TREATMENT OF GASTRO-ESOPHAGEAL REFLUX DISEASE WITH A NOVEL IMPLANTABLE DEVICE-BASED PROCEDURE: 12-19 MONTHS' FOLLOW-UP OF 40 PATIENTS AT A REGIONAL HOSPITAL IN GERMANY

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AIM: Provide real-world clinical data on outcomes following surgery with RefluxStop for the treatment of gastroesophageal reflux disease (GERD) in 40 patients from a high-volume centre in Germany.

Introduction

RefluxStop is a novel nonactive surgical implant for the treatment of GERD.

It restores gastroesophageal junction anatomy (Figure 1) by reinstating an acute angle of His, re-establishing a flap valve, and reinforcing the fundus to maintain the LES in an intra-abdominal position

It avoids encircling the food passageway, postulated to reduce adverse effects such as dysphagia and inability to belch or vomit.

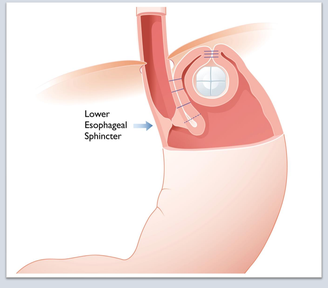


Figure 1. RefluxStop device in situ

PATIENTS AND METHODS

RefluxStop Surgery
- July 2021 - July 2022 total 80 patients underwent surgery
- **40 patients** completed at least 12 months of follow-up
- **Mean follow-up** was **14.5 months** (min 12-max 19)

Primary outcome: GERD-HRQL score

Secondary outcomes:
- Proton-pump inhibitor (PPI) use
- Intra- and post-operative adverse events
- Patient-reported symptoms

Patient characteristics	
Sex, male	22 (55%)
Age, years, mean (SD)	48.2 (14.3)
BMI, kg/m², mean (SD)	26.2 (4.9)
Hiatal hernia, cm, median (IQR)	3.0 (2.0-4.0)
Hiatal hernia > 3 cm, n (%)	15 (37.5%)
PPI duration, years, median (IQR)	2.0 (1.0-5.0)
Symptom duration, years, median (IQR)	5.0 (3.0-10.0)
Esophagitis, n (%)	24 (60%)
Barrett's esophagus, n (%)	7 (17.5%)
Previous surgery, n (%)	9 (22.5%)

RESULTS

***Primary outcome*:**

- **GERD-HRQL** showed a **median (IQR) reduction of 100% (89.6-100)**, from 19 (17-21) to 0 (0-2) (Figure 2),
- Mean (SD) GERD-HRQL decreased 91.9%, from 19.5 (3.8) to 1.1 (2.2).

Secondary outcomes:

- **PPI use** decreased from 39/40 (97.5%) at baseline to only 1/40 (2.5%) at follow-up (Figure 3).

- **Complications and adverse events:**
  - No patients reported dysphagia or regurgitations at follow-up.
  - Bloating was reported by 2 (5%) patients post-operatively.
  - No reoperations needed during follow-up period.



Figure 2. GERD-HRQL score over time, median (IQR)

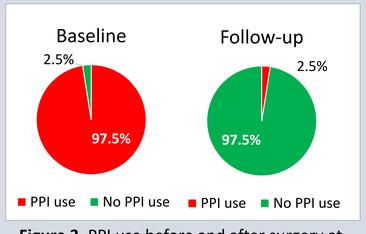


Figure 3. PPI use before and after surgery at follow-up

DISCLOSURE(S)

TL has received consultancy fees and travel grants to conferences from Implantica

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RESULTS (CONT'D)

Secondary outcomes (cont'd):

- **Patient-reported symptoms**

Symptoms at baseline	n (%)
General GERD symptoms	14 (35)
Heartburn	11 (27.5)
Cough	5 (12.5)
Reflux problems	5 (12.5)
Regurgitation	3 (7.5)
Retrosternal burning	3 (7.5)
Hoarseness	2 (5)
Nausea	2 (5)
Abdominal pain, pressure	2 (5)
Epigastric pain, Acid	1 (2.5)
Food retention problems	1 (2.5)
Pain while lying; gargles after eating	1 (2.5)
Scratchy throat	1 (2.5)
Stenosis of Nissen fundoplication	1 (2.5)
Weight loss	1 (2.5)

Symptoms at follow-up	Yes n (%)	No n (%)
Reflux*	2 (5)	38 (95)
Weight loss	2 (5)	38 (95)
Bloating	2 (5)	38 (95)
Regurgitation	0 (0)	40 (100)
Horizontal sleeping without reflux	38 (95)	2 (5)
Dysphagia	0 (0)	40 (100)
Dumping	0 (0)	40 (100)
Abdominal pain	1 (2.5)	39 (97.5)

*reported as mild and occasional

CONCLUSION

This case series demonstrates the excellent effectiveness and safety of this new treatment approach for GERD patients, with 100% improvement in median GERD-HRQL, and no postoperative dysphagia or reoperations during the study period. Additional prospective controlled studies may further validate these clinical practice outcomes with this new implantable device-based therapy.