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## A Retrospective Chart Review of 79 Patients Undergoing the Refluxstop™ Procedure to Manage Gastroesophageal Reflux Disease: Safety and Efficacy

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RefluxStop™ is a novel surgical device that manages gastroesophageal reflux disease (GERD) by restoring the normal structure of the antireflux barrier. This is accomplished by reinstating the acute angle of His and anchoring the gastroesophageal sphincter adequately in the intraabdominal cavity. This study reports the safety and efficacy of 79 patients in the postoperative period.

A retrospective chart review was performed on 79 patients that underwent the RefluxStop™ procedure at a single institution between July 2021 and November 2022. Measures were evaluated to assess the feasibility, safety, and clinical outcomes during the follow-up period.

79 patients (age  $49.8 \pm 14$  years), 46 of which were male, mean BMI was  $25.8 (\pm 4.5)$ .

Associated conditions noted include esophagitis (45.6%), Barrett's esophagus (17.7%). Average axial length of hiatal hernia was 2.9 cm ( $\pm 1.5$ ). Baseline symptoms included general GERD symptoms (35.4%), heartburn (29.1%), regurgitation (11.4%), retrosternal burning (10.1%),

abdominal pain or pressure (3.8%), nausea (2.5%). Baseline GERD health-related quality of life (GERD-HRQL) score was  $21.5 \pm 5.2$  and patients were receiving proton pump inhibitors (PPIs) for a mean of  $4.7 \pm 6.8$  years. After surgery ( $10.7 \pm 3.1$  months), all subjects experienced significant improvement in GERD-related symptoms including dysphagia. Only 2.5% of patients required use of PPIs and no subjects required postoperative esophageal dilatation, no reoperation. And there were no perioperative severe complications.

Postoperatively, the mean GERD-HRQL score was significantly reduced to  $1.6 \pm 3.2$  (92.6% improvement,  $P < .05$ ). This study adds to a growing body of evidence that the RefluxStop™ procedure is safe and effective in management of GERD patients. Notably, a considerable improvement in PPI usage and health-related quality of life parameters were appreciated. Additional studies are required to further validate the role of this procedure in disease management.