REFLUXSTOP IMPLANT FOR GASTROESOPHAGEAL REFLUX DISEASE: CLINICAL OUTCOMES AT ALMOST 2 YEARS IN A POOLED COHORT OF 158 PATIENTS FROM TWO GERMAN HOSPITALS

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OBJECTIVE OF NEW DEVICE

The RefluxStop device treats gastroesophageal reflux disease (GERD) by restoring the anti-reflux barrier in a way that avoids encircling the esophagus, intended to reduce side effects compared with traditional surgical techniques.

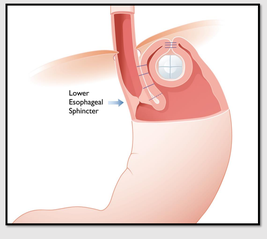


Figure 1. RefluxStop device in situ*

- The device has been implanted in >700 patients in various European centers, and data on patient outcomes are increasing as follow-up continues.
- Data are presented pooled from two German hospitals performing RefluxStop surgery as part of their clinical practice.

PATIENT POPULATION

A total of **158 patients** were included **at two year follow-up** (mean (SD) 20 (7) months). Their characteristics are in Table 1.

Patient characteristics	
Sex, male	81 (51.3%)
Age, years, mean (SD)	49.3 (13.3)
BMI, kg/m², mean (SD)	27.1 (4.5)
Hiatal hernia > 3 cm, n (%)	35 (22.2%)
PPI duration, years, median (IQR)	5 (1-7)
Symptom duration, years, median (IQR)	4 (1-10)
Esophagitis, n (%)	70 (44.3%)
Barrett's esophagus, n (%)	16 (10.1%)

Disclosure(s)

M. Elshafei has received consultancy fees from Implantica.

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DESCRIPTION OF TECHNOLOGY AND METHOD OF USE

The device is comprised of 5 parts held together by a resorbable suture (**Figure 2**). This design serves to minimize risk of obstruction in case of device migration.



Figure 2. RefluxStop device*

The surgical procedure involves hernia and crural repair, a narrow esophagogastric plication (90-110°) (**Figure 3**), and implantation of the device in a pouch created on the outside of the gastric fundus.

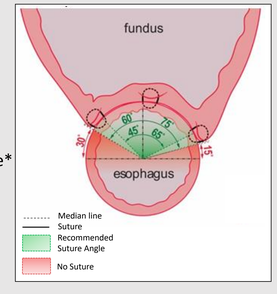


Figure 3. Esophagogastric plication*

The device is delivered into the pouch using a dedicated deployment tool (**Figure 4**) and sutured in position (**Figure 5**).

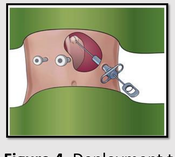


Figure 4. Deployment tool*

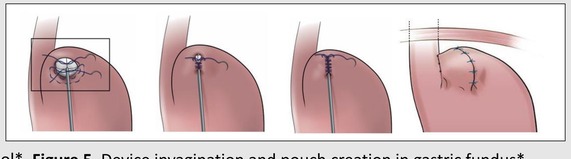


Figure 5. Device invagination and pouch creation in gastric fundus*

The device should be positioned high relative to the lower esophageal sphincter to ensure effectiveness (**Figure 6**). This is achieved by performing an extended dissection high-up in the mediastinum; to achieve a floppy fundus, dissect posteriorly down around to the angle of His.

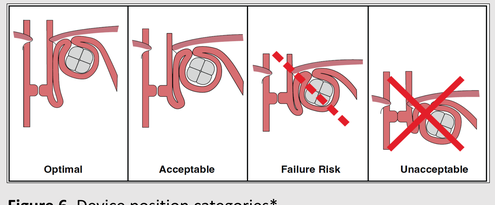


Figure 6. Device position categories*

*Images of device courtesy of Implantica (Zug, Switzerland)

PRELIMINARY RESULTS

GERD-HRQL

- GERD-HRQL score decreased 90.9% from a baseline median (IQR) of 22 (19-31.5) to 2 (0-4) (**Figure 7**).
- Mean score decreased 89.7% from 26.2 (10.1) to 2.7 (3.3).

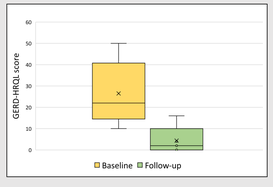


Figure 7 GERD-HRQL, median (IQR)

PPI use

- PPI use decreased 96.4%, from 96.5% of patients at baseline to just 3.6% at follow-up (p<0.001) (**Figure 8**).

Dysphagia and postoperative dilatation

- All patients with dysphagia at baseline (11.4%) had resolution at follow-up.
- Five patients (3.2%) reported de-novo mild dysphagia that resolved spontaneously without intervention.
- No patients required post-operative esophageal dilatation.

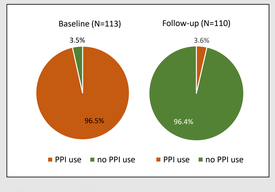


Figure 8 PPI use

Adverse events

- Two patients (1.3%) had early device penetration into stomach cavity without complications, determined to be due to the pouch being sutured too tightly. One of these patients later had re-operation with Toupet fundoplication.
- Hiatal hernia recurred in two patients (1.3%); in both cases the hernia was repaired keeping the device intact in its invaginated fundus pouch that was repositioned.

CONCLUSIONS

In this cohort, RefluxStop was a safe procedure with excellent clinical outcomes in terms of GERD-related quality of life improvement, discontinuation of PPI medication and minimal post-operative adverse events.
These data add to the growing body of clinical evidence on the RefluxStop implant and surgical procedure.