Gastroesophageal Reflux Disease (GERD)\textsuperscript{1,2}

Most patients treat their GERD with OTC or Rx medications—most frequently proton pump inhibitors (PPIs). For some patients, these medications don’t adequately control symptoms or may stop working after extended use. These patients are considered refractory to PPIs. Other patients are uncomfortable with side-effects and long-term dependence. Patients are increasingly uncomfortable with traditional anti-reflux surgery (ARS). The treatment gap for GERD patients refractory to PPIs is significant. Patients are interested in a procedure that improves symptom control and reduces medication dependence.\textsuperscript{3}

**TRANSORAL INCISIONLESS FUNDOPICATION** - the TIF procedure, fills the refractory GERD treatment gap. Using an endoscopic approach - similar to diagnostic EGD - the gastroesophageal valve (GEV) is reconstructed without incisions following principles of traditional fundoplication (see cover illustrations).

The TIF procedure maintains an exemplary safety profile with minimal side-effects. Clinical studies report a less than 3% occurrence of gas bloat and dysphagia. Clinical studies evaluating feasibility, safety and initial learning curve have reported a serious adverse event (SAE) rate of <3%. The commercial SAE rate in more than 17,000 procedures is very low <0.45% (1 in every 250 cases).\textsuperscript{4}

<table>
<thead>
<tr>
<th>LOTUS RCT 5-yr\textsuperscript{5}</th>
<th>PPI</th>
<th>ARS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Serious Adverse Events (SAE)</td>
<td>24.1%</td>
<td>28.6%</td>
</tr>
<tr>
<td>Dysphagia</td>
<td>11%</td>
<td>5%</td>
</tr>
<tr>
<td>Gas Bloat</td>
<td>28%</td>
<td>40%</td>
</tr>
<tr>
<td>Flatulence</td>
<td>40%</td>
<td>57%</td>
</tr>
</tbody>
</table>

\textsuperscript{1} 81 Million Americans suffer with symptoms
\textsuperscript{2} 10 million see a doctor
\textsuperscript{3} 6.7 million receive a diagnosis

Only 30,000 choose traditional surgery as treatment
**2 Years TIF Procedure Durability**

In the US TIF Registry study, at two year follow-up: 6

- All symptom scores improved significantly from before TIF procedure and didn’t change significantly between 6, 12, 24 month follow-up as measured by validated questionnaires
- US Registry data; n = 127

**75% of TIF Patients Off PPIs** 6-16

- Weighted average % of patients completely off PPIs
- 75% completely off PPIs; 10 % occasional use
- 11 studies; n=520 patients (weighted average follow-up at 10 mos.)

**85% of TIF Patients’ Esophagitis Healed** 6,11,15,16

- Weighted average % of patients esophagitis completely healed
- 85% completely healed; 6% improved
- 4 studies; n=79 patients (weighted average follow-up at 9 mos.)

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**Abbreviations:**
- GERD-HRQL = Health Related Quality of Life
- Regurgitation = Reflux Disease Questionnaire
- RSI = Reflux Symptom Index
- GERSS = GastroEsophageal Reflux Symptom Score

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Pre-procedure esophagogastro-duodenoscopy (EGD)

Note: The gastroesophageal junction (GEJ) is displaced; valve and anti-reflux barrier are deteriorated. GEV is loosely adherent to the scope and appears incompetent. Phrenoesophageal membrane lengthens, allowing displacement of the GEJ. Small hiatal hernia present.

EGD after completion of TIF procedure

Note: A 270° fundoplication with a 3cm length valve was created. Small hiatal hernia was reduced. GEV is tight to the endoscope and competent. The intra-abdominal esophageal segment is elongated. The dynamics of angle of His have been restored.

References:
2. Utilization: National Hospital Discharge Survey, National Hospital Ambulatory Medical Care Survey
4. Data on file at EGS.
5. Galmiche et al. (LOTUS 5-yr) JAMA. 2011 May 18;305(19):1969-77

EGD after completion of TIF procedure

The TIF procedure follows well established principles of anti-reflux surgery described in SAGES Guidelines 17

“This patient reports symptoms are completely controlled and remains off PPIs over TWO YEARS after their TIF procedure.”

- Peter Janu, M.D., Chilton, WI

17,000+ 800+ 50+ 2 Cat 1

procedures worldwide since EsophyX® device clearance in 2007

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published randomized controlled trials RESPECT (TIF/placebo vs. sham/PPI) and TEMPO (TIF vs. PPI)

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