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Exploring the feasibility and safety of laparoscopic anti-reflux surgery with the new RefluxStop™ device: a retrospective cohort study of 40 patients

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Summary

AIMS OF THE STUDY: Anti-reflux surgery aims to restore the anti-reflux barrier and reduce the retrograde flow of stomach contents. However, traditional surgical techniques generally involve some degree of encircling of the oesophagus, which can result in adverse effects such as dysphagia and the inability to belch or vomit. Based on the first published results, a novel surgical technique – with the RefluxStop™ device – appears promising for treating gastroesophageal reflux disease (GERD) with minimal postoperative dysphagia. This study describes the initial clinical experience with this procedure in a cohort of patients with chronic gastroesophageal reflux disease to evaluate its feasibility and safety in clinical practice.

METHODS: This retrospective cohort study examined the first 40 patients who underwent laparoscopic anti-reflux surgery with the RefluxStop™ device at a private hospital in Switzerland. The procedure involves implanting a non-active device on the outside of the gastric fundus to stabilise a narrow oesophagogastric plication. Feasibility was assessed based on the proportion of patients in whom the device could be successfully implanted, with a discussion of the operative details. Intraoperative and postoperative complications, adverse effects, and changes in gastroesophageal reflux disease-related quality of life (GERD-HRQL questionnaire) are also reported.

RESULTS: Between May 2020 and April 2022, 40 patients underwent elective surgery for laparoscopic hiatal hernia repair and RefluxStop™ device implantation. All patients had typical symptoms of gastroesophageal reflux disease, such as heartburn and regurgitation; 20 (50%) had preoperative dysphagia. Laparoscopic surgery was feasible in all patients except one who required laparotomy due to adhesions and associated bleeding when accessing the abdomen. The median operating time was 57.5 minutes (interquartile range = 51.75–64.25 minutes) with no device-related intraoperative or postoperative complications. All patients were imaged one day and three months postoperative, confirming the correct placement of the device. Reflux symptoms (heartburn and acid regurgitation) were significantly improved in all patients at three months ($p < 0.0001$).

CONCLUSION: These preliminary results support the feasibility and safety of introducing this novel laparoscopic anti-reflux surgical treatment option in clinical practice.

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Introduction

Gastroesophageal reflux disease (GERD) is a highly prevalent condition, representing a massive disease burden. Globally, around one billion individuals suffer from GERD [1], and a 77.5% increase in prevalence has been reported over recent decades, from 442 million in 1990 to 784 million in 2019 [2], translating to substantial healthcare costs. A recent population-based survey in the USA found that one in three respondents reported GERD symptoms within the past week [3].

The retrograde flow of acidic stomach contents into the oesophagus, and in some cases into the pharynx and respiratory tract, causes inflammation and damage that results in symptoms. However, medical treatment does not treat the fundamental underlying abnormality. Furthermore, proton pump inhibitors, which form the mainstay of medical treatment, fail to adequately control symptoms in up to half of those taking them [3].

Anti-reflux surgery, most commonly in the form of laparoscopic fundoplication, is recommended for chronic gastroesophageal reflux disease [4] and is often performed when pharmacological approaches such as proton pump inhibitors are unsuitable or provide incomplete symptom relief [5]. Patients may also prefer the option of a “definitive” treatment over lifelong medication, although some degree of continued medical treatment may be required. Surgical adverse effects, primarily dysphagia, bloating, and flatulence, are highly relevant [6], and efforts to innovate and refine surgical techniques to reduce their incidence have resulted in methods such as partial fundoplication and magnetic sphincter augmentation [7]. While early trials showed that magnetic sphincter augmentation led to improved outcomes in terms of bloating, postoperative dysphagia remains a common complaint [8–10].

Therefore, efforts to reduce surgical adverse effects, particularly postoperative dysphagia, continue. Consequently, a new surgical implant – the RefluxStop™ device – was designed for use in laparoscopic anti-reflux surgery. The initial *Conformité Européenne* (CE)-mark study involved 50 patients and reported favourable outcomes at one year, as determined by gastroesophageal reflux disease health-related quality of life (GERD-HRQL) scores (86% improvement) and 24 h pH outcomes (normalised in 98% of patients) [11]. Reports following longer follow-up in this ongoing study are awaited.

In 2020, we began to offer this procedure at our institution in addition to other existing anti-reflux surgical options. We present our initial experience with this procedure, seeking to answer two key questions: Would performing this procedure be feasible in all cases? Would the outcomes support the continued use of this technique in clinical practice?

Methods

Study design

This retrospective cohort study examined the first 40 patients with documented typical gastroesophageal reflux disease symptoms who underwent laparoscopic anti-reflux surgery with the RefluxStop™ device (Implantica, Zug, Switzerland) in a private hospital setting in Switzerland. The data was collected from their medical records.

Surgery was performed by a single surgeon (JZ) between May 2020 and April 2022. RefluxStop surgery was offered to patients whom the surgeon judged suitable candidates based on the investigations detailed below and accounting for the patient's situation (figure 1). The patients were informed about the procedure and availability of limited data [11] before obtaining consent. This study was ethically approved by the Institutional Review Board of the University of Bern, Switzerland (approval no. 2018-01827) and conducted according to the Declaration of Helsinki. The costs of the surgery, including the device, were covered by the patient's insurance.

Patient selection

This analysis included all patients who underwent surgery with the RefluxStop™ device at our institution between the above dates. To be eligible for surgery, patients must have documented gastroesophageal reflux disease or typical symptoms of gastroesophageal reflux disease and be aged >18 years. Patients with hiatal hernia >10 cm, long-segment Barrett's oesophagus, or a history of oesophageal or gastric surgery were ineligible for this surgery (figure 1).

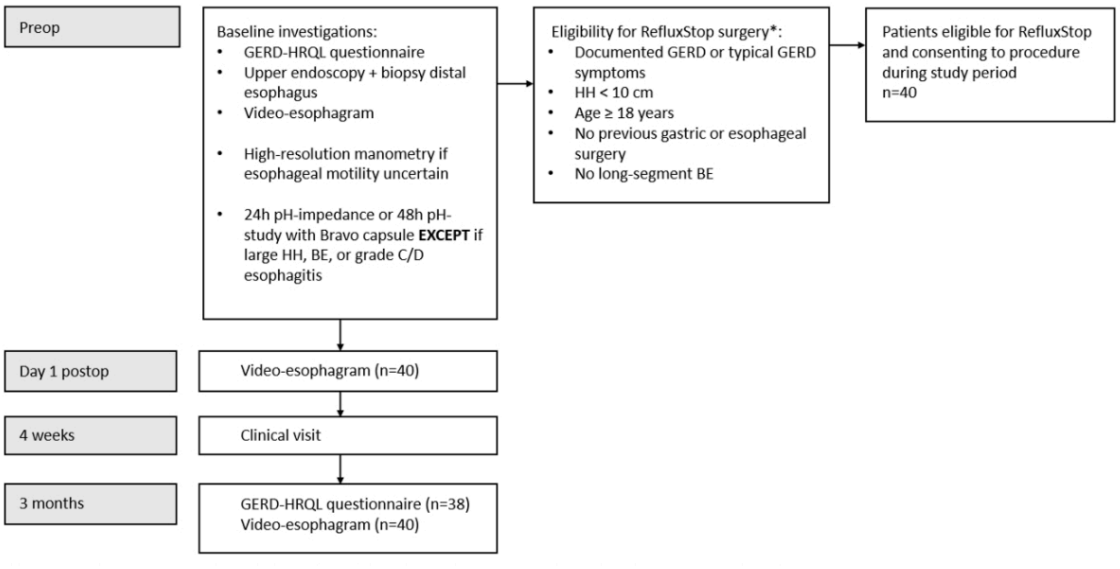
Preoperative assessments

The preoperative work-up consisted of an upper endoscopy with biopsies of the distal oesophagus, a standardised history and physical examination, and a standardised questionnaire for reflux disease (GERD-HRQL, 0–75 points plus an additional quality-of-life question [12]); see figure S1 in the Appendix for the original questionnaire used. Oesophageal motility was assessed by video oesophagram under fluoroscopy, with the contrast-enhanced liquid medium swallowed in upright and supine positions according to a standardised protocol [13]. In selected patients where the assessment of oesophageal motility was inconclusive, high-resolution manometry was performed at a specialised reflux centre. All patients, except those with a large hiatal hernia, Barrett's oesophagus, or reflux oesophagitis Grade C or D according to the Los Angeles classification [14], underwent either a 24 h pH-impedance study or a 48 h pH-study with the Bravo capsule for confirmation and to assess the severity of reflux disease.

Surgical procedure and RefluxStop™ device implantation

The main principles of the RefluxStop technique are that it maintains the lower oesophageal sphincter (LES) in an in-

Figure 1: Flowchart of the eligibility criteria for surgery and follow-up. * Other surgical options available at this institution include complete or partial fundoplication and magnetic sphincter augmentation. GERD: gastroesophageal reflux disease; HH: hiatal hernia; BE: Barrett's oesophagus.



tra-abdominal position, recreates an acute angle of His (often flattened due to a hiatal hernia), and avoids encircling the oesophagus; a 90–110° attachment of the stomach to the oesophagus is formed instead of a 360° or 270° wrap. The device is sutured into a pocket created on the gastric fundus to stabilise the fundus and avoid reherniation of the lower oesophageal sphincter. Additional technical details on implanting the RefluxStop™ device, including the importance of its positioning relative to the lower oesophageal sphincter, have been previously described [11].

The operating room set-up for RefluxStop surgery is similar to other laparoscopic anti-reflux surgery. After creating a pneumoperitoneum in the left upper quadrant, trocars are placed in the typical laparoscopic anti-reflux surgery positions. With an Optiview trocar, the camera is introduced about 5–7 cm above the umbilicus, paramedian to the left. A 10-mm trocar is placed in the left upper quadrant, and a 5-mm trocar in the right upper quadrant and left flank. An epigastric access is created for the Nathanson liver retractor, held by the iron intern, to elevate the left lobe of the liver.

After opening the pars flaccida with a harmonic scalpel, the right crus is identified, and the oesophagus is visualised. The anterior aspect of the oesophagus is dissected with caution to preserve the anterior vagus nerve, and the top of the left crus is identified. The short gastric vessels are taken down, and the complete left crus is visualised and freed from adhesions. An 18 cm long easy-flow drainage tube is placed around the distal oesophagus for retraction. Mediastinal dissection of the distal oesophagus is performed, preserving the vagal nerves, and if present, the hiatal hernia is reduced, and the hernia sac is resected. With sufficient dissection, an intra-abdominal length of at least 4.5 cm should be achieved with only slight traction on the oesophagus, providing a maximum 1.5 cm downward movement of the angle of His. A hiatal hernia closure is performed with 2 to 3 figure-of-eight sutures with Gore Sutures (Gore Inc., Sedona, AZ, USA), avoiding compression of the oesophagus. In cases with excessive fat pad at the angle of His, further resection of the fat pad is performed.

Then, the angle of His is recreated using two rows of sutures with V-loc (Medtronic Inc., Dublin, Ireland) non-resorbable 3–0, creating an oesophagogastric plication. The first row of sutures is placed to approximate the oesophagus and the gastric fundus, starting at the angle of His and working caudocranially until about 4 cm of the distal oesophagus and the fundus are joined. A slight tension on the oesophagus during this plication moves the angle of His downward by no more than 1.5 cm to allow the surgeon to reach higher up the oesophagus. The second row of sutures is placed 1–1.5 cm anteriorly to the first suture row, taking care to avoid creating folds or kinks. Then, a single Gore suture is placed to secure the fundus at the top end between the two suture lines.

After switching out the 5-mm port in the left flank with a 22-mm reusable port, the prepared RefluxStop™ device is introduced with a dedicated deployment tool (Implantica, Zug, Switzerland). Next to the suture line and parallel to the oesophagus, the device is gently placed at the top of the fundus without tension into a fundic pocket. With one suture row from cranial to caudal and a second suture row from caudal to cranial, taking care to avoid narrowing or kinking of the oesophagus, the RefluxStop™ device is secured in position at the top of the fundus next to the oesophagogastric suture line. A safe intra-abdominal position of the RefluxStop™ device is thus achieved without tension on the easy-flow drainage tube. The deployment tool and the easy-flow drainage tube are then removed.

Postoperative follow-up

The follow-up of the patients on postoperative day 1 included a video oesophagram. The patients were on a blended soft diet for the first week postoperative, followed by a soft diet for 3–4 weeks. Hospital visits with history and physical examination were conducted four weeks and three months after the procedure. The patients completed a standardised reflux questionnaire (GERD-HRQL) preoperative and three months postoperative. A second video oesophagram was performed three months postoperative. Reflux symptoms and dysphagia were recorded at each hospital visit. Surgical complications were documented according to the Dindo-Clavien classification [15].

Study outcomes

The primary outcome, relating to feasibility, was the proportion of patients who could undergo the surgery with the device positioned correctly. The device position was determined in line with the manufacturer's instructions for use, which consider the position of its top relative to the upper edge of the lower oesophageal sphincter. The device's position was considered *optimal* if its top was >1 times its size above the upper edge of the lower oesophageal sphincter, *acceptable* if 0.5–1 times above the upper edge of the LES, *failure risk* if 0–0.5 times above the upper edge of the LES and *unacceptable* if its position was entirely below the upper edge of the LES (see figure S2 in the Appendix).

The secondary outcomes included intraoperative complications and postoperative complications within 90 days. These included complications related to the device directly (e.g. migration or penetration of the implant) or the overall procedure (e.g. trocar hernia, infectious complications [wound infection or abscess], and reoperations).

Additional secondary outcomes were the incidence of postoperative dysphagia requiring endoscopic balloon dilatation, improvement in gastroesophageal reflux disease symptoms (defined using the GERD-HRQL score), and improvement in quality of life related to gastroesophageal reflux disease (defined as improvement from "dissatisfied" or "neutral" response to "satisfied" or "neutral" [if initially "dissatisfied"]).

Statistical analyses

The data were collected and stored using Microsoft Excel (version 16.76; Microsoft, Seattle, WA, USA) under licence (Microsoft 365). Statistical analyses were performed using GraphPad Prism (version 9; GraphPad Software, San Diego, CA, USA). Continuous variables are expressed as mean (standard deviation) or median (interquartile range [IQR]), and categorical variables are expressed as frequencies (percentages). Continuous paired preoperative and postoperative observations were compared using the

Wilcoxon signed-rank test. The significance level was set at 0.05. The sample size was based on the available data at the time of writing rather than a sample size calculation.

Results

The patients' demographic characteristics, baseline clinical parameters, and operative and postoperative characteristics are summarised in table 1. Twenty-nine patients (72.5%) had a large hiatal hernia, defined as ≥4 cm, at the time of surgery. In addition, 31 patients had ineffective oesophageal motility (IEM). Moreover, 20 patients (50%) had preoperative dysphagia, of whom 19 (95%) had IEM. All 40 patients (100%) achieved complete follow-up, defined as a video oesophagram three months postoperative and completed clinical visits. The GERD-HRQL questionnaire was completed by all 40 patients preoperatively (100%) and 38 (95.0%) three months postoperative.

Surgery and postsurgical assessments

In all patients, the intended RefluxStop procedure was feasible (i.e. the RefluxStop™ device was successfully implanted in the correct position). The surgery was performed laparoscopically on 39/40 (97.5%) patients. In one patient who had undergone previous open surgery, the procedure was converted to an open procedure due to bleeding adhesions while establishing laparoscopic access to the abdomen. After conversion and correction of the vascular injury, the intended procedure was safely performed as described in the Methods section. The median operating time was 57.5 minutes (IQR = 51.75–64.25 minutes).

Three patients experienced postoperative complications. One underwent an urgent laparoscopic reoperation the same day due to a postoperative haemorrhage caused by dissection of the short gastric vessels at the fundus. One reported persistent fatigue four weeks postoperative due to pericardial effusion. The pericardial effusion, which might have been related to mediastinal dissection or due to cardiac failure, was treated successfully with non-steroidal anti-inflammatory drugs and did not require pericardiocentesis. One developed a trocar hernia in the epigastric area (camera trocar), discovered on postoperative day 24 with acute incarcerated omentum, and underwent direct open closure of the trocar hernia defect.

All patients underwent imaging (video fluoroscopy) on postoperative day one, and the correct positioning of the RefluxStop™ device was confirmed (figure 2). The patients' median hospital stay was four days (IQR = 3–5 days). All patients tolerated the prescribed diet as described in the Methods section.

Clinical outcomes at four weeks and three months

Based on the results of the GERD-HRQL questionnaire, gastroesophageal reflux disease symptoms (heartburn and regurgitation) improved in all 38 patients who completed the questionnaire preoperatively and postoperatively (figure 3). The median (IQR) GERD-HRQL score decreased significantly from 35 (28.5–49.0) preoperatively to 2 (0–3) at three months postoperative ($p < 0.0001$). Sub-scores (0–30 points) for heartburn and regurgitation also showed significant improvement in all patients three months postoperative. Among the 38 patients who answered the question about their quality of life related to gastroesophageal reflux disease preoperatively and postoperatively, 28 (73.7%) initially reported they felt dissatisfied or neutral,

Table 1:
Patients' demographic characteristics, baseline clinical parameters, and operative and postoperative characteristics. Continuous values are expressed as the median [interquartile range].

	Characteristic	n = 40
Demographics	Sex (female), n (%)	16 (40)
	Age (years)	60 [51–71]
	BMI (kg/m^2)	26.3 [24.6–28.9]
	ASA classification (1–6)	2 [2–3]
Reflux-related clinical parameters	Size of hiatal hernia (cm)	4 [3–5]
	Barrett's oesophagus, n (%)	16 (40)
	Ineffective oesophageal motility, n (%)	31 (77.5)
	Preoperative dysphagia, n (%)	20 (50)
Operative characteristics	Device implanted in the correct position	40 (100)
	Operative time (minutes)	57.5 [51.75–64.25]
	Conversion to laparotomy, n (%)	1 (2.5)
	Intraoperative complication, n (%)	1 (2.5)
Postoperative characteristics	Hospital stay (days)	4 [3–5]
	Complications within 90 days*, n (%)	6 (15)
	Grade I	0
	Grade II	1 (2.5)
	Grade IIIa	3 (7.5)
	Grade IIIb	2 (5)
	Grade IVa	0
	Grade IVb	0
	Grade V	0
	Dysphagia requiring dilatations, n (%)	3 (7.5)
	Number of dilatations performed	4 [4–5]

BMI: body mass index; ASA: American Society of Anesthesiologists

* postoperative complications are graded according to the Dindo-Clavien classification system.

and all (100%) reported an improvement three months postoperative (figure 4).

Three patients reported postoperative dysphagia with frequent vomiting and inability to eat a normal diet. However, these patients all had IEM before surgery, and two had preoperative dysphagia. Due to the severity of symptoms in these three patients, early dilations were performed 3–4 weeks postoperative. Following the initial phase and subsequent implementation of a normal diet, additional dilations were required to provide satisfactory results. In one patient, dilations with 18- to 20-mm balloons were successful; in the other two patients, further endoscopic dilations had to be performed after initial dilation with 18- and 20-mm balloons, with an EndoFLIP balloon to 25 mm, to resolve their dysphagia.

At the three-month clinical follow-up, 20 patients who had previously suffered from dysphagia showed a reduction in severity or complete resolution of symptoms (figure 5). No new onset of dysphagia was recorded at the three-month follow-up.

Figure 2: Video oesophagram on postoperative day one depicting the correct positioning of the RefluxStop™ device, leaving the food passageway unaffected.

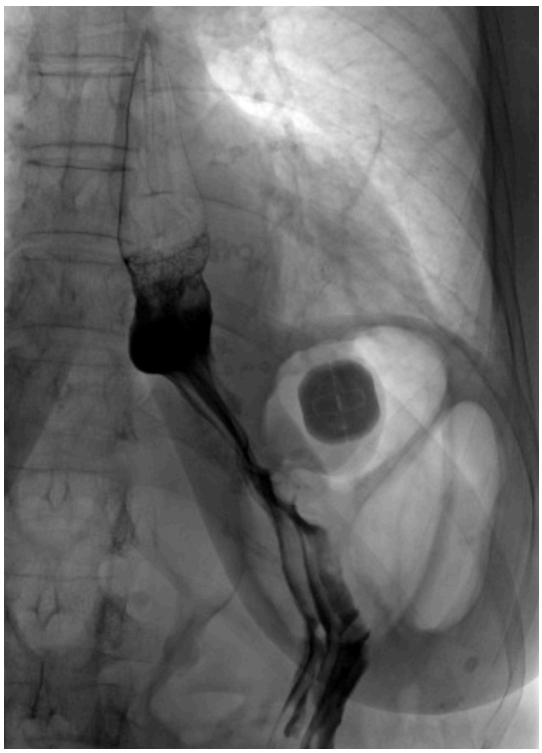
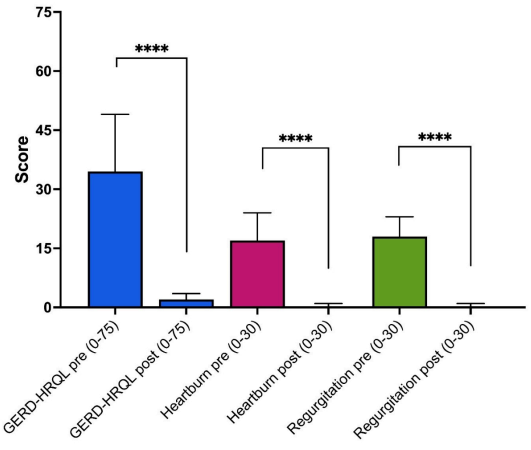


Figure 3: Preoperative and postoperative GERD-HRQL scores (without proton pump inhibitors) for all patients (n = 38) who completed the questionnaire before and three months after surgery, with detailed analysis for heartburn and regurgitation. The scores are presented as the median (box) and interquartile range (whiskers). Paired comparisons had p-values <0.0001 (****). GERD-HRQL: gastroesophageal reflux disease health-related quality of life.



Radiologic outcomes at three months

The video oesophagrams three months postoperatively confirmed the correct positioning of the RefluxStop™ device in all patients, and no device-related complications were observed.

Device-related complications

Overall, there were no device-related complications at surgery or the four-week and three-month clinical follow-ups. No device-related reoperations occurred in this study cohort during the follow-up period.

Discussion

Following the initial study by Bjelovic et al. for the *Conformité Européenne* (CE)-mark [11], this is the second study on laparoscopic anti-reflux surgery with the RefluxStop™ device.

In this initial experience with a cohort of 40 patients undergoing laparoscopic anti-reflux surgery with the RefluxStop™ device in a private hospital setting, the device

Figure 4: Preoperative and postoperative (three months) quality of life related to gastroesophageal reflux disease. Only patients (n = 38) who completed the questionnaire before and three months after surgery were included.

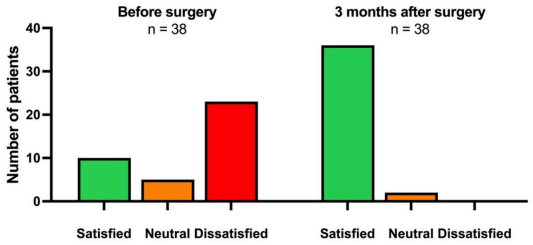
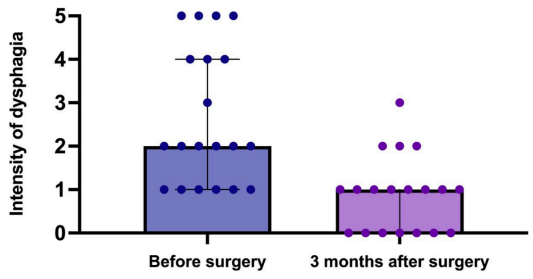


Figure 5: Preoperative and postoperative (three months) dysphagia intensity (0–5) in patients who had preoperative dysphagia (n = 20). The scatter plots show the median (box) and interquartile range (whiskers).



was successfully implanted in all patients who were considered appropriate candidates preoperatively and who consented to undergo the procedure. The device was positioned correctly, and all 40 patients showed improved or resolved reflux symptoms, confirmed by a significant improvement in GERD-HRQL scores and low rates of dysphagia despite many in the cohort having IEM preoperatively. We consider the complication rates at 90 days – with two patients requiring reoperation (acute bleeding and trocar hernia), one developing pericardial effusion, and three patients requiring endoscopic dilations – to be comparable to other laparoscopic anti-reflux surgery techniques. Richter's review of side effects and complications from fundoplication reported open conversion in 0–24% (though <2.4% in high volume centres), bleeding and splenic injury in <1%, severe postoperative nausea and vomiting in 2–5%, and early dysphagia in 10–50% of adults hospitalised for anti-reflux surgery, with 4.7–8.3% having at least one complication [16].

There were no procedure-related complications during surgery, which is indicative of the safety of the implant and its delivery system (deployment tool). The trocar hernia reported by one patient in this series was from the epigastric camera port, not from the port used for the deployment tool.

The goal of the RefluxStop™ device is to fill the existing gap in modern laparoscopic anti-reflux surgery techniques, enabling a non-wrap variation of surgical repair, thereby mitigating the adverse effects seen with current procedures such as laparoscopic Nissen [17] and Toupet [18] fundoplication. Among the most frequently recognised adverse effects of a 360° wrap (Nissen) is the inability to belch and vomit, leading to bloating and flatulence [18]. While such effects are thought to be less common with partial than complete fundoplication [4], at least in the short term [19], they are still reported and deter many patients from undergoing anti-reflux surgery [19]. Therefore, a gap exists for a definitive surgical treatment for gastroesophageal reflux disease that both repairs the underlying dysfunction of the lower oesophageal sphincter and reconstructs the angle of His while avoiding adverse effects such as dysphagia, which is thought to be caused by encircling and putting pressure on the oesophagus.

Recent minimally invasive techniques attempt to mimic or replace fundoplication, often in combination with laparoscopic hiatal hernia repair. Laparoscopic magnetic sphincter augmentation with the LINX™ reflux management system (Johnson & Johnson, Newark, NJ, USA), comprised of a dynamic band of magnetic beads, has been available for over a decade since being approved by the US Food and Drug Administration in 2012. This technique has been shown to have fewer adverse effects (bloating and flatulence) than the Nissen technique and preserved the ability to vomit and belch in most patients [9, 20, 21]. However, the circular placement around the distal oesophagus limits its use to patients with normal oesophageal motility [22–24], and it is not indicated for those with moderate preoperative dysphagia [25]. One postulate advantage of the RefluxStop™ device is less persistent postoperative dysphagia since the oesophagus is not encircled, unlike in Nissen fundoplication [18] and magnetic sphincter augmentation [22]. In this study, three patients with postoperative dysphagia (one of whom had new onset dysphagia) were effectively treated by balloon dilation without recurrence of reflux symptoms. We consider this rate to be relatively low, particularly because 50% (20/40) of the patients had dysphagia preoperatively, of whom 19 had IEM, and 77.5% (31/40) had IEM based on the preoperative video oesophagrams. These preoperative rates of dysphagia and IEM may well have influenced outcomes by leading to a higher rate of dysphagia than would occur in a more general population. This observation is particularly interesting given the limitations of existing treatments for those with IEM and supports the suitability of using the RefluxStop™ device as an alternative to a wrap.

One crucial step of the procedure to ensure a tension-free reconstruction during the oesophagogastric plication is establishing sufficient oesophageal length during the mediastinal dissection. Similarly, the fundic pocket that contains the RefluxStop™ device close to the oesophagogastric suture must be closed without creating tension around the implant since a taut pocket may increase the likelihood of gastric migration. In this study, video oesophagrams at one day and three months postoperative confirmed no cases of device migration. It should be noted that, as a safety measure, the RefluxStop™ device is made of five silicon components, held together with a Vicryl suture (assembled on the back table during surgery). This five-part design, rather than a larger single component, aims to prevent a gastric or intestinal obstruction if migration occurs.

This study had some limitations. Firstly, its follow-up was limited to 3 months, and symptoms and/or hiatal hernia could recur after that time. Secondly, it was limited by its retrospective study design. There were no data on postoperative pH studies or manometry since these are not performed routinely in our clinical practice. However, Bjelovic et al. provided data on postoperative pH [11]. Thirdly, it did not include a control group since the focus was to describe the initial experience with this procedure in clinical practice to assess its feasibility and safety. Such features could be incorporated into future study designs.

This patient population had a high rate of preoperative dysphagia and dysmotility, which may have affected the final results regarding postoperative dysphagia [16], although, as reported above, our findings show a low rate of new-onset or persistent dysphagia. Postoperative dysphagia rates are likely to be lower in a larger cohort with fewer patients with IEM. The high proportion of patients with IEM in this study was influenced by the fact that, at our institution, we also offer other procedures besides the RefluxStop™ device, such as magnetic sphincter augmentation (LINX™). While some patients will have undergone magnetic sphincter augmentation, it is unsuitable for those with IEM; therefore, there will have been a selection bias toward those with IEM undergoing surgery with the RefluxStop™ device. In addition, 72.5% of our patients had a large hiatal hernia. Such patients are often deemed unsuitable for current standard-of-care procedures that encircle the food passageway; this technique appears to offer a solution that can be used successfully in these cases.

Using a video oesophagram to evaluate for IEM before surgery limited the accuracy of the IEM diagnosis in this cohort since it is not a standardised test for evaluating IEM.

We did not systematically collect information about anti-reflux medication use at three months. Nonetheless, as the responses to the GERD-HRQL questionnaire are intended to describe symptoms in the absence of medication, the comparison of the GERD-HRQL scores before and three months after surgery remains valid, and the statistically significant improvement in the score at three months is not confounded by ongoing intake of proton pump inhibitors or other medical anti-reflux therapy.

Assessing or comparing the length of stay in this study with other anti-reflux surgery procedures was not thought to be helpful since, in Switzerland, all patients are kept at least two nights for optimal hospital reimbursement.

Future research should focus on clinical trials comparing outcomes against traditional surgical techniques and look in-depth at the physiology of how this device and procedure exert their effect.

Conclusions

In this explorative study, our preliminary observations indicate that the RefluxStop™ device is a feasible treatment option for gastroesophageal reflux disease to introduce in similar healthcare settings since the device was safely and correctly implanted in all 40 patients with a low complication rate. Furthermore, it appears suitable for a broader patient population that includes IEM since short-term clinical outcomes were favourable in this patient cohort. Further studies with larger patient cohorts and longer follow-ups are required.

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Potential competing interests
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References

1. Nirwan JS, Hasan SS, Babar ZU, Conway BR, Ghori MU. Global Prevalence and Risk Factors of Gastro-oesophageal Reflux Disease (GORD): Systematic Review with Meta-analysis. Sci Rep. 2020 Apr;10(1):5814. http://dx.doi.org/10.1038/s41598-020-62795-1. PubMed. 2045-2322
2. Zhang D, Liu S, Li Z, Wang R. Global, regional and national burden of gastroesophageal reflux disease, 1990-2019: update from the GBD 2019 study. Ann Med. 2022 Dec;54(1):1372–84. http://dx.doi.org/10.1080/07853890.2022.2074535. PubMed. 1365-2060
3. Delshad SD, Almario CV, Chey WD, Spiegel BM. Prevalence of Gastroesophageal Reflux Disease and Proton Pump Inhibitor-Refractory Symptoms. Gastroenterology. 2020 Apr;158(5):1250–1261.e2. http://dx.doi.org/10.1053/j.gastro.2019.12.014. PubMed. 1528-0012
4. Slater BJ, Dirks RC, McKinley SK, Ansari MT, Kohn GP, Thosani N, et al. SAGES guidelines for the surgical treatment of gastroesophageal reflux (GERD). Surg Endosc. 2021 Sep;35(9):4903–17. http://dx.doi.org/10.1007/s00464-021-08625-5. PubMed. 0930-2794
5. Savarino V, Marabotto E, Zentilin P, Demarzo MG, de Bortoli N, Savarino E. Pharmacological Management of Gastro-Esophageal Reflux Disease: An Update of the State-of-the-Art. Drug Des Devel Ther. 2021 Apr;15:1609–21. http://dx.doi.org/10.2147/dddt.S306371. http://dx.doi.org/10.2147/DDDT.S306371. PubMed. 1177-8881
6. Greenberg JA, Stefanova DI, Reyes FV, Edelmuth RC, Harik L, Thiesmeyer JW, et al. Evaluation of post-operative dysphagia following anti-reflux surgery. Surg Endosc. 2022 Jul;36(7):5456–66. http://dx.doi.org/10.1007/s00464-021-08888-y. PubMed. 1432-2218
7. Dunn C, Bildzukewicz N, Lipham J. Magnetic Sphincter Augmentation for Gastroesophageal Reflux Disease. Gastrointest Endosc Clin N Am. 2020 Apr;30(2):325–42. http://dx.doi.org/10.1016/j.giec.2019.12.010. PubMed. 1558-1950
8. Sheu EG, Nau P, Nath B, Kuo B, Rattner DW. A comparative trial of laparoscopic magnetic sphincter augmentation and Nissen fundoplication. Surg Endosc. 2015 Mar;29(3):505–9. http://dx.doi.org/10.1007/s00464-014-3704-6. PubMed. 1432-2218
9. Reynolds JL, Zehetner J, Wu P, Shah S, Bildzukewicz N, Lipham JC. Laparoscopic Magnetic Sphincter Augmentation vs Laparoscopic Nissen Fundoplication: A Matched-Pair Analysis of 100 Patients. J Am Coll Surg. 2015 Jul;221(1):123–8. http://dx.doi.org/10.1016/j.jamcollsurg.2015.02.025. PubMed. 1879-1190
10. Ayazi S, Chowdhury N, Zaidi AH, Chovanec K, Komatsu Y, Omstead AN, et al. Magnetic sphincter augmentation (MSA) in patients with hiatal hernia: clinical outcome and patterns of recurrence. Surg Endosc. 2020 Apr;34(4):1835–46. http://dx.doi.org/10.1007/s00464-019-06950-4. PubMed. 1432-2218
11. Bjelović M, Harsányi L, Altorjay Á, Kincses Z, Forsell P, Gunjić D, et al.; Investigators of the RefluxStop™ Clinical Investigation Study Group. Non-active implantable device treating acid reflux with a new dynamic treatment approach: 1-year results : RefluxStop™ device; a new method in acid reflux surgery obtaining CE mark. BMC Surg. 2020 Jul;20(1):159. http://dx.doi.org/10.1186/s12893-020-00794-9. PubMed. 1471-2482
12. Velanovich V. 25 Years of the GERD-HRQL symptom severity instrument: an assessment of published applications. Surg Endosc. 2023 Jan;37(1):255–65. http://dx.doi.org/10.1007/s00464-022-09463-9. PubMed. 1432-2218
13. Allen JE, White C, Leonard R, Belafsky PC. Comparison of esophageal screen findings on videofluoroscopy with full esophagram results. Head Neck. 2012 Feb;34(2):264–9. http://dx.doi.org/10.1002/hed.21727. PubMed. 1097-0347
14. SS Sami KR. The Los Angeles Classification of Gastroesophageal Reflux Disease. Video Journal and Encyclopedia of GI Endoscopy. 2013;1(1):103-4 DOI: http://dx.doi.org/10.1016/S2212-0971(13)70046-3. .
15. Dindo D, Demartines N, Clavien PA. Classification of surgical complications: a new proposal with evaluation in a cohort of 6336 patients and results of a survey. Ann Surg. 2004 Aug;240(2):205–13. http://dx.doi.org/10.1097/01.sla.0000133083.54934.ae. PubMed. 0003-4932
16. Richter JE. Gastroesophageal reflux disease treatment: side effects and complications of fundoplication. Clin Gastroenterol Hepatol. 2013 May;11(5):465–71. http://dx.doi.org/10.1016/j.cgh.2012.12.006. PubMed. 1542-7714
17. Ayazi S, DeMeester SR, Hagen JA, Zehetner J, Bremner RM, Lipham JC, et al. Clinical Significance of Esophageal Outflow Resistance Imposed by a Nissen Fundoplication. J Am Coll Surg. 2019 Aug;229(2):210–6. http://dx.doi.org/10.1016/j.jamcollsurg.2019.03.024. PubMed. 1879-1190
18. Schwameis K, Zehetner J, Rona K, Crookes P, Bildzukewicz N, Oh DS, et al. Post-Nissen Dysphagia and Bloating Syndrome: Outcomes After Conversion to Toupet Fundoplication. J Gastrointest Surg. 2017 Mar;21(3):441–5. http://dx.doi.org/10.1007/s11605-016-3320-y. PubMed. 1873-4626
19. Analatos A, Håkanson BS, Ansorge C, Lindblad M, Lundell L, Thorell A. Clinical Outcomes of a Laparoscopic Total vs a 270° Posterior Partial Fundoplication in Chronic Gastroesophageal Reflux Disease: A Randomized Clinical Trial. JAMA Surg. 2022 Jun;157(6):473–80. http://dx.doi.org/10.1001/jamasurg.2022.0805. PubMed. 2168-6262
20. Rona KA, Reynolds J, Schwameis K, Zehetner J, Samakar K, Oh P, et al. Efficacy of magnetic sphincter augmentation in patients with large hiatal hernias. Surg Endosc. 2017 May;31(5):2096–102. http://dx.doi.org/10.1007/s00464-016-5204-3. PubMed. 1432-2218
21. Warren HF, Reynolds JL, Lipham JC, Zehetner J, Bildzukewicz NA, Taiganides PA, et al. Multi-institutional outcomes using magnetic sphincter augmentation versus Nissen fundoplication for chronic gastroesophageal reflux disease. Surg Endosc. 2016 Aug;30(8):3289–96. http://dx.doi.org/10.1007/s00464-015-4659-y. PubMed. 1432-2218
22. Tsai C, Steffen R, Kessler U, Merki H, Lipham J, Zehetner J. Postoperative Dysphagia Following Magnetic Sphincter Augmentation for Gastroesophageal Reflux Disease. Surg Laparosc Endosc Percutan Tech. 2020 Aug;30(4):322–6. http://dx.doi.org/10.1097/sle.0000000000000785. http://dx.doi.org/10.1097/SLE.0000000000000785. PubMed. 1534-4908

23. Rona KA, Tatum JM, Zehetner J, Schwameis K, Chow C, Samakar K, et al. Hiatal hernia recurrence following magnetic sphincter augmentation and posterior cruroplasty: intermediate-term outcomes. Surg Endosc. 2018 Jul;32(7):3374–9. http://dx.doi.org/10.1007/s00464-018-6059-6. PubMed. 1432-2218
24. Baison GN, Jackson AS, Wilshire CL, Bell RC, Lazzari V, Bonavina L, et al. The Impact of Ineffective Esophageal Motility on Patients Undergoing Magnetic Sphincter Augmentation. Ann Surg. 2023 Apr;277(4):e793–800. http://dx.doi.org/10.1097/sla.0000000000005369. http://dx.doi.org/10.1097/SLA.0000000000005369. PubMed. 1528-1140
25. Bonavina L, DeMeester TR, Ganz RA. LINX(™) Reflux Management System: magnetic sphincter augmentation in the treatment of gastroesophageal reflux disease. Expert Rev Gastroenterol Hepatol. 2012 Dec;6(6):667–74. http://dx.doi.org/10.1586/egh.12.47. PubMed. 1747-4132

Appendix

Figure S1: The GERD-HRQL questionnaire used to assess patients before and three months after surgery.

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1chirurgie

□ vor Operation
□ nach Operation Operationsdatum: _____

_____Monate postop.

Name, Vorname:_____ Geburtsdatum: _____ Datum:_____

Bitte bewerten Sie den Schweregrad Ihrer Beschwerden ***(ohne Medikamente)*** anhand des folgenden Punktesystems von «keine Beschwerden» = «0» bis «Beschwerden, die mich im Alltag einschränken» = «5»:

0 = keine Beschwerden
1 = leichte Beschwerden, nicht störend
2 = leichte Beschwerden, manchmal auftretend, aber nicht dauernd störend
3 = täglich auftretende Beschwerden
4 = Beschwerden, die mich im Alltag stören
5 = Beschwerden, die mich im Alltag behindern

	AKTUELL (letzte 2 Wochen)	
1	Wie stark ist das Sodbrennen? □0 □1 □2 □3 □4 □5	
2	Wie stark ist das Sodbrennen im Liegen? □0 □1 □2 □3 □4 □5	
3	Wie stark ist das Sodbrennen im Stehen / Aufrecht? □0 □1 □2 □3 □4 □5	
4	Stärke des Sodbrennens nach dem Essen? □0 □1 □2 □3 □4 □5	
5	Beeinflusst Sodbrennen Ihre Essgewohnheiten? □0 □1 □2 □3 □4 □5	
6	Haben Sie Schlafprobleme wegen Sodbrennen? □0 □1 □2 □3 □4 □5	
7	Haben Sie Schluckstörungen? □0 □1 □2 □3 □4 □5	
8	Haben Sie Schmerzen beim Schlucken? □0 □1 □2 □3 □4 □5	
9	Beeinträchtigt die Einnahme von Reflux-Medikamenten Ihren Alltag? □0 □1 □2 □3 □4 □5	
10	Wie stark ist der Reflux? □0 □1 □2 □3 □4 □5	
11	Haben Sie Reflux im Liegen? □0 □1 □2 □3 □4 □5	
12	Haben Sie Reflux im Stehen? □0 □1 □2 □3 □4 □5	
13	Haben Sie Reflux nach dem Essen? □0 □1 □2 □3 □4 □5	
14	Beeinflusst Reflux Ihre Essgewohnheiten? □0 □1 □2 □3 □4 □5	
15	Haben Sie Schlafprobleme wegen Reflux? □0 □1 □2 □3 □4 □5	
16	Wie ist Ihre Lebensqualität? □ Gut □ Neutral □ Nicht gut	

Herzlichen Dank für Ihre Antworten

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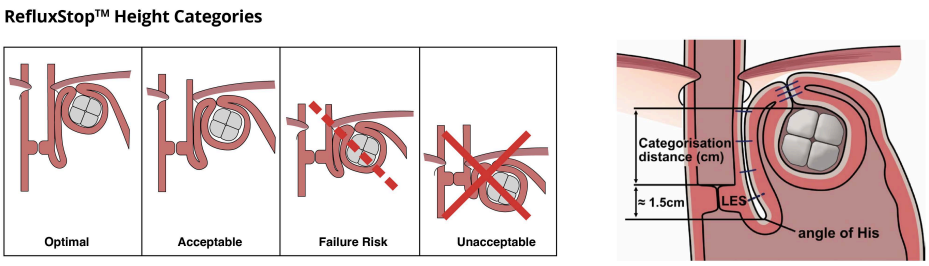
Figure S2: Device position categorisation according to the manufacturer's instructions for use, reproduced with the kind permission of Implantica (Zug, Switzerland).



1 Optimal: Device top placed more than 1 time the device size above the upper edge of the LES
2 Acceptable: Device top placed 0.5 - 1 time the device size above the upper edge of the LES
3 Failure Risk: Device top placed 0 - 0.5 time the device size above the upper edge of the LES
4 Unacceptable: Device position is fully below the upper edge of the LES