



MUSE procedure with Endoflip[®] demonstrates LES diameter reduction

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Patient Background

44 year old male, 5' 10", 194 lbs (BMI =27.8) suffered from daily GERD symptoms for 10 years. GERD-HRQL patient questionnaire total score of 43. Additional symptoms included intermittent regurgitation, sensation of a lump in the throat, belching, and hoarseness. The patient reported total dissatisfaction with his present condition.

Gastroesophageal reflux studies were performed May 2014 on a regimen of Dexilant 60mg daily. There was inadequate suppression of esophageal acid exposure, which was noted to be markedly elevated (43%) with an elevated DeMeester score of 160. Impedance showed increased numbers of reflux episodes, the bulk of which were acidic. There were also frequent episodes of prolonged esophageal stasis observed. There were 9 symptoms of heartburn, 6 of which correlated with an episode of gastroesophageal reflux.

High resolution esophageal manometry (HREM) testing performed May 2014 revealed hypotensive resting LES pressure, weak peristalsis with large peristaltic defects and hypotensive UES resting pressure.

Treatment

The procedure was conducted under general anesthesia. The same anti-emetic protocol used for Per-oral Endoscopic Myotomy (POEM) patients was used, which consisted of Zofran 4 mg every 6 hours.

A 20mm overtube was introduced using a standard gastroscope. The proximal and distal esophagus appeared normal. A regular Z-line was observed at 44 cm from the incisors. There were two, 3mm, isolated islands of salmon colored mucosa located at the 6 o'clock and 11 o'clock positions. There was no evidence of esophagitis, erosions or esophageal ulcers. The scope then traversed the gastroesophageal junction (GEJ) without resistance. The appearance of the fundus, body and antrum was normal. Retroflexion revealed a non-prominent gastroesophageal valve. With breathing movements the cardia presented occasional periods of opening and rapid closing around the scope consistent with valve Type II per Hill Classification.

The scope was withdrawn and the MUSE transoral stapling device was introduced. The device was retroflexed and the internal video camera allowed direct visual guidance. After identifying a stapling location, the MUSE was gently pulled back to place the staple cartridge in the esophagus approximately 3 cm proximal to the GEJ. An articulation knob was used to bend the device tip to press the fundus against the esophagus at the level of the staple cartridge. As the tissues were compressed, and direct visualization was no longer possible, the ultrasonic range finder automatically engaged to display the tissue thickness. When the tissue thickness was between 1.4-1.6mm, a quintuplet of 4.8mm titanium surgical staples was fired. After firing was complete, the MUSE was withdrawn to replace the staple cartridge. A total of three quintuplets were placed.

The overtube was completely withdrawn from the patient and the gastroscope was reintroduced into the distal esophagus. Direct and retroflexed views of the GEJ suggested successful plication. Estimated blood loss was minimal. There were no immediate complications.

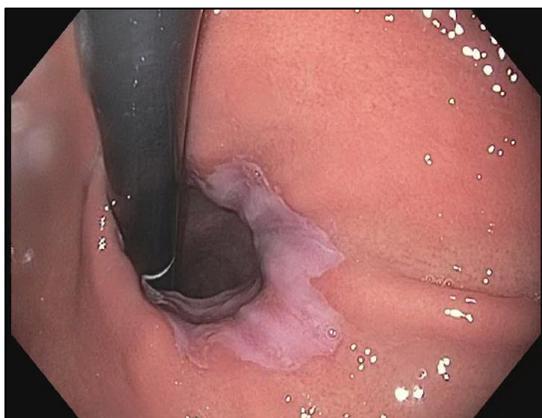


Figure 1: Pre-procedure view of GEJ

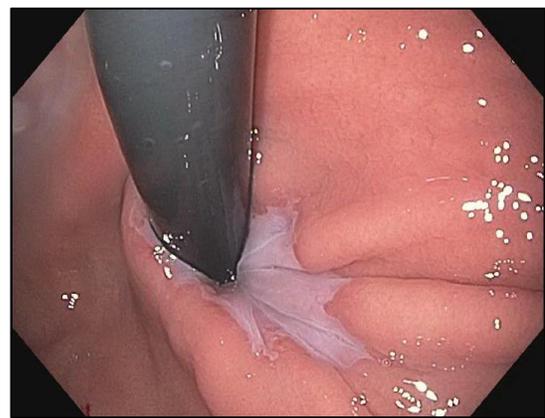


Figure 2: Post MUSE Procedure view of GEJ



Endoflip[®] Observations

The Endoflip[®] catheter was used to conduct evaluations pre-, mid and post-procedure. The catheter allows real time dynamic imaging of the lower esophageal sphincter. The results indicate the MUSE procedure significantly reduced the diameter and cross-sectional area (CSA) of the sphincter.



Figure 1: Screen graphic of Endoflip catheter during measurement of LES

Endoflip Metrics		Pre-Procedure	Mid-Procedure (after 2 sets of staples)	Post-Procedure
30ml	Diameter [mm]	11.2	7.6	6.4
	CSA [mm ²]	98	46	33
	Pressure [mmHg]	42.8	26.9	33.9
40ml	Diameter [mm]	14.6	7.7	7.6
	CSA [mm ²]	166	46	45
	Pressure [mmHg]	39.6	35.8	41.3
50 ml	Diameter [mm]	14.1	12.5	11.1
	CSA [mm ²]	156	122	96
	Pressure [mmHg]	47.3	48.2	60.1

Post-procedure Observations and Plan

The patient experienced some epigastric pain that radiated to his chest similar to his past GERD episodes. He also noted some 'lung pain' when he inhaled deeply. He was monitored closely overnight and was tolerating clear liquids at discharge. The patient was discharged home the next day.

- NPO day of procedure (ice to suck is OK for comfort)
- Intravenous fluids
- Analgesia as needed
- BID PPI IV
- Regular antiemetics - Ondansetron 4 mg IV
- Advance diet as follows:
 - Clear liquids for 48 hours starting at post-op Day 1
 - 1 week of regular liquid diet
 - 10 days of pureed food
 - 1 week of soft food
 - Regular diet