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## Laparoscopic Omega-type fundoplication ( $\Omega$ TF) is a Safe and Effective Method for GERD – Data on Radiologic and Clinical Follow-Up

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### ABSTRACT

**Background:** Laparoscopic  $\Omega$ -type fundoplication ( $\Omega$ TF) is a novel technique for gastroesophageal reflux disease (GERD), combining hiatoplasty with His-angle reconstruction by a 150° two-layered left-sided fundoplication. This retrospective analysis evaluated safety and efficacy of  $\Omega$ TF during one-year follow-up.

**Methods:** 198 consecutive patients undergoing  $\Omega$ TF at the Medical University Vienna were included. Safety, symptoms, hernia recurrence, and quality of life were evaluated. GERD-HRQL scores and contrast swallow X-rays were performed during follow-up.

**Results:** Early hernia recurrence occurred in 4 patients, 2 requiring revisional surgery. Normal food intake by day 2 was achieved in 98.6%, median hospital stay was 1day (IQR: 1–2). At mean follow-up of 1.1 (0.7–1.5) years, PPI use decreased from 88.0% to 5.1%. Reflux, bloating and dysphagia decreased to 4.6%, 8.8% and 4.0% ( $p < 0.001$ ), while new onset dysphagia occurred in 2.6%. GERD-HRQLs improved from  $25 \pm 9.6$  to  $4 \pm 7.5$  ( $\Delta -17$ ,  $p < 0.001$ ). Suboptimal clinical response was reported by 4.5% ( $n = 9$ ), whereas radiologic recurrence occurred in 6 cases (3.0%). Revisional surgery was required in 7 cases (3.5%). Overall, 82.4% reported improved postoperative satisfaction and QoL ( $p < 0.001$ ).

**Conclusion:**  $\Omega$ TF appears safe and effective, providing substantial symptom relief, improved QoL, and low short-term hernia recurrence. Prospective studies are required to confirm these results.

**KEYWORDS**  $\Omega$ -type fundoplication; gastroesophageal reflux disease; his angle reconstruction; modified Lortat-Jacob fundoplication; upper gastrointestinal surgery

### BACKGROUND

Gastrointestinal Reflux Disease (GERD) is one of the most prevalent gastrointestinal disorders, currently affecting more than one fourth of the western population [1–3]. In addition to nutritional behavior and lifestyle factors, functional and anatomical alterations of the anti-reflux barrier, as defined by the American Foregut Society (AFS), play a key-role in GERD development. The three primary components of this barrier are the lower esophageal sphincter (LES), the crural diaphragm and the gastrointestinal flap valve (GEFV). Additional anatomical factors such as the esophageal hiatus, the angle of his and the esophagogastric junction (EGJ) further contribute to barrier function [4–6]. Dysfunction of the LES, weakness of the diaphragmatic sphincter, widening of the hiatus or a disruption of the GEFV can result in GERD [7]. Symptoms can vary and range from heartburn and regurgitation to dysphagia and laryngo-pharyngeal reflux (LPR) [8]. GERD, although benign, may progress to Barrett's esophagus (BE), a premalignant metaplasia at the EGJ that can evolve into esophageal adenocarcinoma (AEG) [9,10]. Accurate and timely diagnosis as well as appropriate treatment of GERD is essential.

The standard diagnostic work-up for GERD includes clinical assessment by performing symptom related questionnaires, including the GERD-Health-Related Quality of Life (GERD-HRQL) scores,

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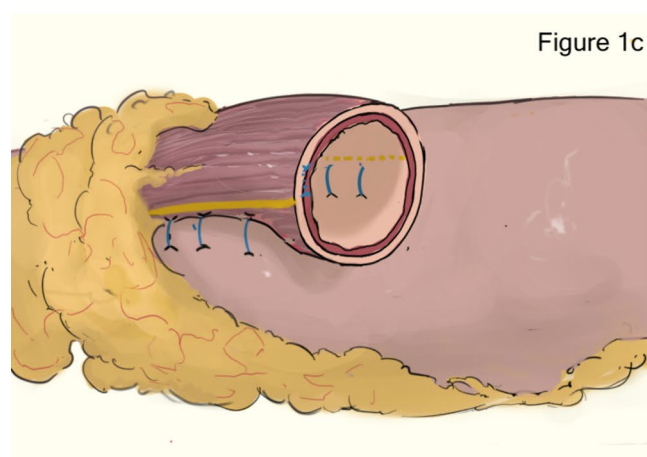
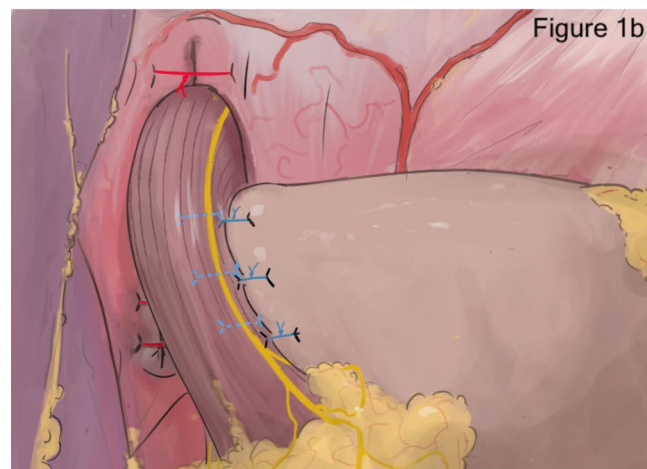
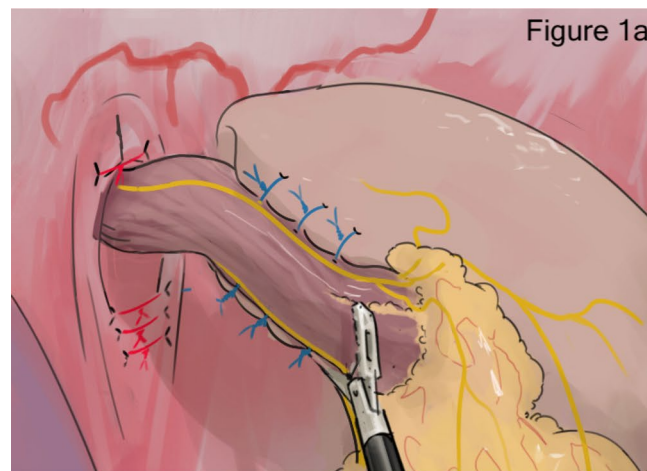
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esophagogastroduodenoscopy (EGD) for diagnosis of Hiatal Hernia (Hill classification, AFS classification) and esophagitis (LA-classification A-D, a 24-h multichannel intraluminal impedance-pH monitoring (24-hMII-pH) and high-resolution manometry (HRM) to assess esophageal peristalsis and identify motility disorders, including ineffective esophageal motility (IEM). Clinical assessment is performed by symptom related questionnaires and GERD-Health-Related Quality of Life (GERD-HRQL) scores.

Dysfunction of the GEFV is often associated with the presence of a Hiatal Hernia (HH), increased esophageal acid exposure and abnormal morphology of the EGJ. Consequently, GEFV integrity is considered as a key element of the anti-reflux barrier and therefore incorporated into the AFS classification as a relevant diagnostic parameter [11].



**Figure 1.** Laparoscopic  $\Omega$ -type fundoplication from multiple angles.

When conservative treatment – including lifestyle modification and acid suppressive therapy – fails, laparoscopic anti-reflux surgery (LARS) is indicated [8,12]. Laparoscopic Nissen fundoplication (LNF) remains the international gold standard for GERD, offering long-term effective symptom control. However, adverse effects such as postoperative dysphagia, gas-bloat syndrome, and impaired ability to belch or vomit continue to limit patient's acceptance of the procedure. As a result, alternative techniques including partial fundoplications such as Toupet- or Dor, magnetic sphincter augmentation (MSA) and the RefluxStop™ device have gained increased attention over the past years [13–16].

The laparoscopic  $\Omega$ -type fundoplication ( $\Omega$ TF), which can be understood as a modified procedure from the Lortat-Jacob fundoplication, is a novel technique, aiming to restore the original anatomy by recreating the GEFV mechanism while preserving the luminal patency and normal esophageal transit [17,18]. It combines an anterior and posterior hiatoplasty with a two-layered esophago-fundopexy, thereby reconstruction the angle of His. The wrap is positioned on the left-posterior side of the esophagus and a posterior fundo-phrenicopexy is performed to prevent posterior migration (Figure 1a,b). Potential advantages of this technique include preservation of the short gastric arteries and avoiding fundus mobilization, reduced risk of dysphagia, decreased incidence of postoperative gas-bloat syndrome and maintenance of normal gastric emptying and motility. This technique has been established at the Upper-GI Unit of the Department of Surgery, Medical University of Vienna (MUV) in May 2022. This retrospective single-center study aims to evaluate the safety, morbidity, efficacy and quality of life outcomes of laparoscopic  $\Omega$ -type fundoplication ( $\Omega$ TF), as well as radiologic HH recurrence and recurrence of clinical symptoms after a one-year follow-up.

## METHODS

### *Patient Selection*

All consecutive patients undergoing laparoscopic  $\Omega$ TF for GERD (LA A-C positive 24h-MIIpH, presence of HH) between 05/2022 and 08/2024 at the Department of General Surgery, Medical University of Vienna (MUV), were included in this retrospective, single-center cohort study. Patients' data were routinely assessed during patients' medical treatment and included in a prospective, pseudonymized institutional database. A clinical and radiologic follow-up was mandatory during clinical follow-up. Therefore, 198 patients could be included in this analysis. Initially, patients with LPR and LA classification (LA) A with a positive 24h-MIIpH and small HH were considered eligible for  $\Omega$ TF, but indications were adapted to LA A-C and medium or large HH further on after promising short-term results. To date,  $\Omega$ TF is also offered to patients with LA A-D.

### *Patient Characteristics*

Demographic parameters such as sex, age, Body Mass index (BMI), and comorbidities were recorded. Index surgery was a primary laparoscopic  $\Omega$ TF procedure, performed for symptomatic GERD. All operations were performed at the Department of General Surgery, MUV, by a consistent team of two specialized Upper- gastrointestinal (GI) surgeons. Preoperative assessment included documentation of GERD symptoms such as heartburn, chest pain and regurgitation as well as the frequency and effect of PPI intake. Also, comorbidities such as obesity, recurrent respiratory infection or airway symptoms (chronic cough, hoarseness, sore throat) as well as smoking were evaluated. Patients with GERD and an BMI  $\geq 35$  kg/m<sup>2</sup> were excluded and referred to the Unit for Metabolic-Bariatric Surgery. Postoperative evaluation included operative time, postoperative contrast swallow x-ray (postoperative day 1, month 3 and month 12), evaluation of failed symptom relief or suboptimal clinical response (SOCR), procedure-related complications as necessity for re-intervention (surgery, endoscopic intervention), severe complications after index surgery (blood transfusions, deep venal thrombosis/pulmonary embolism, cardiac event, death) and duration of hospital stay.

## Perioperative Examinations

Data from preoperatively performed Upper-GI endoscopy as well as results of endoscopically obtained biopsies (esophagitis and Barrett's esophagus) were included in the database. HH size was characterized from 1 to 3 (1: 1-3cm, small; 2: 3-5cm medium; 3: >5cm large), esophagitis was classified regarding the LA-Classification (A-D). HILL classification (I-IV) and the AFS Hiatus grade, ranging from 1 to 4 on behalf of hiatal length (cm), hiatal aperture (cm) and presence of the GEFV were described [11]. If available, results from esophageal HRM and 24h-MIIpH [19] were collected and used to assess esophageal motility and reflux burden. In cases where HRM was not available, dynamic esophagography was performed to assess esophageal motility and identify disorders such as ineffective esophageal motility (IEM). Detailed results from those examinations, if eligible, were included in the prospective database.

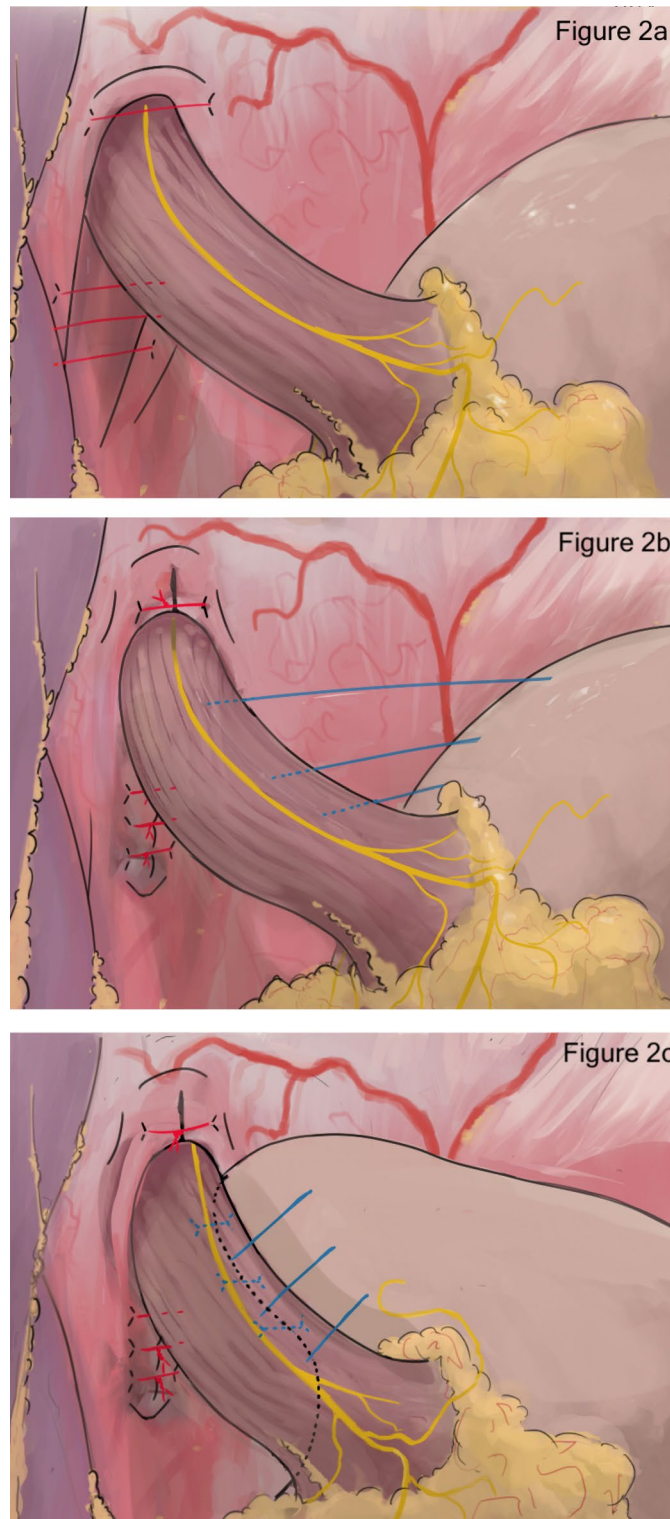
A standardized pre- and postoperative interview was conducted by the same physician, assessing alimentary satisfaction, tolerance of solid and liquid food, frequency and efficacy of PPI intake and overall symptom control. Quality of Life was measured using the GERD-Health-related-Quality-of-Life Score (GERD-HRQLs) as subjective parameter [20]. Patients served as their own control when comparing pre- and postoperative scores of validated questionnaires including the GERD-HRQLs during outpatient follow-up visits at 3 and 12 months. The frequency and severity of postoperative symptoms, including new-onset dysphagia, bloating, regurgitation, and PPI use, were assessed using the GERD-Health-Related Quality of Life (GERD-HRQL) questionnaire (0-5 points per item, higher scores indicating greater severity). In addition, symptom frequency was categorized as none/rare (once per week) or regular (daily) [21].

Radiologic follow-up using highly standardized contrast swallow x-ray was performed on postoperative day 1 and at 3, 6, and 12 months to detect radiologic hernia recurrence and assess radiologic reflux, esophageal motility, deglutition and gastric emptying [22]. Postoperatively performed endoscopies, and need for re-intervention such as endoscopic pneumatic dilatation or revisional surgery due to HH recurrence were precisely collected.

## Surgical Technique

Laparoscopic  $\Omega$ -type fundoplication, a modification of the Lortat-Jacob procedure, is designed to restore the anti-reflux barrier while maintaining esophageal patency and normal food passage. This procedure combines posterior and anterior hiatoplasty with a two-layered reconstruction of the angle of His by performing a left sided esophago-fundopexy and a posterior fundo-phrenicopexy (Figure 1a,b). The configuration resembles an inverted letter " $\Omega$ ", inspiring the nomenclature of this technique (Figure 1c). The first essential step is extended circumferential mobilization of the distal esophagus, both intrathoracically and intraabdominally, to ensure adequate and tension free intraabdominal length of the esophagus of at least 3-4cm. Mobilization of the fundus and division of suspensory ligamentary structures such as the gastrophrenic ligament and the short gastric arteries are avoided deliberately. Throughout dissection and mobilization, careful attention has to be paid to preserve the pleura and the anterior and posterior vagal nerve. Hiatal repair is performed with 2-3 non-absorbable sutures at the posterior crus and 1-2 sutures anteriorly to avoid axial kinking of the esophagus (Figure 2a). For posterior esophago-fundopexy, the esophagus is gently rotated counterclockwise, and single knotted, non-absorbable sutures are placed from the LES upward, attaching the fundus to the left posterior side of the esophagus over at least 3 cm of length (Figure 2b). The anterior row is constructed similarly, using the anterior vagal nerve as landmark to form a small anterior wrap (Figure 2c). Finally, the posterior fundo-phrenicopexy is performed to anchor the fundus at the right posterior crus with one or two sutures, aiming to avoid posterior intrathoracic slipping of the fundus. In selected cases, where the pexie was not possible tension-free, it was avoided. Particular care was taken to avoid axial rotation or twisting of the esophagus during reconstruction.

Postoperatively, a standardized oral food intake concept was implemented: all patients received fluids until confirmation of intact anatomy during contrast swallow x-ray. Followed by soft food on day one and solid food thereafter.



**Figure 2.** Surgical steps to performing laparoscopic  $\Omega$ TF.

### **Statistical Analysis**

Statistical analysis was performed using SPSS® statistics 29.9 (IBM, Armonk, NY). Continuous variables are presented as median with interquartile range (IQR) or mean  $\pm$  standard deviation (SD), as appropriate. Categorical variables were assessed using the Fisher exact test and continuous data using the Wilcoxon Rank test or McNemar Test. ANOVA was applied for multiple groups comparisons.

Clinical and radiologic outcomes were correlated accordingly. Statistical significance was defined as a  $p$  value  $< 0.05$ .

### **Ethical Approval**

This study was approved by the institutional ethics committee of the Medical University of Vienna (Nr:2388/2024). All procedures were carried out in accordance with the Declaration of Helsinki and relevant institutional guidelines and regulations. Individual informed consent was not acquired due to the retrospective study design and pseudonymized data collection.

## **RESULTS**

198 consecutive patients who underwent  $\Omega$ TF for GERD were included in this retrospective analysis. Median follow-up (FUP) after surgery was 1.1 (0.7–1.5) years. 177 (89.8%) did complete 3-month FUP, 152 (76.8%) patients did accomplish a clinical and radiological one-year FUP. The mean age at surgery was 57.1 years (IQR: 47.6–66.1), with 100 (50.5%) female and 98 (49.5%) male patients. The mean BMI was 25.8 kg/m<sup>2</sup> (23.0–28.9) and 88.0% ( $n=168$ ) of patients regularly used PPI preoperatively. Nicotine consumption was documented in 16.1% of patients ( $n=23$ ).

Preoperative diagnostic workup consisted of endoscopy ( $n=198$ ; 100%), 24-hMII-pH ( $n=104$ ; 53.0%) and HRM ( $n=93$ ; 47.0%). In preoperative endoscopy, a HH was present in 183 cases (92.4%), whilst 20.9% ( $n=31$ ) had a small HH (1–3cm), 48.6% ( $n=72$ ) a hernia of 3–5cm and 30.4% ( $n=45$ ) a large hernia greater than 5 cm. GEFV was evaluated by the HILL and AFS classification, whereas HILL grade 4 was found in 72 (48.7%) and AFS °IV in 88 cases (59.5%). The mean DeMeester Score in preoperatively performed 24h-MIIpH was 40 (IQR: 12.8–65.0) and IEM was detected in 21.8% ( $n=43$ ) of patients on HRM. Detailed information on patient's characteristics and preoperative diagnostics is summarized in [Table 1](#). All patients did undergo laparoscopic  $\Omega$ TF. All surgical procedures were performed by the same team of specialized Upper-GI surgeons. The mean operative time was 55 min (IQR: 45–68). A bioabsorbable mesh, placed in a horseshoe configuration, was used in 12 patients (6.1%) in case a large HH was present. In those cases, the posterior fundoplication was adapted individually. Postoperative contrast swallow x-ray on postoperative day 1 (POD1) was performed in all 198 patients (100%) and showed a correct positioning of the fundoplication without any sign of recurrence or slipping in 194 cases (98.0%). While early radiologic hernia recurrence occurred in 4 cases (2%), two (1.0%) required immediate revisional surgery. The standardized postoperative food intake concept was successful in 98.9% of patients ( $n=196$ ), allowing solid food intake at the 2nd postoperative day. In one case, postoperative bleeding was observed during hospital stay but without necessity of blood transfusion or revisional surgery. No further severe procedure-related complications were detected within the first 90 days after surgery. Mean hospital stay was 1 day (IQR: 1–2) after surgery ([Table 1](#)).

At a median follow-up of 1.1 (0.7–1.5) years, daily PPI intake resumed significantly from 88.0% ( $n=168$ ) to 5.1% ( $n=9$ ;  $p<0.001$ ). Preoperative symptoms of reflux, bloating, dysphagia, regurgitation and reflux associated airway symptoms were reported in 119 (77.8%), 41 (27.2%), 23 (15.1%), 30 (19.7%) and 101 (66.9%) cases regularly and decreased significantly postoperatively to 8 (4.6%,  $p<0.001$ ), 15 (8.8%,  $p<0.001$ ), 7 (4.0%,  $p<0.001$ ), 9 (6.0%,  $p<0.001$ ) and 11 (6.4,  $p<0.001$ ) cases ([Table 2](#)). New-onset dysphagia occurred in 2.6% ( $n=4$ ). GERD-HRQLs improved significantly from 25 ( $\pm 9.6$ ) to 4 ( $\pm 7.5$ ), ( $p<0.001$ ,  $\Delta-17\pm 10.3$ ). Patient's postoperative overall satisfaction improved significantly from 1.9% to 82.3%,  $p<0.001$ . Course and history of symptoms is presented in [Table 2](#).

All patients ( $n=198$ ) underwent at least one standardized contrast swallow x-ray. Median time span between surgery and last esophagogram was 0.96 (0.3–1.13) years. At latest contrast swallow, the absence of a radiologic hiatal hernia recurrence was observed in 93.0% ( $n=184$ ). Further radiologic parameters such as sign of reflux, impaired esophageal motility, impaired bolus transport or delayed gastric emptying were evaluated and described in 0.5% ( $n=1$ ), 5.7% ( $n=6$ ), 0.5% ( $n=1$ ) and 0.5% ( $n=1$ ) and shown in [Table 3](#). A regular contrast swallow study performed 12 months after  $\Omega$ TF

**Table 1.** Patient's characteristics and perioperative period.

Patients characteristics	n = 198 (IQR,%)
<b>Sex</b>	
Female	100 (50.5)
Male	98 (49.5)
<b>Age</b>	57.1 (47.6–66.1)
<b>BMI</b> (kg/m <sup>2</sup> )	25.8 (23.0–28.9)
<b>PPI preoperative</b> (yes)	168 (88.0)
<b>Smoking</b> (yes)	23 (16.1)
<b>Preoperative diagnostics</b>	
EGD	198 (100)
24-hMII-pH	104 (53.0)
HRM	93 (47.0)
<b>DeMeester Score</b>	40 (12.8–65.0)
<b>IEM</b>	43 (21.8)
<b>HH present</b>	183 (92.4)
<b>Hernia size</b>	n = 148
Small (<3cm)	31 (20.9)
Medium (3-5cm)	72 (48.6)
Large (>5cm)	45 (30.4)
<b>HILL-Grade</b>	n = 148
2	31 (29.9)
3	45 (30.4)
4	72 (48.7)
<b>AFS Classification</b>	n = 148
II	16 (10.7)
III	44 (29.7)
IV	88 (59.5)
<b>Surgery</b>	198 (100)
Duration (min)	55 (45–68)
Resorbable Mesh used	12 (6.1)
Contrast swallow (1st POD)	198 (100)
Early hernia Recurrence	4 (2.0)
Revisional Surgery (1st POD)	2 (1.0)
Adverse events (bleeding)	1 (0.5)
Normal food intake concept (2nd POD)	196 (98.9%)
Hospital stay (days)	1 (1–2)

BMI: Body Mass Index, kg/m<sup>2</sup>, PPI: Protone Pump Inhibitor, EGD: esophagogastroduodenoscopy; 24-hMII-pH: 24-h multichannel intraluminal impedance-pH monitoring; HRM: high-resolution manometry; IEM: ineffective esophageal motility; HH: Hiatal Hernia, AFS: American Foregut Society; POD: Postoperative day.

**Table 2.** History of symptoms.

Symptoms	Preoperative	Postoperative	p
	n, %	n, %	
<b>Reflux</b>			<b>&lt;0.001</b>
none, rarely	34 (22.2)	167 (95.4)	
regularly	119 (77.8)	8 (4.6)	
<b>Bloating</b>			<b>&lt;0.001</b>
none, rarely	110 (72.8)	156 (91.2)	
regularly	41 (27.2)	15 (8.8)	
<b>Dysphagia</b>			<b>&lt;0.001</b>
none, rarely	129 (84.9)	164 (96.0)	
regularly	23 (15.1)	7 (4.0)	
New Onset postoperative	–	4 (2.6)	
<b>Regurgitation</b>			<b>&lt;0.001</b>
none, rarely	122 (80.3)	142 (94.0)	
regularly	30 (19.7)	9 (6.0)	
<b>Airway symptoms</b>			<b>&lt;0.001</b>
none, rarely	50 (33.1)	159 (93.6)	
regularly	101 (66.9)	11 (6.4)	
<b>GERD HRQLs</b>	25 (±9.6)	4 (±7.5) <b>Δ-17</b> (±10.3)	<b>&lt;0.001</b>
<b>PPI intake</b> (yes)	168 (88.0)	9 (5.1)	<b>&lt;0.001</b>
<b>Satisfaction QoL &amp; surgery</b> (yes)	3 (1.9)	144 (82.3)	<b>&lt;0.001</b>

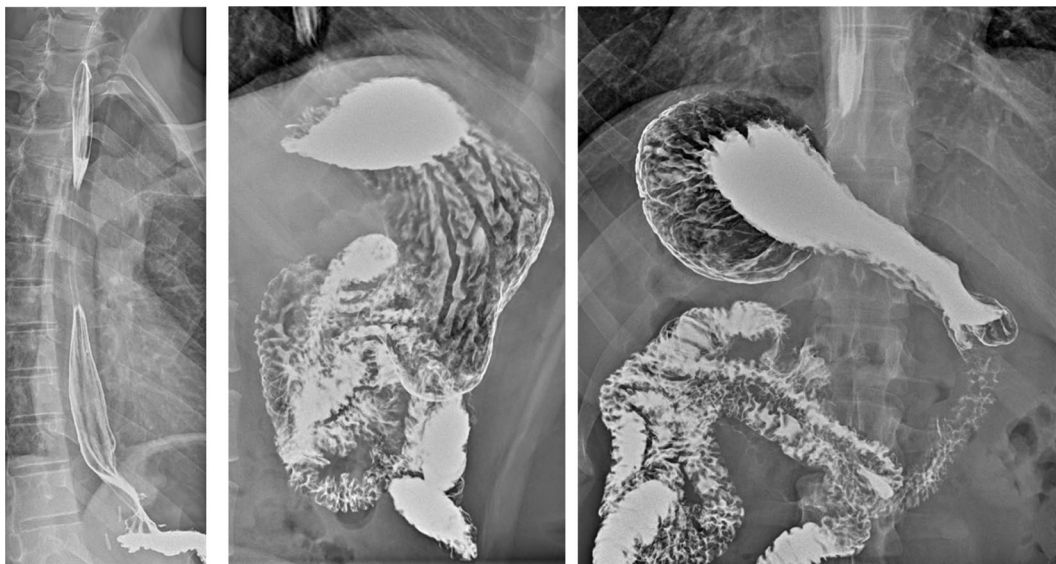
GERD HRQLs: GERD-Health-related-Quality-of-Life Score; PPI: Protone Pump Inhibitor; QoL: Quality of Life.

is demonstrated in [Figure 3](#). During patient's clinical follow-up, suboptimal clinical response (SOCR) was found in 9 (4.5%) cases. Of those, a concomitant radiologic recurrence was found in 4 (2.0%) cases, resulting in revisional surgery in 3 (1.5%) patients. New onset reflux was observed in 2 cases (1.0%) at last follow-up. A clinical and radiologic recurrence was observed in 6 (3.0%) cases. In total,

**Table 3.** Clinical and radiologic follow-up.

Follow-up	<i>n</i> (%;IQR); <i>p</i>
<b>Median FUP</b> (years)	1. (0.7–1.5)
<b>FUP accomplished</b>	
3 Months	177 (89.8)
12 Months	152 (76.8)
<b>Contrast swallow X-ray</b>	
At least 1	151 (100.0)
2	74 (37.2)
3	31 (15.6)
<b>Median time surgery – latest contrast swallow</b>	0.96 (0.3–1.13)
<b>Latest contrast swallow</b>	
Radiologic Hernia Recurrence	14 (7.0)
Radiologic sign of reflux	1 (0.5)
Impaired esophageal motility	6 (5.7)
Impaired bolus transport	1 (0.5)
Delayed gastric emptying	1 (0.5)
<b>Clinical course</b>	
<b>SOCR</b>	9 (4.5)
SOCR+ Radiologic recurrence	4 (2.0)
SOCR+ Radiologic recurrence+ revisional surgery	3 (1.5)
<b>New onset reflux</b> (at last FUP)	2 (1.0)
<b>Clinical+ Radiologic Recurrence</b> (during FUP)	6 (3.0)
<b>Hernia Recurrence (clinical or radiologic)</b>	
1st POD	4 (2.0)
<3 months	2 (1.0)
>3 months	9 (4.5)
<b>Revisional Surgery</b> (in total)	7 (3.5)
<30 days after index surgery	2 (1.0)
>30 days after index surgery	5 (2.5)
<b>Endoscopy during FUP</b>	47 (23.7)
Hernia recurrence	4 (2.0)
Necessity for pneumatic dilatation	3 (1.5)
<b>Patient's satisfaction (QoL)</b>	144 (82.4), <0.001

FUP: Follow-up; IQR: Interquartile Range; SOCR: Suboptimal clinical response; POD: Postoperative day; QoL: Quality of Life.

**Figure 3.** Radiologic contrast swallow x-ray 12 months after  $\Omega$ TF.

revisional surgery was necessary in 7 cases (3.5%) throughout the whole observational period. During follow-up, endoscopy was performed in 47 patients (23.7%), with the necessity for pneumatic dilatation in 3 cases (1.5%), if patients suffered from dysphagia. An endoscopic image of the GEFV 3 months after surgery is demonstrated in Figure 4. Detailed information regarding patients' course of clinical- and radiologic follow-up is demonstrated in Table 3. Overall, patient's satisfaction improved significantly to 82.4% ( $n=144$ ) at last follow-up ( $p<0.001$ ).



**Figure 4.** Endoscopic image of the GEJV 3 months after  $\Omega$ TF.

## DISCUSSION

Laparoscopic  $\Omega$ -type fundoplication ( $\Omega$ TF) represents a novel surgical approach within LARS, combining hiatal repair with a two-layered reconstruction of the angle of His (esophago-fundopexy) and a posterior fundophrnicopexy. This technique is a modification to the Lortat-Jacob method, in which the lower esophagus is anchored to the hiatus with non-absorbable sutures after mobilization, supplemented by esophago-fundopexy as well as anterior fundophrnicopexy to reestablish normal anatomy with particular attention to the angle of His [17]. In the present retrospective single-center study, 198 consecutive patients with GERD underwent  $\Omega$ TF within a 26-month period and a median clinical- and radiologic follow-up of median 1.1 (0.7–1.5) years was conducted.

Currently, LNF represents the surgical gold standard for GERD patients due to its long-term data on reflux control. However, well-documented postoperative side effects such as dysphagia, gas bloat syndrome and impaired ability to belch or vomit, limit patient satisfaction and the willingness to undergo surgery [23,24].

Consequently, alternative techniques such as partial fundoplication (Toupet or Dor), endoscopic techniques (Stretta, TIF or c-TIF), and implantable devices (MSA, Reflux Stop™) have been explored [8,25–27]. These aim to reinforce the anti-reflux barrier while preserving physiological function.

Under physiological conditions, native anatomical structures such as the esophageal hiatus, the diaphragmatic crura and a sharp angle of His effectively contribute to GERD prevention [11]. In patients without a HH, these structures, together with the GEJV form an active anti-reflux barrier. More recently, techniques such as the RefluxStop™ device have been introduced, aiming to maintain the anatomical position of the EGJ by stabilizing the gastric fundus relative to the diaphragm without creating a constrictive mechanical barrier [14]. In 2022, Zhang et al. evaluated laparoscopic His angle reconstruction in patients with GERD and reported comparable reflux control to LNF but fewer functional side effects, suggesting that sufficient his-angle reconstruction without creating a full wrap can be sufficient for GERD prevention [28]. Similarly, Feka et al. reported that His angle reconstruction combined with the RefluxStop™ device in patients with IEM and GERD significantly improved GERD-HRQL scores and reduced PPI dependency [29]. Compared to  $\Omega$ TF, the RefluxStop™ technique doesn't restore EGJ anatomy but rather relies on mechanical stabilization of the gastric fundus and EGJ, resulting in enhanced durability of reflux control while maintaining a low risk of postoperative dysphagia. Since short-term results are promising, its effectiveness and value in LARS shall be evaluated in an upcoming international, multicenter randomized controlled trial.

The concept underlying the principle of  $\Omega$ TF aligns with these principles but avoids the use of foreign materials. By anatomically reestablishing the His angle through direct suturing and performing a posterior fundophrnicopexy,  $\Omega$ TF seeks to reconstruct the native anti-reflux mechanism while minimizing mechanical constriction. These results suggest  $\Omega$ TF as safe and effective therapeutic method in patients with GERD with low rates of perioperative morbidity and short hospital stay as

well as rapid postoperative recovery. Significant improvement in reflux symptoms and GERD-HRQL scores with low rates of persistent dysphagia, short-term recurrence and associated comorbidities was found. A standardized follow-up protocol for postoperative HH recurrence was assessed *via* clinical follow-up at the outward patient clinic and by standardized radiologic contrast swallow studies at POD1, month 3 and 12.

Strengths of this study are that all procedures were performed at a specialized, certified Upper-GI surgery center by the same dedicated surgeons, ensuring consistency in preoperative diagnostics (24h-MIIpH, HRM, endoscopy), perioperative management and especially, surgical technique ( $\Omega$ TF) regarding this novel method. The high one-year follow-up rate of 152 (76.8%) is notable, considering that GERD patients with restored QoL after successful treatment tend to high loss to follow-up. Postoperative care was standardized, including analgesia protocols, contrast swallow radiography on POD1, and a structured dietary progression protocol, allowing solid food intake on POD2. The rapid diet advancement, allowing patients to return to a normal diet on POD2, is a great advantage over common post-operative dietary pathways following LNF. Clinical outpatient follow-up was also conducted exclusively by the same surgical team.

Radiologic contrast swallow X-ray served as primary objective measure of anatomical recurrence, focusing on radiologic signs of HH recurrence, reflux as well as contrast passage dynamics [30]. The consistent radiological follow-up of 152 patients at  $\geq 1$  year by contrast swallow x-ray is noteworthy. Although it is less sensitive for reflux quantification than 24h-MIIpH, its easy-access and tolerability likely ensured higher compliance of especially asymptomatic patients after successful  $\Omega$ TF [22]. All contrast swallow studies were interpreted by a dedicated radiology team, using a standardized protocol and ensuring high diagnostic consistency. Prospective long-term follow-up, including postoperative 24h-MIIpH, is ongoing and will be essential for interpretation and direct comparison with LNF outcomes.

Despite encouraging results, this study has several limitations. The retrospective design and relatively small study cohort restrict the interpretation and value of these findings. The one-year observational period, which can be explained by the recently implemented surgical technique, is short and refuses conclusions regarding long-term durability of this method to date. Nevertheless, complete one year follow-up of 23.2% is missing to date, mainly due to early drop-out ( $n=20$ ; 10%) immediately after hospital discharge or surgery performed close to the end of the observational period. Reoperation rate of 3.5% within the observational period and aligns with results on LNF reported by Nikolic et al. but appears higher compared to results by Zhou et al., which might reflect a potential overestimation due to the excluded number of patients [24,31]. Therefore, these results must be interpreted with caution and longer follow-up is necessary for adequate evaluation. As mentioned before, contrast swallow x-ray, although standardized and consistently interpreted by designated radiologists, is less sensitive for reflux quantification than 24h-MIIpH but still highly sufficient indicators for early hernia recurrence and severe pathology. Nevertheless, these first short-term results indicate that  $\Omega$ TF is a safe, effective, and physiologic alternative to traditional fundoplication techniques.

## CONCLUSION

$\Omega$ TF appears to be a safe laparoscopic anti-reflux procedure that achieves sufficient symptom control and high patient satisfaction while minimizing postoperative side effects, serving as promising alternative to LNF.  $\Omega$ TF reconstructs the physiologic anti-reflux mechanism without luminal restriction. However, prospective multicenter, randomized controlled trials with long-term follow-up are necessary to validate these findings and allow direct comparison of  $\Omega$ TF with established techniques.

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## AUTHORS CONTRIBUTIONS

CRediT: **Lisa Gensthaler**: Conceptualization, Data curation, Investigation, Methodology, Project administration, Writing – original draft; **Max Stauffer**: Data curation; **Milena Bologheanu**: Writing – review & editing; **Dagmar Kollmann**: Writing – review & editing; **Joy Feka**: Writing – review & editing; **Gerd Jomrich**: Writing – review & editing; **Erwin Rieder**: Writing – review & editing; **Marcel Philipp**: Data curation, Writing – review & editing; **Franz M. Riegler**: Investigation, Writing – review & editing; **Reza Asari**: Writing – review & editing; **Sebastian F. Schoppmann**: Conceptualization, Supervision, Validation, Writing – review & editing.

## HUMAN RIGHTS/COMPLIANCE WITH ETHICAL STANDARDS

All 198 human participants were included in this study in accordance with the ethical standards of the ethics committee (IRB approval number: 2388/2024) and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards.

## INFORMED CONSENT

Informed consent was not obtained, since the transferred data was completely anonymized, and data was evaluated retrospectively.

## DISCLOSURE STATEMENT

Lisa Gensthaler, Max Stauffer, Milena Bologheanu, Dagmar Kollmann, Joy Feka, Gerd Jomrich, Erwin Rieder, Marcel Philipp, Franz M. Riegler, Reza Asari have no conflicts of interest or financial ties to disclose. Sebastian F. Schoppmann has no conflict of interest but reports a financial disclosure: Unrestricted research fund from Implantica and Ethicon.

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## DATA AVAILABILITY STATEMENT

The data supporting the findings of this study are available on request from the corresponding author.

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