

# Bell/TIF Registry - Transoral Incisionless Fundoplication (TIF®): 2-year Results from the Prospective Multicenter U.S. Study



## BACKGROUND

The aim of the study was to assess prospectively 2-year outcomes of Transoral Incisionless Fundoplication (TIF) in a multi-center setting.

## METHODS

14-center U.S. registry was designed to evaluate the effects of the TIF 2.0 procedure on chronic gastroesophageal reflux disease (GERD) in over 100 patients. Primary outcome was symptom assessment. Secondary outcomes were proton pump inhibitor (PPI) use, degree of esophagitis, safety and changes in esophageal acid exposure.

## RESULTS

127 patients underwent TIF between January 2010 and April 2011. 19 (15%) were lost to follow-up. No serious adverse events were reported. GERD Health-Related Quality of Life and regurgitation scores improved by 50% or greater in 63 of 96 (66%) and 62 of 88 (70%) patients who had elevated preoperative scores. The Reflux Symptom Index score normalized in 53 of 82 (65%) patients. Daily PPI use decreased from 91% to 29%. In patients amenable to postoperative testing, esophagitis healed in 12 of 16 (75%) and esophageal acid exposure normalized in 8 of 14 (57%).

## CONCLUSION

Safely achieved and sustained symptomatic control over a 2-year period in 2/3 of patients demonstrates durability of relief of typical and atypical GERD symptoms, and the absence of de novo side effects.

## KEY POINTS

1. Dysphagia, Bloating, Flatulence: No incidence of de novo dysphagia was observed at 24-month follow-up measured by GERD-HRQL or GERSS dysphagia questions.
2. Median GERD-HRQL improved from 26 to 6.
3. Regurgitation: 70% had a 50 percent or greater reduction in their score.
4. Reflux Symptom Index: 82 patients with an abnormal RSI score, greater than 13, at presentation was normal, 13 or less, in 53 patients (65%) at 2-year follow-up.
5. Principle findings of the current study:
  - TIF could be performed safely in the community setting.
  - TIF resulted in successful clinical outcomes, measured by various QOL measurements in 65% RSI, 66% GERD-HRQL, 71% GERSS and cessation of daily PPI use in 70% of patients.
  - TIF side effect profile almost nonexistent; global diminutions in dysphagia, bloating and flatulence.

Bell, RCW	Fox, MA
Barnes, WE	Freeman, KD
Carter, BJ	Gunsberger, T
Sewell, RW	Hausmann, MG
Mavrelis, P	Dargis, D
Ihde, GM	DaCosta Gill, B
Hoddinott, KM	Wilson, E

*Ambulatory Surgery*  
2014

<https://www.ncbi.nlm.nih.gov/pubmed/25347499>

Learn more about the TIF® Procedure for Reflux

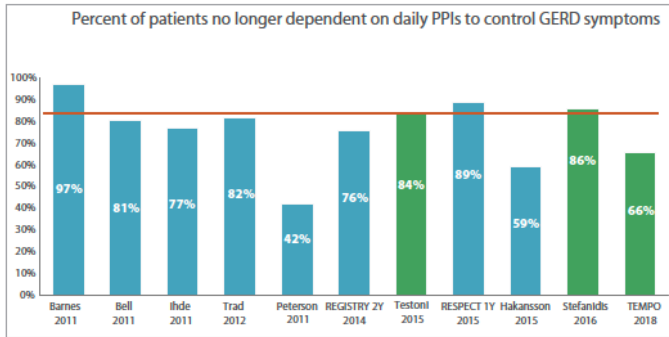


# Data Supports GERD Treatment Gap Option



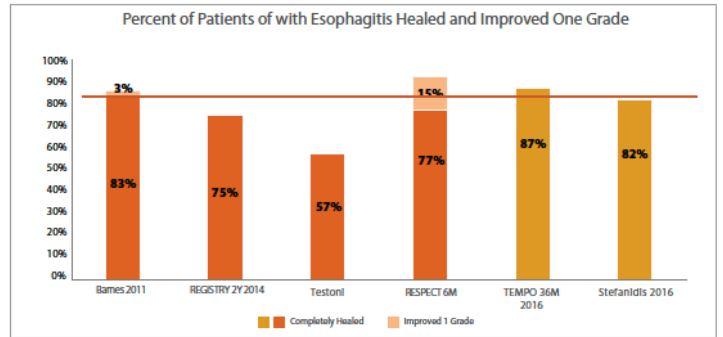
**81%** of TIF patients no longer use PPIs daily

**84%** Esophagitis healed or improved one grade



Weighted incidence is 81.41% across 11 studies with follow-up > 6mo in 568 patients

Weighted incidence is 78.35% across 3 studies follow-up > 59 mo in 120 patients

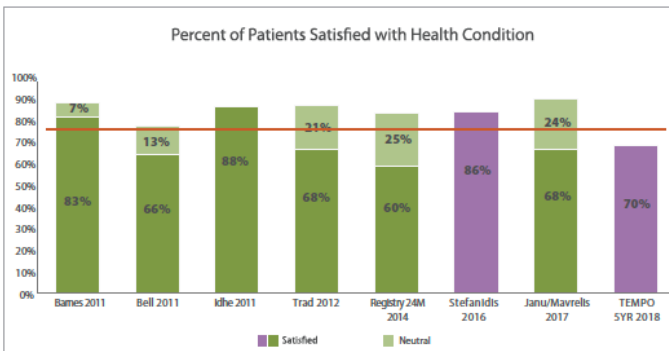


Weighted incidence is 80.25% across 6 studies follow-up > 6mo in 122 patients)

Weighted incidence is 83.94% across 2 studies follow-up > 36mo in 56 patients)

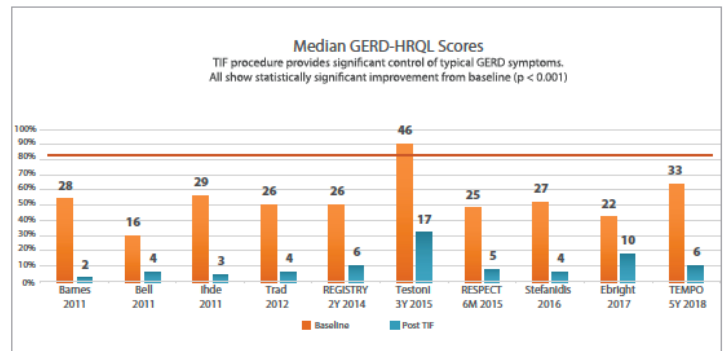
**78%** of TIF patients were satisfied with their health condition

**81%** Significantly improved quality of life scores



Weighted incidence is 73.1% across 8 studies follow-up > 6mo in 495 patients)

Weighted incidence is 78.4% across 2 studies follow-up > 59mo in 88 patients)



In the 10 studies where the follow-up was >=6 months, the weighted average percent reduction in the median score from the pre-study median baseline was 80.81%

## TIF Procedure Delivers 10-Year Durability

