TITLE: Longer-term Follow-up after Endoscopic Treatment of GERD with the Medigus SRS™ Endoscopic Stapling Device

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ABSTRACT BODY: Introduction: Gastroesophageal Reflux Disease (GERD) is a common is a problem.

While the majority of patients are well controlled with medical therapy, surgical approaches are the mainstay for refractory disease and for patients wishing to avoid adverse effects and costs of long-term use of proton pump inhibitor therapy (PPI). Endoscopic approaches to the treatment of GERD include the Medigus SRS™ stapling device which is a flexible endoscope, coupled with a surgical stapler is used to create an anterior fundoplication. Six month data from the multi-center pilot trial has been published (Gastroenterology 2012; 142(5):S1076) and resulted in FDA approval [510 (K):K120299;5/18/12]. We report on up to two year results of patients treated with the SRS™ system at our institution.

Methods: In this prospective trial, patients with pH probe documented GERD with good response to PPI were treated with the SRS™ device. Under general anesthesia, a flexible endoscope, coupled with an ultrasound range finder was used to place 2-3 staple quintuplets to create an anterior fundoplication. Up to two years post-procedure, GERD-HRQL scores, use of PPIs, H2RAs and antacids as well as overall satisfaction were obtained by phone interview. No additional pH or endoscopic studies were done. Three year data is expected by May, 2013.

Results: Twenty-two patients were treated at Indiana University with the SRS™ device. One patient experienced a GI bleed 4 days after the procedure requiring blood transfusion. Bleeding stopped spontaneously and no therapy was required. Mean follow up GERD-HRQL scores, with baseline score measurement (on or off PPI) determined by PPI use at selected time point (year 1 or 2), improved (See Table 1; Figure 1). Of patients taking any PPI post-stapling, mean omeprazole equivalent doses were decreased from baseline of 47.7 mg/d to 26.8 mg/day at one year and 19.7 mg/d at 2 years. The majority of patients were satisfied at years 1 and 2 and the majority of patients remained off of daily PPI at all time points.

Discussion: At our institution the Medigus SRS™ stapling device proved relatively safe and efficacious for patients with PPI-responsive moderate-to-severe GERD. Fewer than 5% of patients experienced complications and greater than half of patients remained off daily PPI at 2 years post-procedure. Further studies involving multiple centers with larger numbers of patients are required to better understand the role of the Medigus SRS™ device in the future of endoluminal GERD therapy.

Table 1: HRQL scores, patient satisfaction and PPI use after Medigus SRS™ stapling device

	Year 1 Mean Score: Baseline	Year 2 Mean Score: Baseline
HRQL of patients off daily PPI	8.16: 28.3 (n=12)	5.07: 29.7 (n=13)
HRQL of patients on daily PPI	11.0: 12.4 (n=5)	8.4: 11.0 (n=5)
% satisfied	67	78
% off daily PPI	67	67