RefluxStop Surgery for Gastroesophageal Reflux Disease: A Multicenter Retrospective Analysis of Clinical Outcomes in Spain and Italy with Minimum 12-Month Follow-up in 56 Patients

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INTRODUCTION

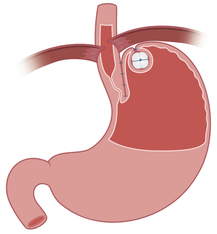
RefluxStop (Figure 1) restores the anatomical and functional integrity of the anti-reflux barrier. The recently published 5-year clinical outcomes of the device from a prospective multicenter trial were exceptional [1,2] and this study supports larger real-world clinical evidence reported from routine surgical practice [3,4].

Purpose: A multicenter clinical study was performed on the RefluxStop procedure to treat gastroesophageal reflux disease (GERD).

Figure 1. The RefluxStop procedure

Basic procedural steps:

- Extensive esophageal and fundic dissection
- Hiatal repair, loosely to avoid postoperative dysphagia
- Narrow (90-120°) esophagogastric plication between vagal trunks
- Loose invagination of implant in superiorly oriented fundic pouch, fully closed



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METHODS AND PROCEDURES

A retrospective analysis evaluated clinical outcomes at mean (SD) follow-up 12.1 (3.5) months of RefluxStop procedure patients (N=56) with GERD across nine centers in Spain and Italy. The clinical outcomes assessed included GERD Health-Related Quality of Life (GERD-HRQL), proton pump inhibitor (PPI) use, patient satisfaction, adverse events, and the incidence of dysphagia (i.e., GERD-HRQL dysphagia score >2).

Disclaimers:
RefluxStop is not approved in the USA. RefluxStop is not for sale in the USA.

References:
1) Harsányi et al. *Surg Endosc.* 2025;39(9):6163-6179. 2) Harsányi et al. *Surg Endosc.* 2025;39(7):4615-4627. 3) Zehetner et al. *J Gastrointest Surg.* 2025;30(2):102293 4) Elshafei et al. *J Laparoendosc Adv Surg Tech A.* 2025;35(5):357-364.

RESULTS

Baseline characteristics are presented in Table 1

- Hiatal hernia in 60.9% (28/46); average (SD) size 2.8 (1.9) cm
- Esophagitis present in 48.1% (26/54)
- Barrett's esophagus present in 14.3% (8/56)

Table 1. Baseline demographics and clinical characteristics (N=56)

Parameters	N=56
Gender, n (%)	
Female	28 (50%)
Male	28 (50%)
Age (years), mean (SD)	50.4 (14.0)
BMI (kg/m^2), mean (SD)	27.5 (2.6)
Hiatal hernia, n (%); N=46	60.9%
Hernia axial length (cm), mean (SD)	2.8 (1.9)
Median (IQR), Min-max	3.1 (1.0); 0-6.0
Barrett's esophagus, n (%)	8 (14.3%)
Esophagitis, n (%); N=54	26/54 (48.1%)
LA grade C	4/54 (7.4%)
LA grade D	1/54 (1.8%)
Dysphagia, n (%)	16 (28.6%)
PPI use, n (%)	53 (94.6%)

Clinical effectiveness

- Median (IQR) total GERD-HRQL score decreased from 28.0 (14.5; N=54) at baseline to 2.0 (6.0; N=53) at mean (SD) 12.1 (3.5) months follow-up, reflecting median 92.9% improvement; 92.2% had >50% improvement
- Regular daily PPI use decreased from 94.6% (53/56) preoperatively to 3.6% (2/55) after surgery
- Dissatisfaction at baseline was 86.7% (46/53) as compared to lack of dissatisfaction in 94% at follow-up
- Incidence of dysphagia decreased from 28.6% (16/56) at baseline to 2.0% (1/49) at follow-up, a 93.0% relative reduction

Safety results

- Adverse events were minimal with one reoperation due to vomiting-induced damage to hiatal repair
- The fundus was repositioned and a new hiatal repair was performed with the device untouched in its pouch and the patient well-treated

CONCLUSIONS

A multicenter retrospective evaluation of RefluxStop in routine surgical practice across Spain and Italy demonstrated excellent clinical outcomes in GERD treatment in line with currently reported real-world data. One successful reoperation unrelated to the device with fundus, including the device intact in its pouch re-arranged, due to a re-herniation caused by intensive vomiting. The GERD-HRQL median improvement of 93%, PPI use decreased to two patients (2/55), and the incidence of dysphagia declined to one case of dysphagia at follow-up (based on GERD-HRQL dysphagia question with score >2) are excellent results.

Figure 2. Total GERD-HRQL score (0-50)

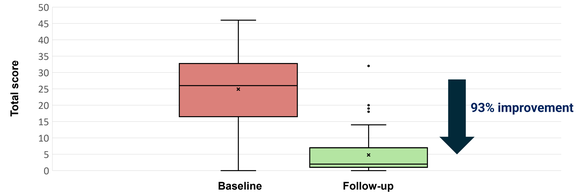


Figure 3. Regular daily PPI use

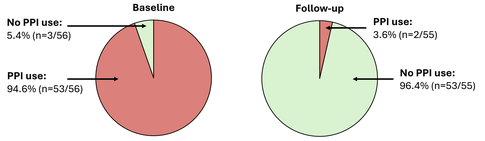
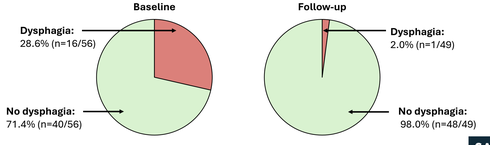


Figure 4. Dysphagia



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