

Reflux Patients with Ineffective Esophageal Motility:

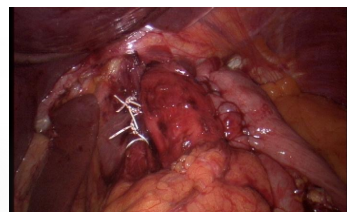
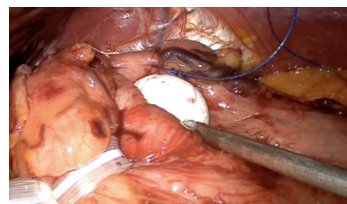
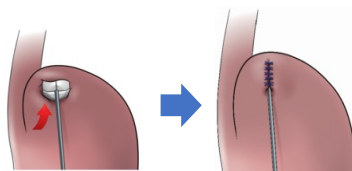
12-Month Follow-up Results of Laparoscopic Hiatal Hernia Repair with *RefluxStop

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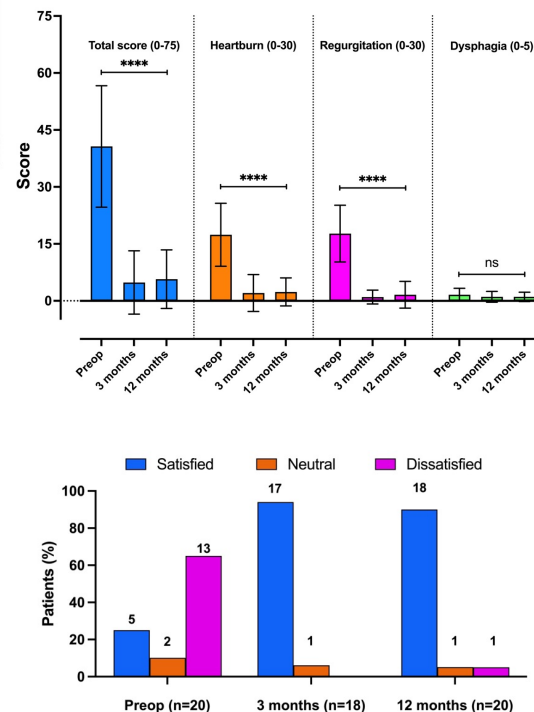
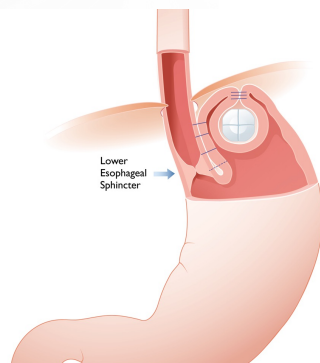
Background

A novel surgical anti-reflux technique with Implantica's RefluxStop is promising to treat patients with gastroesophageal reflux disease (GERD). Ineffective esophageal motility is often concomitant with GERD; it deteriorates the outcome after reflux-surgery and is a major factor taken into account when choosing the operative technique. The aim of this study was to assess safety and feasibility of laparoscopic hiatal hernia repair with RefluxStop in patients with GERD, hiatal hernia and diagnosis of ineffective esophageal motility.



Methods

A retrospective chart review was performed of 20 patients with GERD and hiatal hernia, diagnosed with ineffective esophageal motility, who consented and underwent hiatal hernia surgery with the RefluxStop implant. The operative technique and outcomes were evaluated to assess safety and feasibility, hiatal hernia recurrence, dysphagia and patient satisfaction.



Results

Between June 2020 and November 2022 there were 20 patients, with ineffective esophageal motility at baseline, that underwent laparoscopic hiatal hernia repair with RefluxStop and reached the 12-months follow-up period. All patients had typical symptoms of GERD, like heartburn and regurgitation, and 12 patients (60%) had preoperative dysphagia. Median hiatal hernia size was 4.5 cm (IQR, 3.75 – 5). Median operating time was 59.5 minutes (IQR, 50.25 - 64) with no intra- and postoperative complications related to the implant. One patient required laparotomy due to adhesions and associated bleeding when accessing the abdomen. All patients had postoperative imaging (video fluoroscopy) on postoperative day 1, and then at 3 and 12 months, confirming the correct location of the RefluxStop. No recurrence of hiatal hernia was reported in this cohort. A diagnostic laparoscopy with adhesiolysis was performed in one patient (5%) 11 months after the index operation due to persistent left-sided thoracic pain. Three patients (15%) required postoperatively balloon dilatation due to persistent dysphagia. Mean GERD-HRQL Score (0-75 points) was 40.7 ± 16.0 before surgery, 4.8 ± 8.3 at 6 months, and 5.7 ± 7.7 at 12 months, demonstrating a significant resolution of reflux symptoms (p <0.001). Eighteen patients (90%) were satisfied after 12 months compared to 5 patients (25%) before surgery (p <0.001).

Conclusion

Despite the ineffective esophageal motility in those GERD patients, laparoscopic hiatal hernia repair with RefluxStop showed excellent outcomes at 3 and 12 months postoperatively, with all patients showing complete resolution or significant improvement of reflux symptoms.

*RefluxStop is not for sale in the USA