

Hiatal Hernia Repair Followed By TIF Demonstrated Significant Symptom Control With No Long-Term Side Effects



BACKGROUND

The TIF (transoral incisionless fundoplication) 2.0 procedure is indicated for patients with a hiatal hernia less than or equal to 2cm. Many patients with gastroesophageal reflux disease (GERD) require hiatal hernia repair. This study examined the safety and efficacy when repairing defects in 2 anatomical structures (hiatus and lower esophageal sphincter) in a concomitant set of procedures in patients with hiatal hernias between 2 and 5 cm.

METHODS

Prospective data were collected from 99 patients who underwent hiatal hernia repair followed immediately by the TIF procedure (HH + -TIF). GERD-HRQL (Health-Related Quality of Life), RSI (Reflux Symptom Index), and GERSS (Gastroesophageal Reflux Symptom Score) questionnaires were administered before the procedure and mailed at 6 and 12 months.

RESULTS

99 patients were enrolled, and all were symptomatic on PPI medications with hiatal hernias between 2 and 5 cm. Overall baseline GERD-HRQL scores indicated daily bothersome symptoms. At 12-month follow-up, median GERD-HRQL scores improved by 17 points, indicating that subjects had no bothersome symptoms. The median GERSS scores decreased from 25.0 at baseline to 1.0 and 90% of subjects reported having effective symptom control (score <18) at 12 months. 77% of subjects reported effective control of laryngopharyngeal reflux (LPR) symptoms at 12 months with an RSI score of 13 or less. At 12 months, 74% of subjects reported that they were not using proton pump inhibitors. All measures were statistically improved at $P < .05$. There were no adverse effects reported.

CONCLUSION

Most patients reported durable symptom control and satisfaction with health condition at 12 months. By combining laparoscopic hiatal hernia repair with a TIF 2.0 valve reconstruction, a greater population of patients could be considered candidates for surgical treatment of their refractory reflux disease without being exposed to the potential effects of traditional laparoscopic anti-reflux procedures.

KEY POINTS

1. Symptoms were considered as clinically significantly improved if the total GERD-HRQL, GERSS, and RSI scores are reduced by $\geq 50\%$ at 6 months (primary) and 12 months (secondary) post-procedure.
2. The median GERSS scores decreased from 25.0 at baseline to 1.0 at month 12. At 12 months, 90% of subjects reported having effective control of their symptoms (score <18).
3. Median GERD-HRQL scores reduced from baseline 26 to 2 at 12 months.
4. Number of SerosaFuse fasteners used varied from 13-14 and 19-20 at each site.
5. GERD-HRQL has a specific question measuring gas bloat. At baseline, median score was 3.11 and at 6- and 12-month follow-ups, it was reduced to 1.42 and 1.30, respectively. Traditional fundoplication patients frequently report an increase in gas bloat.
6. Median RSI scores decreased from 26 points at baseline to 15 and 16 points at months 6 and 12, respectively, indicating a return to a normal status of reflux.
7. At baseline, only 8% of subjects were satisfied with the current state of their health, whereas 68% of subjects were satisfied with the health condition at month 12.
8. Over 60% of subjects reported using PPIs daily at baseline. At month 6, only 11% of subjects were using PPIs daily and 70% reported never using PPIs. At month 12, 74% of subjects reported that they were not using PPIs.

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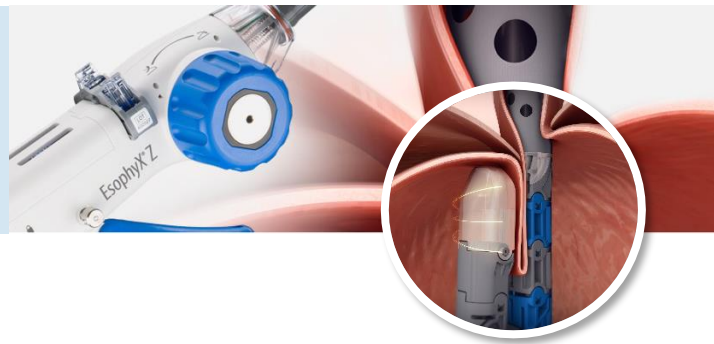
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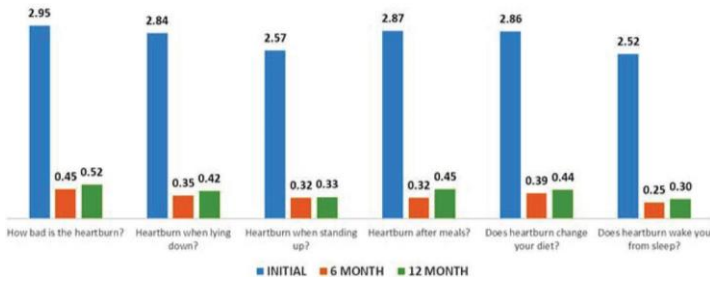
Learn more about the TIF® Procedure for Reflux



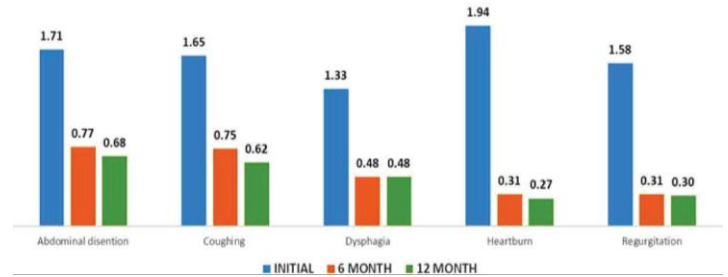
Laparoscopic Hiatal Hernia Repair and Transoral Incisionless Fundoplication with EsophyX Device Efficacy and Safety in Two Community Hospitals - 99 Patients



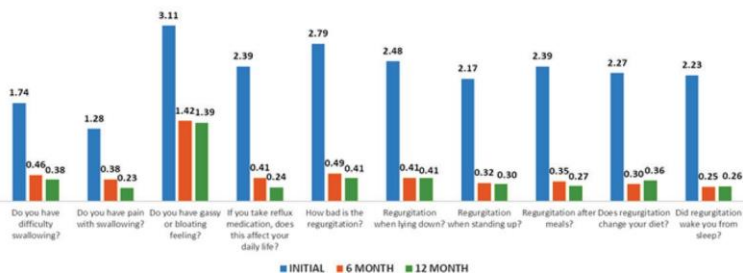
Section GERD-HRQL: Average Scores by Survey Period
Scale: 0 (No Symptoms) - 5 (Severe)



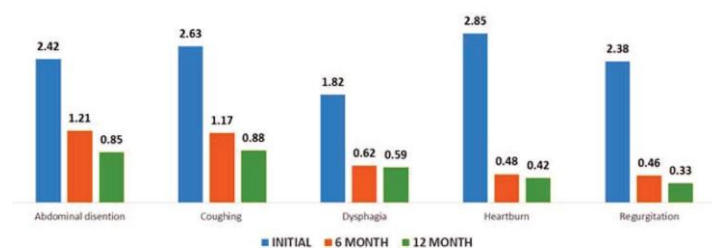
Section GSRS: Average Scores by Survey Period
Q: How much has ... bothered you on a daily basis?
Scale: 0 (Not at all) - 3 (Severely)



Section GERD-HRQL: Average Scores by Survey Period
Scale: 0 (No Symptoms) - 5 (Severe)

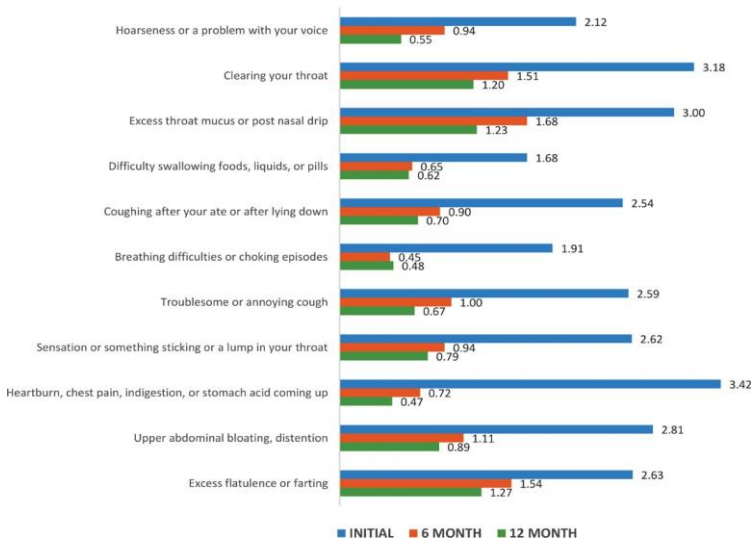


Section GSRS: Average Scores by Survey Period
Q: How often have you experienced...?
Scale: 0 (Never) - 4 (Daily)



Section RSI: Average Scores by Survey Period

Q: Within the last 7 days how have the following problems affected you?
Scale: 0 (None) - 5 (Severe)



Q: How satisfied are you with your current health condition?

