal junction or fundus occurred and required surgical revision. However, conversion to open surgery was not needed in any case, demonstrating the procedure's safety. The major morbidity rate (defined as a Clavien Dindo ≥ 3) was 8% (16/194).

Discussion

Key findings—We found that redo fundoplication effectively manages reflux symptoms in 77% of patients with recurrent hiatal hernia at a mean follow-up of 4.7 years. The cumulative failure-free rate at 10 years was 69%. The data also show that revision is safe, with a complication rate of 9%—conversion to open surgery did not occur. When we analyzed the patterns of hiatal failure at the time of the revision, we noticed that most patients exhibited medium-sized, i.e., smaller than five centimeters, as well as predominantly concentric and anteriorly located defects.

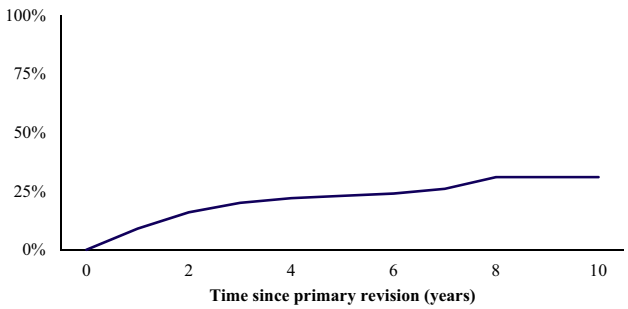

Fig. 4 Cumulative risk of revision failure, N = 194

Table 2 Annual Risk of Revision Fundoplication Failure

Year	0	1	2	3	4	5	6	7	8	9	10
Failure rate %	–	9%	7%	4%	2%	1%	1%	2%	5%	0%	0%
At risk	194	151	136	117	96	75	51	37	19	12	5

Table 3 Postoperative complications, Clavien-Dindo classification

Grade		Complication	Treatment	n (%)
I	(n = 1)	Pleural effusion	Breathing therapy	1 (1%)
II	(n = 1)	Abscess	Antibiotics	1 (1%)
IIIa	(n = 12)	Pneumothorax	Drainage	1 (1%)
		Dysphagia	Endoscopy	11 (6%)
IIIb	(n = 4)	Perforation/ ischemia EG-junction	Surgical revision	4 (2%)
IV	0			
Total				18 (9%)

Patterns of failure of the primary fundoplication—More than half of patients who required revision of their fundoplication did so within 3 years. This finding aligns with prior large-scale studies on redo surgery, reporting that primary fundoplication mostly fails within 2–3 years [17, 18]. Our analysis demonstrates that anterior and concentric defects comprise over 90% of hiatal hernias during this early period. This range coincides with the findings by Suppiah et al.: they report that most patients requiring revision suffer from anterior–posterior/concentric or anterior (90%) but rarely isolated posterior (10%) defects [11]. They also find that small to medium-sized hernias comprise 50% of their sample–contrasting with around 70% in this study. Given the lack of research with a comparable analysis, we cannot gauge whether this delta is due to differences in measurement technique or discrepancies in patient characteristics. To further classify crural misalignment, we compared the hernia surface area (HSA) in patients who received primary surgery at our clinic. We found that 70% of those patients continued to exhibit a reduction of more than 25% of the HSA at the time of revision compared to initial fundoplication. The overall findings on hiatal anatomy beg the question about a standardized measuring and classification tool for fundoplication research, as the application of methods is incoherent across the literature. We conclude that anterior stabilization techniques may reduce fundoplication failure rates.

Efficacy of redo fundoplication—The surgical revision and medication re-uptake rates after redo fundoplication were 9% and 14% at a mean follow-up of 4.7 years, respectively. Three major studies have been published on secondary redo rates: In a cohort of 307 patients examined by Smith et al., 7% and 17% of patients underwent a second redo or used anti-secretory medications at a median follow-up of 1.2 years, respectively [18]. A second study in 275 patients by Awais et al. revealed a re-operation rate following revision of 11% at a median follow-up of 3.3 years; no information was given on medication re-uptake [17]. In a recent follow-up of redos in 288 patients, daily PPI intake was 12% at a mean follow-up of 6.5 years [7]. Merging our results with the literature, long-term PPI re-uptake and secondary redo fundoplication may be expected in 10–15% and 10% of patients, respectively.

Our findings also underscore the challenge in predicting treatment failure following redo fundoplication. Traditional predictors, including demographic variables, hernia characteristics, and surgical technique, did not exhibit significant predictive value in our study. This may likely be attributed to the inherently high risk of failure in revision surgeries and possibly complex, unmeasured patient-specific factors. Future research may benefit from exploring broader, multidimensional datasets to predict surgical outcomes in this high-risk group.

Safety of redo fundoplication—The major morbidity and conversion rates in this study were 8% and 0%, compared to 5% and 6% reported in a recent meta-analysis by Schlottman et al. [10]. While our results lie within the rate ranges provided in their study, it seems likely that the comparatively low conversion rate across our cohort may be explained by increased laparoscopic proficiency over the past decade. On average, later studies in this meta-analysis demonstrate lower conversion rates—supporting the argument of a learning effect in the field. In addition, we present one of the most extensive case series published today, and high-volume hospitals are known to provide improved anti-reflux surgery [19]. Our findings thus suggest that, with experience, conversion rates to open surgery diminish in redo fundoplication. Accordingly, patients may be streamlined toward centers with a high caseload.

Outlook—The surgical safety of redo fundoplication has improved dramatically over recent decades. In response, researchers aim to decrease failure rates further. Given that mesh grafts remain the standard of care to treat inguinal and abdominal wall hernias, some surgeons propose its use in hiatal hernia treatment. Strengthening the crura using a prosthetic mesh may improve outcomes by preventing recurrent detachment. This is supported by the fact that we found many anterior and concentric defects, which lend themselves to mesh repair. A study of 31 individuals undergoing revision anti-reflux surgery using polypropylene mesh

implementation reported that no patient required revision surgery after 1 year [20]. Similarly, in a study of 73 patients receiving re-intervention, mesh repair was associated with reduced postoperative symptoms compared to conventional fundoplication [2]. This technique may become an essential solution for patients whose primary fundoplication failed.

Summary and limitations—We present novel data, including one of the most extended follow-ups published from a single surgical center on PPI reuptake and revision rates after redo fundoplication. Merging our findings with previous research, redo surgery appears to be a safe and efficient option for patients suffering from persistent gastroesophageal reflux disease with underlying recurrent hiatal hernia. Future studies should develop standardized techniques for assessing the hiatal defect—as we could not identify any established method. Recently, researchers proposed categorizing patients based on the hiatal surface area before primary fundoplication using computer tomography-based measurements—an approach that has yet to be proven cost-effective and non-hazardous [21, 22]. Given the high incidence of anterior and concentric failures after primary fundoplication, the evaluation of mesh augmentation as a surgical treatment for reflux disease due to hiatal hernia could improve outcomes in the future.

Conclusion

The main objective of this study was to assess the long-term efficacy and safety of a laparoscopic approach to redo fundoplication in patients with recurrent hiatal hernias. Our data clearly show that redo surgery is associated with low complication rates (9%) and resolves symptoms in 70% of patients after 10 years—with less than 10% requiring additional surgery. We conclude that laparoscopic redo fundoplication is safe and efficient for patients with persistent reflux symptoms after primary surgery.

The majority of redos occurred within 3 years of primary fundoplication. We also conclude that most recurrent hiatal defects after primary fundoplication are medium-sized ($\leq$5 cm) and appear anteriorly or concentric around the esophagus. Further research on hiatal stabilization techniques, including mesh implementation for primary and revision fundoplication, is warranted.

Author contributions All authors contributed to the study's conception and design. Björn Siemssen and Marius Ibach performed material preparation, data collection, and analysis. Marius Ibach wrote the first draft of the manuscript, and all authors commented on previous versions of the manuscript. All authors—Björn Siemssen, Florian Hentschel, and Marius Ibach—read and approved the final manuscript.

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Declarations

Ethical Statement All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and national research committee and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

Conflict of interest Dr. Ibach, Dr. Siemssen, and Dr. Hentschel declare that they have no conflict of interest.

Informed consent Informed consent was obtained from all individual participants included in the study.

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