The Endoscopic Management of GERD

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Disclosures

• Consultant, EndoGastric Solutions, Inc.
PPI Therapy: not perfect!

20 - 40% of GERD-patients do not adequately respond to standard or even high-dose PPI therapy

Castell et al. Am J Gastroenterol 2002; 97: 575-83
Incomplete Response

- Cross-sectional survey of patients on chronic PPI therapy, a substantial number of patients remained symptomatic despite therapy
- Regurgitation is likely to be an important factor for determining incomplete response to PPI treatment in GERD

Kahrilas et al. Am J Gastroenterol 2011; 106:1419-1425
Fundoplication (LNF) vs. PPI

- LOTUS Trial, 5-year, Multicenter, RCT, LNF vs. PPI

- RCT, 3 year outcomes LNF vs. PPI

- Meta-analysis
  - Cochrane review 2010
Regurgitation

Better controlled with surgery
The Treatment Gap

- Gap: percentage of patients refractory to proton pump inhibitor (PPI) not interested in undergoing anti-reflux surgery (ARS)
- Demand for incisionless, safe, non-altering & effective antireflux procedures

Adapted from Subramanian et al. Gastroenterology Report (2014) 1-13
Endoscopic GERD Therapeutic Options

- Energy based LES augmentation
- Endoscopic Fundoplication
Stretta by Mederi (formerly Curon Medical)

- Thermal radiofrequency energy to the lower esophageal sphincter (LES) to reduce GERD symptoms.
- Flexible catheter with a balloon-basket assembly and nickel-titanium needle electrodes to deliver the radiofrequency energy into the esophageal wall and LES complex
- Simultaneous irrigation of the overlying mucosa to prevent heat injury
Radiofrequency Energy Delivery to the Lower Esophageal Sphincter Reduces Esophageal Acid Exposure and Improves GERD Symptoms: A Systematic Review and Meta-analysis

- Meta-analysis of randomized controlled trials and cohort studies to assess the impact of this treatment
- Total of 1441 patients from 18 studies included
- Radiofrequency treatment improved heartburn scores ($P = 0.001$) and produced improvements in quality of life as measured by GERD–health-related quality-of-life scale ($P = 0.001$) and quality of life in reflux and dyspepsia score ($P = 0.001$)
- Esophageal acid exposure decreased from a preprocedure Johnson-DeMeester score of 44.4 to 28.5 ($P = 0.007$)
No Evidence for Efficacy of Radiofrequency Ablation for Treatment of Gastroesophageal Reflux Disease: A Systematic Review and Meta-Analysis

- Four trials and a total of 165 patients (153 patients were analyzed).
- Three trials compared Stretta vs sham
- One trial compared Stretta with PPI therapy
- The overall quality of evidence was very low

No Evidence for Efficacy of Radiofrequency Ablation for Treatment of Gastroesophageal Reflux Disease: A Systematic Review and Meta-Analysis

- Pooled results showed no difference between Stretta and sham or management with PPI in patients with GERD for the outcomes of mean (%) time the pH was less than 4 over a 24-hour time course, LESP, reduced use of PPIs, or HRQOL.

Transoral Fundoplication
Current Players

• Medigus Ultrasonic Surgical Endostapler
  - MUSE™

• EsophyX® Transoral Incisionless Fundoplication
  - TIF
Gastroesophageal Junction (GEJ) Endoscopic View

Lesser Curvature

Greater Curvature

Anatomical Landmarks define clock face
Diaphragmatic Crus – Examples
Liver and Spleen

Spleen is located postero-lateral to stomach

Liver is located on the anterior side of the stomach
Hill Grade Classification
The MUSE System

- Disposable endostapler
- Control console
- Accessories (monitor, overtube, cartridges)
- CE Mark, FDA 510k clearance 2014
The MUSE Endostapler

Rigid Section - contains cartridge
The MUSE Endostapler

- Single operator
- Internal video camera
- LED illumination
- Ultrasound assesses tissue thickness
- Alignment mechanism ensures proper staple formation
The MUSE Console

- Single, compact unit
- Provides lighting control, connections to insufflation and irrigation
- Processes all signals appearing on monitor
Medigus Ultrasonic Surgical Endostapler (MUSE™)

**Indications**
- Similar to the indications for laparoscopic surgery.*
- Objective evidence for GERD or its sequelae (positive acid exposure test or endoscopic evidence of esophagitis) AND either:
  - Inadequate symptom control with acid suppression
  - Patient preference for surgery over medications
  - Extra-esophageal manifestations (asthma, hoarseness, cough, chest pain aspiration)

**Contraindications**
- Irreducible hiatal hernia of any size
- BMI < 20 or > 35
- Hiatal hernia >3cm
- Previous failed fundoplication
- Esophageal motility disorders
- Esophageal diverticula, strictures or varices
- Grade IV esophagitis
- Short esophagus
- Gastric outlet obstruction
- Significant co-morbidity (ASA Grade 3 or higher)
The MUSE Console Display

- Automatically switches between direct visualization and ultrasound guidance
- Software controls and messages guide steps and minimize user error
MUSE Procedure

- Overtube placed
- Stapler inserted and retroflexed
- Tissue clamped and staples fired
MUSE Procedure

- Advance into stomach and retroflex
- Retract MUSE system to 3cm proximal to GE Junction, clamp tissue and staple fundus to esophagus
- Remove MUSE to change stapling cartridge and repeat in 2-4 locations to create flap valve (150–180° anterior wrap)

Each application fires 5 staples (quintuplet)
Standard 4.8mm titanium surgical staples
Anterior Fundoplication

- Suggested to be as effective as Nissen (Level 1a evidence)\(^1\)
- Low incidence of dysphagia and gas bloat
- Most common anti-reflux operation in children

Pre-MUSE | Post-MUSE

MUSE™ System Data

Endoscopic Anterior Fundoplication With The Medigus Ultrasonic Surgical Endostapler (MUSE™) For Gastroesophageal Reflux Disease: 6-month Results From A Multi-Center Prospective Trial
MUSE™ Data

• Multi-center, prospective study, 69 patients, 6 months
  – 66 patients in primary efficacy analysis

• Endoscopic anterior fundoplication with a video- and ultrasound-guided transoral surgical stapler

• At least 50 % reduction in GERD-HRQL score (off PPI) from pre-procedure values was achieved in 48 of 66 patients (73%, 95 % CI 60–83 %)

• Forty-two patients (64.6 %) were no longer using any daily PPI or other acid reducing medication

• Reduction, not normalization in acid exposure

• Two SAEs were rated as severe and required intervention

Zacherl et al. Surg Endosc Published online: 19 August 2014
Long-term Follow-up Results of Endoscopic Treatment of Gastroesophageal Reflux Disease with the MUSE™ Endoscopic Stapling Device

• Efficacy and safety data for 37 patients were analyzed at baseline, 6 months, and 4 years post-procedure.

• The proportions of patients who remained off daily PPI were 83.8 % (31/37) at 6 months and 69.4 % (25/36) at 4 years post-procedure.

Long-term Follow-up Results of Endoscopic Treatment of Gastroesophageal Reflux Disease with the MUSE™ Endoscopic Stapling Device

- GERD-Health Related Quality of Life (HRQL) scores (off PPI) were significantly decreased from baseline to 6 months and 4 years post-procedure.
- The daily dosage of GERD medications, measured as omeprazole equivalents (mean ± SD, mg), decreased from 66.1 ± 33.2 at baseline to 10.8 ± 15.9 at 6 months and 12.8 ± 19.4 at 4 years post-procedure (P < 0.01). 

EsophyX® Z Device
EsophyX® Technology Platforms: Old and New
EsophyX® Z Device

- Previous EsophyX delivered trailing leg next to leading leg
- EsophyX Z trailing leg prejudiced to esophageal mucosa
- Designed to engage strength of esophagus
Types of Fundoplication - Laparoscopic View

- Toupet: transabdominal fundoplication
  - 270° posterior wrap

- Nissen: transabdominal fundoplication
  - 360° posterior wrap
The TEMPO Trial

TIF EsophyX vs. Medical PPI Open Label Trial

- Randomized, multicenter, Level I comparative study
- 7 centers in the U.S.A. (3 GI, 4 surgical practices)
- IRB (s) approved study
- Target randomization ratio 2:1 (TIF:PPI)

Trad et al. Surg Innov. 2014 Apr 21
Transoral Incisionless Fundoplication Effective in Eliminating GERD Symptoms in Partial Responders to Proton Pump Inhibitor Therapy at 6 Months: The TEMPO Randomized Clinical Trial

- 63 randomized patients (40 TIF and 23 PPI)
- 3 were lost to follow-up leaving 39 TIF and 21 PPI patients for analysis.
- 6-month follow-up, troublesome regurgitation was eliminated in 97% of TIF patients versus 50% of PPI patients
- Troublesome heartburn was eliminated in 90% of TIF patients versus 13% of PPI patients
- 62% of TIF patients experienced elimination of regurgitation and extraesophageal symptoms versus 5% of PPI patients
- EAE was normalized in 54% of TIF patients (off PPIs) versus 52% of PPI patients
- 90% of TIF patients were off PPIs
- 12 month follow up similar

Trad et al. Surg Innov. 2014 Apr 21
TEMPO RCT
6 & 12 Month Summary

- All outcome measures of TIF were sustained and statistically unchanged between 6- and 12–M follow-up
- 84% of TIF patients remained completely off PPI at 12-M vs. 90% at 6-M follow-up
- Esophagitis was healed or reduced in 100% of TIF patients at 12-M vs. 90% at 6-M
- 77% of TIF patients experienced global elimination of regurgitation and atypical symptoms off PPIs at 12-M
- Troublesome heartburn was eliminated in 84% of TIF patients
- In the crossover group of patients, 71% were completely off PPIs 6 months post-TIF
- In crossover patients, TIF was superior to high-dose PPIs in eliminating typical and atypical GERD symptoms
Regurgitation (TEMPO RCT)

Sustained elimination of troublesome regurgitation after TIF

% of patients with eliminated daily troublesome regurgitation

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<th>6 months</th>
<th>12 months</th>
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<tr>
<td></td>
<td>97%</td>
<td>93%</td>
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29/30

28/30

P = NS

P < 0.001

(6-M and 12-M vs. screening ON PPIs)

Evaluated with Reflux Disease Questionnaire (RDQ)
Atypical symptoms (TEMPO RCT)

% of patients reporting troublesome atypical symptoms

- Hoarseness
- Difficulty swallowing foods, liquids, or pills
- Troublesome or annoying cough

Screening on PPIs
Screening off PPIs
6-month off PPIs
12-month off PPIs

6- and 12- M P values < 0.001 in all cases (vs screening ON or OFF PPIs)

Evaluated with Reflux Symptom Index (RSI)
Heartburn (TEMPO RCT)

Evaluated with GERD Health-related Quality of Life Questionnaire (GERD-HRQL)

% of patients with eliminated daily troublesome heartburn

- 6 months: 90% (26/31)
- 12 months: 84% (28/31)

P = NS

P < 0.001 (6-M and 12-M vs. screening ON PPIs)
PPI Use (TEMPO RCT)

82% reported complete freedom of PPIs 12 months post-TIF

% of patients reporting PPI use

- Daily
- Occasionally
- None

Screening:
- 100% Daily
- 0% Occasionally
- 0% None

6-month:
- 2% Daily
- 8% Occasionally
- 90% None

12-month:
- 3% Daily
- 15% Occasionally
- 82% None

P = NS
RESPECT Trial

Randomized EsophyX vs Sham, Placebo-Controlled Transoral Fundoplication

- Randomized, multicenter, sham controlled, Level I comparative study
- 8 academic and community centers in the US
- Randomization ratio 2:1 (TIF+Placebo vs Sham+PPI)
- First RCT focused on regurgitation
RESPECT Trial

- **129 patients** randomly assigned to receive either transoral incisionless fundoplication (TIF) plus 6 months of placebo or a sham procedure plus 6 months of 40 mg omeprazole once or twice daily with assessments at 2, 12 and 26 weeks.

- At 6 months, **68% of TIF** patients reported elimination of troublesome regurgitation compared with 46% of sham patients (P=.041).

- TIF was associated with decreased intraesophageal acid exposure (P<.001) compared with no improvement in pH observed with sham patients.

- Dysphagia and bloating were improved in both groups, adverse events were similar except postoperative epigastric pain and early treatment failure occurred more commonly in sham patients.

This study reports the quality of life (QOL), GERD symptoms and pH outcomes of TIF more than 12 months post procedure.

Troublesome regurgitation was eliminated in 72% (> 12 months) of TIF patients.

Median heartburn score decreased from 17 (range 0-28) to 5 (0-21) at 6 months and to 3 (0-30) at > 12 months post TIF (p < 0.001).

Mean DeMeester Score decreased from 33.6 to 23.9 at 6 months and to 24.7 at > 12 months post TF (p < 0.05).

Complete cessation of PPI therapy was achieved in 72% of TIF patients > 12 months after surgery.

QOL improved more after TF/placebo than after sham/PPI (Figure 2). 76% of sham/placebo group elected crossover to TIF after unblinding.
Lundell RCT 2015

TIF is NOT a SHAM

- EU TIF vs. SHAM study (SHAM arm OFF PPI’s)
- SHAM arm is a true SHAM off PPI’s
- 5 sites
- N=44 (121 screened), 2 years trial, TIF 2.0 technique
- Difficult population at baseline:
  - Hiatal Hernia < 3 cm
  - Hill Grade II (27% of patients)
  - Hill Grade III (73% of patients)
Lundell RCT 2015
TIF is NOT a SHAM

• Primary endpoint: time to treatment failure (% of patients in clinical remission at 6M follow up) LOTUS and SOPRAN trials used this clinical endpoint – high quality of evidence

• Success in 59% of patients
Lundell RCT 2015
TIF is NOT a SHAM

• pH normalized in 69% of TIF patients
• pH normalized in 20% of SHAM patients
• Hiatal hernia reduced on all patients, reflux episodes reduced, and LES pressure significantly improved
• No post-fundoplication SAE’s and minimal SE’s. TIF is safe and efficacious
Long Term Efficacy of TIF
A prospective study with 6Y follow up

Aim: assess the long term of TIF2.0 on GERD patients with daily PPI dependence

• 50 patients underwent TIF 2.0 procedure. At baseline, 6M, 12M and 24M, all patients have been evaluated by:
  • GERD-HRQL
  • GERD-QUAL
  • EGD
  • Manometry
  • 24h pH impedance
  • PPI consumption, Gastric emptying time by scintigraphy

• Subsequent yearly evaluation at 3Y, 4Y, 5Y and 6Y by:
  • GERD-HRQL
  • GERD-QUAL
  • PPI consumption

Long Term Efficacy of TIF
A prospective study with 6Y follow up

• All patients complained of heartburn and regurgitation
• All patients were on PPI’s twice a day
• All patients were operated under deep sedation with propofol
• 28 patients had TIF2.0 standardized
• 22 patients had rotational TIF2.0 procedure described by Bell
• Hill Grade I in 3 patients
• Hill Grade II in 34 patients
• Hill Grade III in 12 patients
• Hill Grade IV in one patient
Long Term Efficacy of TIF
A prospective study with 6Y follow up

• Ineffective esophageal motility in 36% (18/50) of patients
• Gastric emptying time abnormal in 48% (24/50) of patients
Long Term Efficacy of TIF
A prospective study with 6Y follow up

Assessments:

• Symptomatic responses were assessed 6M and 1-6Y post TIF, classified as below:
  – Complete responders: completely stopped PPI’s
  – Partial responders: halved the previous PPI dose
  – Non-responders: still using the pre-TIF PPI dose
Long Term Efficacy of TIF
A prospective study with 6Y follow up

- Responders: 61.2% to 53.1% in first 3 Years
- Although lack of control group, symptom control persisted 3-6 Years indicates there was no placebo effect in the first 6M-12M
SAE & SE, Complications:

- 3.9% of patients: 2 pneumothoraxes discharged in 3 days post TIF (in early learning curve)
- 44% of patients: Mild to moderate epigastric pain in 6h post TIF (analgesics)
- 64% of patients: complained of pharyngeal irritation for 24h
- None of the patients reported either dysphagia or gas bloating
Conclusions:

- 3Y results are stable at 6Y
- TIF achieved long lasting elimination of daily dependence on PPI’s in 75-80% of cases for up to 6 years
- TIF results were inferior to Nissen but similar to Toupet or Dor.
- 8.1% of cases underwent surgical revision (early in the operator’s learning curve)
- TIF may offer an effective and safe option for carefully selected symptomatic GERD patients:
  - Hill Grade I and II
  - HH < 2cm
  - Patients who refuse life-long therapy or surgery, are intolerant to PPI, or have some risk of developing post-surgical side effects
## TIF Appears Safer than Lap Anti-reflux Surgery

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<tr>
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<th>TIF</th>
<th>Lap Nissen</th>
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<td><strong>Intraoperative complications:</strong></td>
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<td>- Perforations</td>
<td>0.1%</td>
<td>1-4%</td>
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<td>- Esophageal leaks</td>
<td>0.1%</td>
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<td>- Intraluminal bleeding</td>
<td>0.1%</td>
<td>1-6%</td>
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<td>- Pleural effusion</td>
<td>0.1%</td>
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<td>- Mediastinal abscess</td>
<td>0.1%</td>
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<td>- Splenectomy</td>
<td>0.0%</td>
<td>0.9%</td>
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<td>- Mortality</td>
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<th><strong>Postoperative complications:</strong></th>
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<td>- Abdominal pain</td>
<td>9-14%</td>
<td>10-40%</td>
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<tr>
<td>- Dysphagia</td>
<td>4-11%</td>
<td>44-90%</td>
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<td>- Diarrhea</td>
<td>0-5%</td>
<td>18-20%</td>
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<tr>
<td>- Gas bloat</td>
<td>3-59%</td>
<td>10-82%</td>
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<tr>
<td>- Nausea</td>
<td>2-11%</td>
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<td>- Herniation</td>
<td>0.0%</td>
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<th><strong>Long-term complications:</strong></th>
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<tr>
<td>- Chronic dysphagia</td>
<td>0.0%</td>
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<td>- Gas bloat syndrome</td>
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**References for TIF**


**References for Lap Nissen**

# The Reimbursement Pathway

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<th>Esophagogastrectomy Fundoplasty Trans-Orifice Approach</th>
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<th><strong>Accepted addition</strong> of code 432XX1 to describe trans-oral esophagogastrectomy fundoplasty</th>
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Health Economics

- CPT application supported by SAGES and Tri-GI societies
- Submitted using solely EndoGastric Solutions data
- Approved March 2015
- Will be effective January 2016
- Code will be 43210
- RUC survey complete Spring 2015
- RUC evaluation published with Medicare’s Final Rule for physician Fee Schedule, 2015
## 2016 MEDICARE PHYSICIAN PRODUCTIVITY COMPARISON - SURGICAL

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<th>PROCEDURES</th>
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1 Estimated using CY2016 National Base Rate, facility, global payment.
Physician: Medicare Payment – CY2016
Gastroenterologist Rates Comparison

2016 MEDICARE PHYSICIAN PRODUCTIVITY COMPARISON - GASTROENTEROLOGY

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Estimated using CY2016 National Base Rate, non-facility, global payment.
Summary

• PPIs often do not completely control symptom - especially regurgitation

• Endolumenal fundoplication can safely and effectively treat regurgitation

• TIF can treat failed traditional fundoplication

• Reversibility not possible with all the technologies

• Endoscopic therapies can fill the GERD treatment GAP
Conclusion

• It is time to adopt new skill sets

• Transoral fundoplication reimbursement supersedes all other endoscopic procedures

• Safety and durability

• Understanding extraluminal anatomy

• Management of significant crural defects and larger hiatal hernias requires collaboration with our laparoscopic surgical colleagues

• Blending of techniques and technology

• Optimize patient selection