

Ultrasound Assisted Endoscopic Full Thickness Fundoplasty, Single Center Experience in the First 14 U.S. Patients

Ali Lankarani, MD¹, Anand Patel, MD¹, John Petersen, DO¹, Scott Cooper MD¹, Jose Nieto, DO¹
¹ Borland Groover Clinic, Advanced Therapeutic Endoscopy Center, Jacksonville, FL, USA

Abstract

Endoscopic Full Thickness Fundoplasty (EFTF) appears to be a promising alternative to surgical fundoplication in treatment of patients with symptomatic GERD. EFTF results in a comparable outcome with a lower complication profile. Current generation of Ultrasound assisted EFTF (Medigus Ultrasonic Surgical Endostapler or MUSE) was approved by the FDA in march of 2015 for use in the United States market. Here we present our experience using this device in treatment of 14 consecutive patients in a single center.

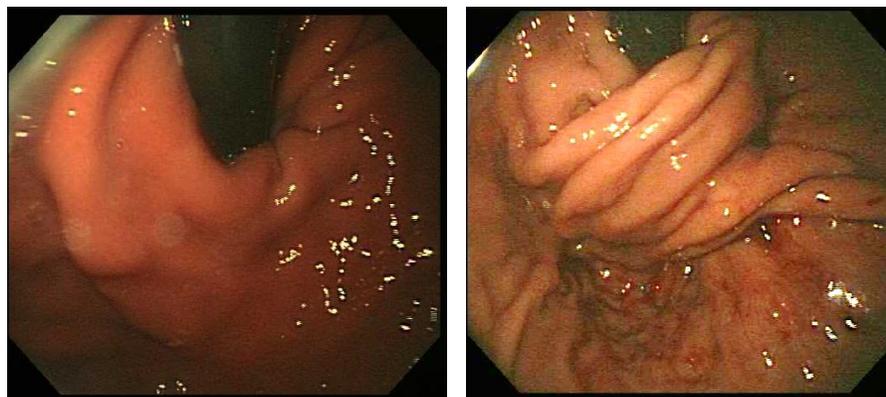
Device

MUSE is a single-use flexible transoral stapler equipped with an ultrasonic sight and range finder and the world's smallest CCD camera. This device is used for creation of incisionless anterior partial Fundoplasty. Full thickness endoscopic plication is achieved by placement of titanium surgical staples between the gastric fundus and esophagus. This creates a high pressure zone 3 cm proximal to the gastroesophageal valve and restores the angle of His.

Patient selection

The MUSE procedure is generally offered to patients with one of the following conditions:

- Refractory GERD and regurgitation despite PPI therapy
- Refractory "extra-esophageal" symptoms such as chronic cough, hoarseness of the voice, noncardiac chest pain despite PPI therapy
- Frequent "breakthrough" symptoms on PPI
- Not tolerating PPIs due to side effects



Before and after MUSE Ultrasound Assisted Full Thickness Fundoplasty

Pre-Procedure Workup

All of the patients had a diagnostic EGD with ambulatory pH monitoring before the intervention to quantify the amount of acid reflux and to confirm the symptom correlation. Esophageal manometry was done in any of the patients with suspicion for esophageal motility disorders. All of the procedures were done under the Institutional Review Board protocol to monitor for procedure-related adverse events and procedure durability up to 3 years post procedure. Patients with Hiatal hernia >3 cm, irreducible hernia of any size or grade IV esophagitis and patients unresponsive to PPI therapy were excluded.

Procedure

All procedures were performed under general anesthesia with endotracheal intubation and ventilation with PEEP of 5 mmHg in a therapeutic endoscopy suite. Hiatal hernia was able to be reduced in all patients with the PEEP and intragastric air insufflation. The transoral stapler advanced into the stomach through an overtube and under direct visualization and each of the stapling locations were identified. The device tip was used to compress the fundus against the esophagus under ultrasonic sight and range finder. When safety of each location confirmed, five standard 4.8 mm surgical staples were simultaneously placed at each location.

Postoperative Care & Outcome

A Single dose of prophylactic antibiotics and two antiemetics were administered before the end of each procedure. All patients were admitted to the hospital for overnight observation post procedure. All patients were discharged the next day on omeprazole 40 mg for 14 days and instruction to remain on a soft diet for one week. The mean operating time for stapling was 77 minutes (range, 37-128 minutes). A mean of 15 staples were used (range, 10-20). Post-procedure 200-degree fundoplasty (range, 180–200 degrees) noted in all patients. Procedure resulted in the conversion of Hill grade 2 and 3 valves to Hill grade 1 in all patients. At discharge, mild epigastric pain and sore throat were the only symptoms noted. This was resolved in 1 to 3 days post procedure. No serious adverse events were reported among our patients. The first three patients were evaluated six months post fundoplasty as part of the MUSE registry protocol and underwent ambulatory pH monitoring. All three subjects had >50 % improvement in GERD - Health Related Quality of Life Questionnaire (HRQL) scores. Significant reductions in average percent total time and upright time pH <4, as well as total number of reflux episodes noted in all three patients.

Conclusions

Ultrasound Assisted EFTF is a safe and promising alternative to surgical fundoplication in treatment for patients who are intolerant to medical treatment, unwilling to take PPIs, or refractory to PPI therapy if there is objective evidence that ongoing reflux is the cause of the refractory symptoms.