

Safety and Effectiveness of Endoscopic Fundoplication Platform System (SRS)

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Laparoscopic Nissen Fundoplication is an effective antireflux operation. The SRS endoscopic stapling device is a new tool capable of creating a totally endoscopic fundoplication (e-fpn). This modified endoscope, once in position, fires 3 rows of staples covering 120 degrees in the coronal plane, effectively plicating the fundus onto the esophagus. The retroflexed scope tip fires the staples from the fundus, once aligned with the complementary segment designed on the scope shaft positioned in the esophagus.

Objectives: Assess the safety and effectiveness of the SRS Endoscopic Stapling System for an e-fpn in patients with GERD.

Methods: A prospective IRB approved trial was designed. A totally endoscopic anterior fundoplication was made using an SRS endoscope. Inclusion criteria were: Documented GERD by pH probe, absence of > 2cm hiatal hernia by EGD, BMI < 35, age 18-75 yrs, ASA class <3 and a normal esophagogram (except reflux). General anesthesia was used and patients were kept overnight. A chest xray and a hematocrit level were checked post operatively. Follow up was at 1, 2, 4, 12 and 24 weeks when an EGD with pH capsule and manometry were repeated. Patient satisfaction, antireflux medications (PPI) use and quality of life (QOL) were monitored using the Velanovich gastroesophageal health related quality of life questionnaire.

Results: Over a 12-months, 15 patients were selected and underwent e-fpn. Their mean (range) age was 51 years (27-71), BMI 24.6 (22-33) and duration of symptoms /PPI use was 11.3 yrs (2-30). Male to female ratio was 3:2. Heartburn and reflux were the consistent symptoms. Operating times decreased from 102.6 min (75-125) to 47.2 min (30-80) after the first 5 cases. There were no complications. Major postoperative symptoms were sore throat in 2, bloating in 2 and constipation in 1 patient. Return to work was in < 7 days. Symptoms in 12 patients significantly improved immediately post e-fpn and were off PPI at 1, 2, 4, 12 weeks followup. They were satisfied and would do e-fpn all over again. Three patients (earlier cases) noted no change and were dissatisfied. The average Velanovich QOL score, off PPI dropped from 26.9 to 5.36 (80% decrease) at 12 weeks and 8.9 (6.7% decrease) at 24 weeks.

Conclusion: SRS endoscopic fundoplication is a safe and affective antireflux procedure. There appears to be a short and steep learning curve.