



Efficacy and patient satisfaction of single-session transoral incisionless fundoplication and laparoscopic hernia repair

Catherine Gisi¹ · Kelly Wang¹ · Farhaad Khan² · Sonya Reicher³ · Linda Hou³ · Clark Fuller⁴ · James Sattler⁴ · Viktor Eysselein³

Received: 24 March 2020 / Accepted: 7 July 2020
© Springer Science+Business Media, LLC, part of Springer Nature 2020

Abstract

Background and aims Transoral incisionless fundoplication (TIF) is an effective endoscopic treatment for refractory GERD with small or absent hiatal hernia (< 2 cm in length and width). The single-session laparoscopic hernia repair followed by transoral incisionless fundoplication (HH + TIF) aims to repair mechanical defects in the lower esophageal sphincter that leads to GERD in patients with hiatal hernias ≥ 2 cm. The procedure effectively treats GERD without causing added post-surgical dysphagia and gas bloating commonly associated with partial laparoscopic fundoplication. We aimed to assess patient satisfaction, symptom resolution, safety, and proton pump inhibitor use following the HH + TIF procedure.

Methods Thirty-three patients underwent single-session laparoscopic hernia repair with intraoperative TIF using the Eso-phylX Z device (EndoGastric Solutions, Inc.) between June 2015 and June 2018. The presence of GERD and normal esophageal motility were confirmed with pH testing and manometry prior to the procedure. Data were collected on pre- and post-procedure symptoms, patient satisfaction, PPI use, and complications. Median post-procedure follow-up with symptom surveys was 9 months (11–29 months).

Results Patients reported significant decreases in common GERD symptoms including heartburn, regurgitation, cough, and hoarse voice. Eighty-one percent (27/33) of patients were off daily PPIs. Ninety-four percent (31/33) of patients reported 75% or greater satisfaction with the procedure and outcomes. One patient had a superficial mucosal laceration after the procedure, likely due to vomiting, which was treated conservatively.

Conclusions The majority of patients reported 75% or greater satisfaction with the procedure and had an improvement in GERD symptoms as well as decreased PPI use. There were no serious adverse events.

Keyword GERD · TIF · HH + TIF · hiatal hernia

Abbreviations

GERD Gastroesophageal reflux disease
TIF Transoral incisionless fundoplication

HH + TIF Same session laparoscopic hiatal hernia
 repair followed by transoral incisionless
 fundoplication
PPI Proton pump inhibitor

✉ Catherine Gisi
ckulaga@dhs.lacounty.gov

Kelly Wang
kelly.wang@cshs.org

Farhaad Khan
fkhan0023@gmail.com

Sonya Reicher
sreicher@sbcglobal.net

Linda Hou
Lhou@dhs.lacounty.gov

Clark Fuller
fullerc@cshs.org

James Sattler
jasattler@gmail.com

Viktor Eysselein
veysselein@lundquist.org

¹ Department of Internal Medicine, Harbor-UCLA Medical Center, Torrance, USA

² Keck School of Medicine at USC, Los Angeles, USA

³ Division of Gastroenterology, David Geffen School of Medicine at UCLA, Harbor-UCLA Medical Center, Torrance, USA

⁴ Torrance Memorial Medical Center, Torrance, USA

LES	Lower esophageal sphincter
HRQL	Health-related quality of life
RSI	Reflux symptom index
GERSS	GERD symptom score
SD	Standard deviation

Recent studies report that 20–30% of Americans suffer from frequent GERD symptoms. Pharmaceutical treatment of GERD incurs billions of dollars per year in direct annual costs in the United States, which is more than any other digestive disease [1]. Most patients initially try pharmacologic treatment with antacids, H₂-blockers, and proton pump inhibitors (PPIs). However, it is estimated that more than 30% of patients have GERD that is refractory to PPIs [2]. There are two main mechanical components of the body's inherent anti-reflux system. These include the lower esophageal sphincter (LES) and the pinching forces of diaphragmatic crura on the gastroesophageal junction [3]. Hiatal hernias disrupt these mechanisms leading to the development of GERD [3, 4]. Fundoplication with hiatal hernia repair involves complete hiatal hernia dissection, circumferential mobilization of the gastroesophageal junction below the hiatus, and approximation of the right and left crura using sutures followed by a 360 degree gastric wrap to restore the muscular pinch on the distal esophagus [3]. Nissen is still considered the standard of care for the treatment of severe refractory GERD, and most surgical societies recommend that these patients seek surgical consultations for invasive treatments. However, many patients and providers hesitate to pursue Nissen fundoplication due to common post-procedural complications, such as gas bloating and dysphagia [3, 5].

Recent studies comparing the partial posterior fundoplication (also known as the Toupet procedure) to the Nissen fundoplication showed only slight improvement in dysphagia to solid food 1-year post-procedure, without statistically significant differences in liquid dysphagia over that time period. Though partial fundoplication has shown to be as efficacious and durable at controlling reflux symptoms as total fundoplication, the side effects of these procedures remain a concern [6].

The transoral incisionless fundoplication (TIF) procedure has been well studied in patients with GERD refractory to maximal medical therapy with hiatal hernias less than 2 cm in length and width. TIF treats common GERD symptoms of regurgitation, heartburn, and cough in the long term without causing symptoms of gas bloating and dysphagia that are frequently reported after the laparoscopic total and partial fundoplications [6–10]. However, the EsophyX Z device used to perform the TIF is only capable of reducing hernias less than 2 cm [11]. For this reason, many patients with hernias larger than 2 cm are not candidates for the TIF

procedure. One retrospective study in 2019 by Ihde et al. showed that combining TIF with hiatal hernia repair resulted in significant improvement in GERD symptoms and normalized pH and reflux scores in 21 out of 22 patients at 6-month follow-up. There were also no serious adverse events and no reports of gas bloat or dysphagia after the procedure [11]. Though the TIF procedure has been well-studied, there are few studies on the combined, single-session hiatal hernia repair with TIF 2.0 [11, 12, 13]. More information is needed on this combined procedure regarding patient satisfaction, durability, and efficacy. We propose that combining laparoscopic hernia repair with same session TIF is a safe and effective treatment for patients with refractory GERD who have large hiatal hernias.

Ethical approval

Approval was obtained from the Torrance Memorial Medical Center Institutional Review Board, Torrance, CA. Written and verbal consents were obtained from each patient.

Materials and methods

Thirty-three patients underwent single-session laparoscopic hernia repair with intraoperative TIF between June 2015 and June 2018. Inclusion criteria were adults (> 18 years) with GERD refractory to medical therapy. Most patients had hiatal hernias > 2 cm (Table 1). Two patients had hiatal hernias < 2 cm (1 cm and 1.4 cm) but had severe GERD that was refractory to medical therapy. Exclusion criteria were BMI > 35 kg/m², presence of portal hypertension and/or varices, presence of grade C or D esophagitis, and presence of fixed esophageal stricture. Average age was 66 years (41–84 years); 55% (18/33) of patients were female. Recruitment to the study was solely based on referral of the patient to the performing gastroenterologists' office for severe, refractory GERD. Pre-procedure, patients were surveyed regarding the presence of regurgitation, heartburn, hoarseness, cough, and their PPI use. All patients had pre-procedure 24-h pH studies confirming GERD using the

Table 1 Characteristics of patients who underwent HH + TIF

Patient characteristic		
Female	18/33	
Male	15/33	
Mean age (years)	63	Range 41–84
Mean hiatal hernia size (cm)	3.5	Range 1–7
Paraesophageal hernia	<i>N</i> = 1	

Two patients had hiatal hernias less than 2 cm (1 cm and 1.4 cm)

DeMeester scoring system, in which scores > 14.72 were diagnostic of reflux disease. Each patient underwent esophageal manometry prior to the procedure to confirm normal esophageal motility. All procedures were performed under general anesthesia by the same surgeon and two gastroenterologists, starting with hernia repair (Fig. 1). The right and left crura were approximated posteriorly using 3–4 sutures and if needed one anterior suture over a 60 French bougie. No mesh was used. The laparoscopic incision sites were closed at which point the surgeon no longer had to be present in the operating room. Then, the TIF procedure was performed (Fig. 2). The EsophyX Z device was inserted into the stomach with endoscopic guidance (Olympus GIF 190, Olympus Inc., USA) after dilation of the esophagus with a 54 French bougie dilator. The endoscope was retroflexed in the stomach to confirm the appropriate positioning of the EsophyX Z device (EndoGastric Solutions, Redmond,

WA). The device was placed in the 11 o'clock position and a helix was engaged into the cardia at the Z-line. The cardia was pulled down using the helix after exsufflation. The instrument was then rotated clockwise, the invaginator was applied to suction and six H-fasteners were placed. The procedure was repeated at 1 o'clock position. Fasteners were also applied at 5 and 7 o'clock position. Four engagements of the helical retractor at the GEJ resulted in deployment of an average of 20–26 fasteners, securing the new partial fundoplication. Patients were observed for up to one day in the hospital post-procedure and were discharged on a full liquid diet for 2 weeks and then were able to resume a regular diet. All patients were surveyed post-procedure by phone regarding the presence of GERD symptoms and their PPI use. All patients were asked to complete the following validated symptom surveys: GERD Health-Related Quality of Life (HRQL), RSI (Reflux Symptom Index), as well

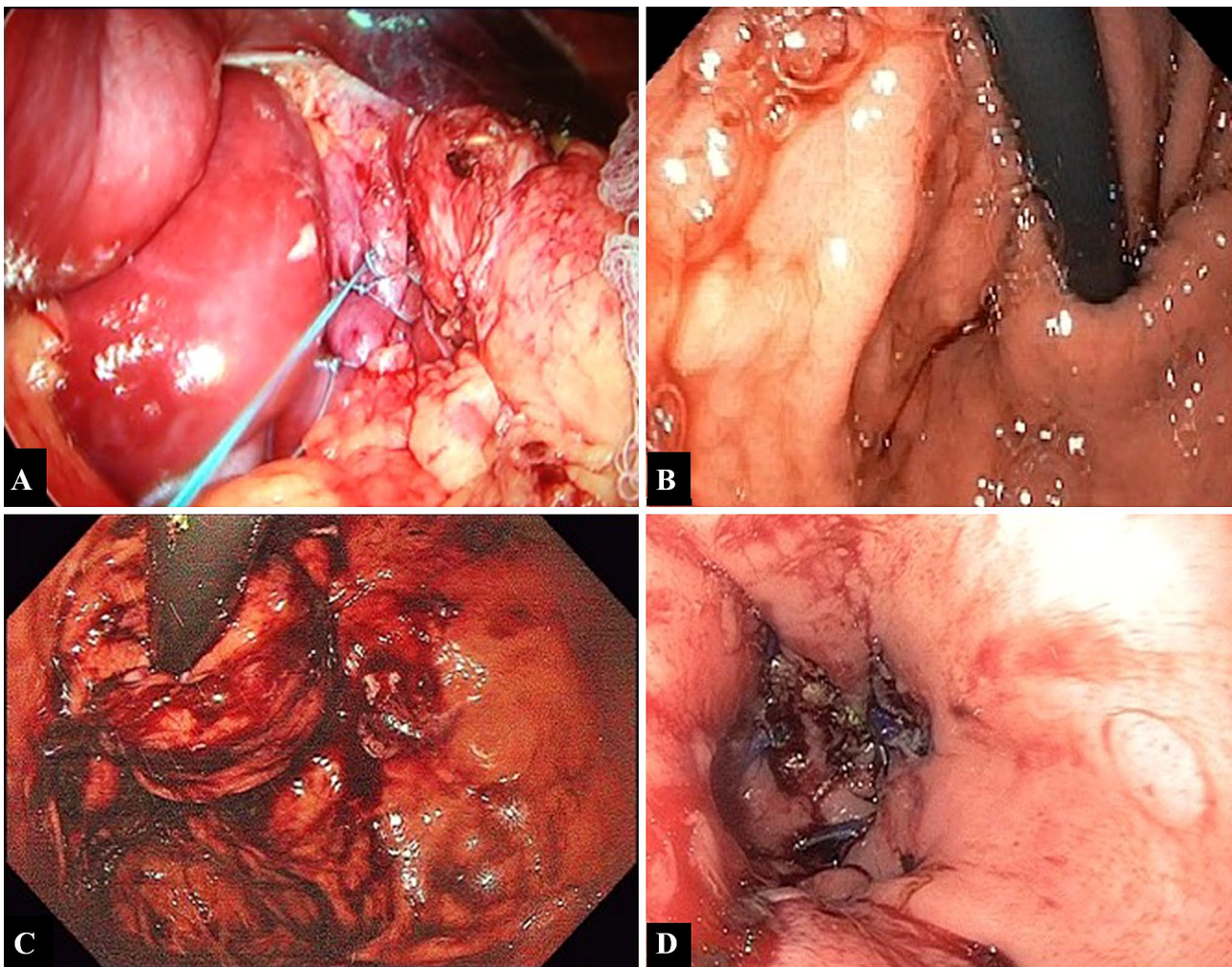


Fig. 1 Endoscopic photographs illustrating hiatal hernia repair and subsequent TIF procedure. Approximation of diaphragmatic crura during laparoscopic hiatal hernia repair (**A**). Gastroesophageal junction after hiatal hernia repair (**B**). Gastroesophageal junction after hiatal hernia repair and TIF (**C**). Intra-esophageal view of gastroesophageal junction after hiatal hernia repair and TIF (**D**)

tion after hiatal hernia repair (**B**). Gastroesophageal junction after hiatal hernia repair and TIF (**C**). Intra-esophageal view of gastroesophageal junction after hiatal hernia repair and TIF (**D**)

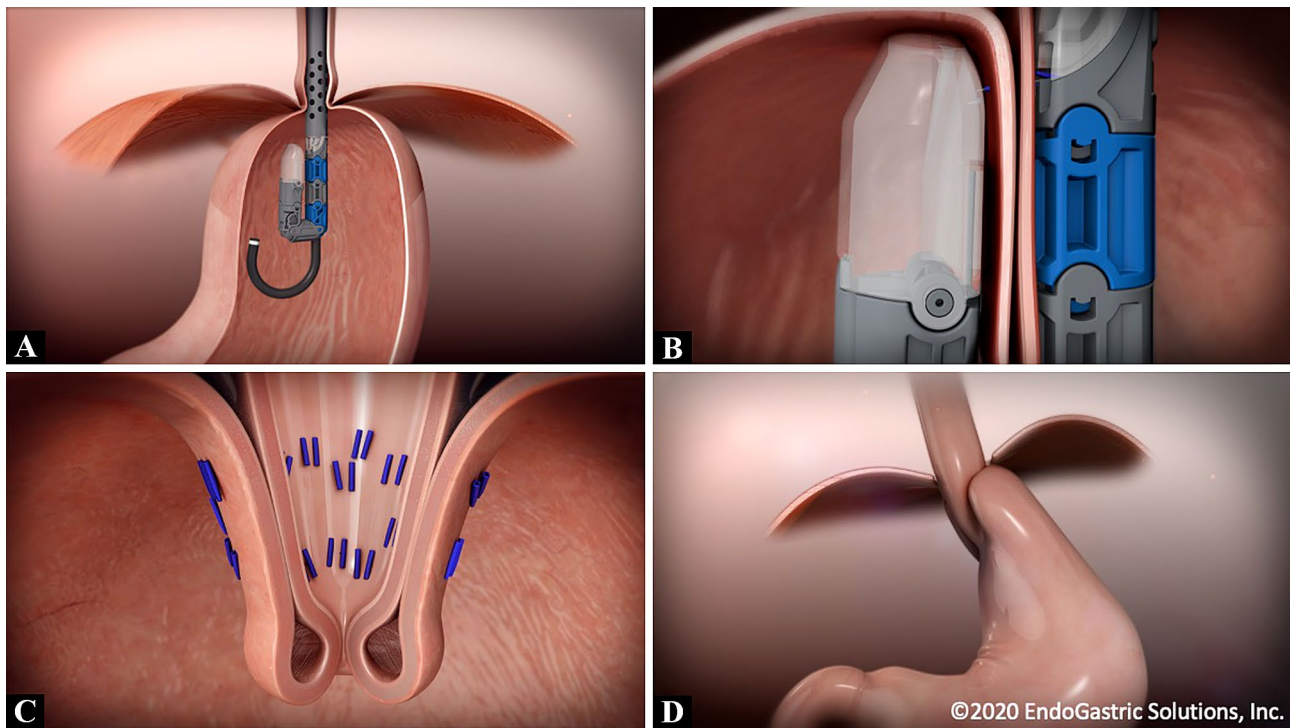


Fig. 2 EsophyX Z+[®] device used in the TIF 2.0[®] procedure. Device is shown at the gastroesophageal junction (A) and gastric tissue is retracted into the tissue mold (B). H-fasteners at reconstructed gas-

troesophageal junction (C). Finished product (D). Images reproduced with permission. ©2020 EndoGastric Solutions, Inc

as the GERD Symptom Score (GERSS) [14–17]. Surveys were collected from patients between 11–29 months post-procedure. Median post-procedure follow-up was 9 months. Symptom intensity was reported on a Likert scale of 0–5. A score of 0 represented “no symptom”, and 5 represented “symptoms are incapacitating to do daily activities.”

Patients reported the presence and intensity of gas bloat and dysphagia as part of the GERD-HRQL and RSI surveys, respectively.

Statistical analysis was performed using GraphPad[®] Prism Version 8.1.1 (224) on all three pre- and post-procedure GERD symptom survey scores using the Wilcoxon rank test. Patients were asked to rate their satisfaction with the procedure on an incremental scale from 0 to 100% satisfaction. These percentages were assigned a score in order to perform statistical analysis. An answer of 25% satisfaction correlated with score of 1, 50% to 2, 75% to 3, and 100% to 4. Wilcoxon rank test was performed on these answers comparing them to a baseline score of 0 pre-procedure.

Results

Pre-procedure, 85% of patients (N = 11/13) reported gas bloat with a mean intensity score of 2.6 and 77% (N = 10/13) reported dysphagia with a mean intensity score of 1. Post-procedure, 54% (7/13) of patients had gas bloat with a mean

intensity score of 1 and 31% (4/13) had dysphagia with a mean intensity score of 1 as extrapolated from the GERD-HRQL surveys.

Pre-procedure 66% (22/33) of patients complained of heartburn, 60% (20/33) had regurgitation; 30% (10/33) had a cough; 21% (7/33) had hoarseness; and 63% (21/33) of patients had more than one symptom (Fig. 3). Post-procedure, 24% (8/33) had heartburn, 9% (3/33) had regurgitation, 12% (4/33) had cough, and 9% (3/33) reported having hoarse voice. Patients were also asked to retrospectively complete GERD-HRQL, RSI, and GERSS surveys post-procedure. Thirteen patients completed the surveys. Mean GERD-HRQL score decreased from 38.6 to 9.46, mean RSI scores decreased from 25.6 to 11.7, and mean GERSS scores decreased from 9.23 to 2.84 post-procedure (Fig. 4). All results were significant with a $p < 0.01$ using a two-tailed *T*-test. Eighty-one percent (27/33) of patients were off daily PPIs. Ninety-four percent (31/33) of patients reported 75% or greater satisfaction with the procedure and outcomes (Fig. 5). Satisfaction scores were significant with a $p < 0.0001$ using the Wilcoxon rank test.

One patient had post-procedural superficial mucosal laceration at the cardia thought to be a Mallory–Weiss tear secondary to vomiting post-procedure. No bleeding or tear was visualized upon removal of the endoscope in the procedure. The laceration was treated conservatively.

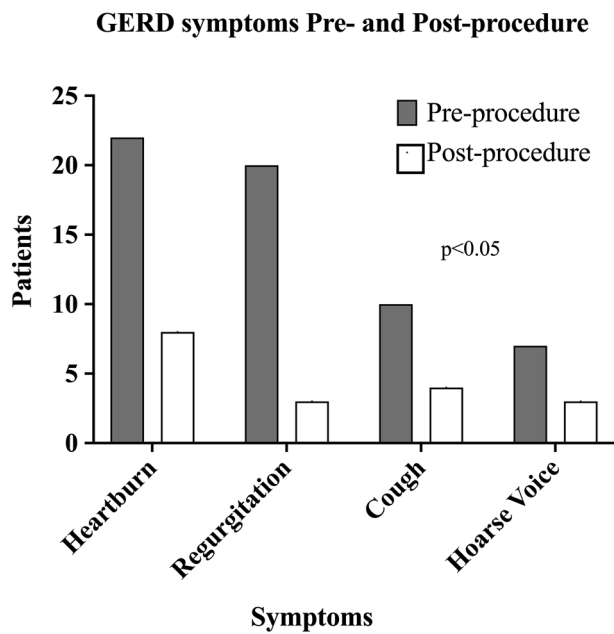


Fig. 3 Prevalence of heartburn, regurgitation, cough, and hoarse voice pre- and post-procedure in 33 patients

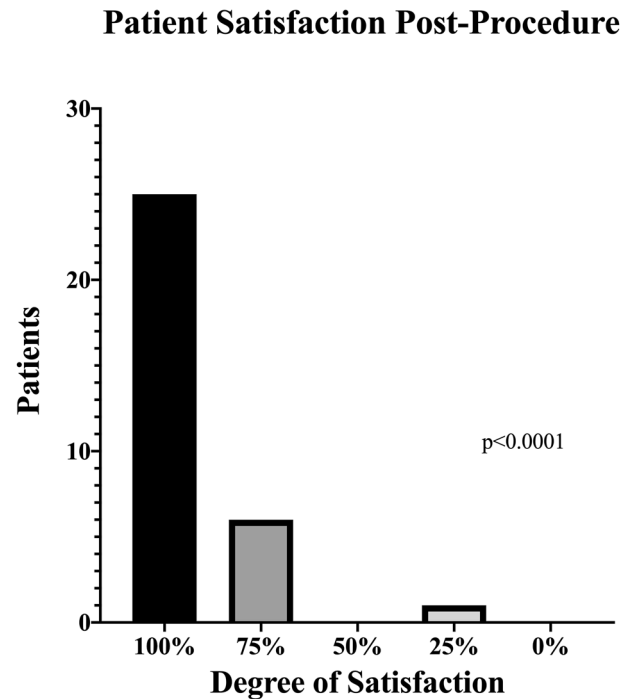


Fig. 5 Patient satisfaction scores post-procedure

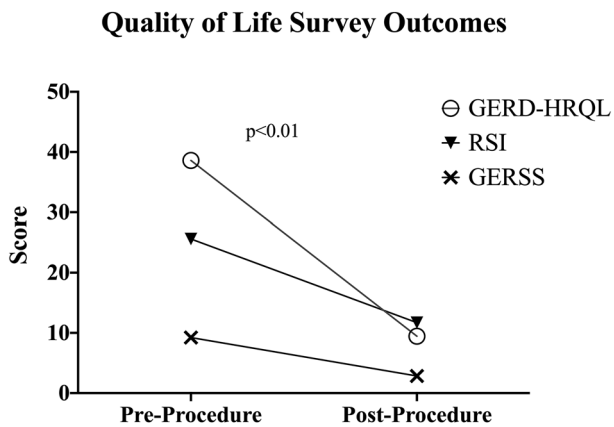


Fig. 4 GERD-Health-Related Quality of Life (GERD-HRQL), Reflux Symptom Index (RSI) and GERD Symptom Score (GERSS) pre- and postHH + TIF procedure

Each hiatal hernia repair took approximately 1 h to complete while the subsequent TIF took between 50–90 min in each patient. Total cost per procedure was not assessed.

Discussion

Our study supports the hypothesis that single-session hiatal hernia repair and TIF could be a safe and effective strategy to treat refractory GERD in patients who do not qualify for TIF alone.

Data extrapolated from GERD-HRQL and RSI surveys showed that a majority of patients had gas bloat and dysphagia prior to the HH + TIF that improved post-procedure. However, the procedure did not completely resolve pre-existing dysphagia and gas bloat symptoms presumably caused by GERD. Håkanson et al. demonstrated that total and partial laparoscopic fundoplication were associated with a slight increase in dysphagia from baseline postoperatively [6]. It is possible that TIF is associated with less gas bloat and dysphagia because the newly created valve is less tight and always calibrated over a 60 French bougie compared to a surgical procedure. In addition, the partial fundoplication during HH + TIF is created by placing anchoring fasteners while the stomach is inflated. This may create a fundoplication that is more durable and tolerant of air that accumulates with meals [12]. It has also been noted that partial wraps less than 360 degrees (such as the Toupet) result in lower rates of dysphagia but control less GERD symptoms [18, 19]. Longer follow-up of HH + TIF patients is needed to assess gas bloat and dysphagia. For comparison, one study by Nikolic et al. reported 12.7% incidence of post-operative gas bloat and 2% incidence of persistent dysphagia 4 years after laparoscopic Nissen fundoplication.

The desire to minimize mechanical adverse effects of the traditional Nissen fundoplication has prompted the exploration of more minimally invasive techniques that have comparable efficacy [6]. However, there are still no head-to-head trials comparing traditional surgical and

laparoscopic funduplications with the TIF. Laparoscopic magnetic sphincter augmentation is another alternative reflux intervention with comparable efficacy to the TIF procedure, though there are no trials comparing this method directly to the HH + TIF [20].

The durability and safety of the HH + TIF procedure must be explored further. Five-year follow-up of patients in the TEMPO trial revealed that 5% of patients required a revision surgery after their initial TIF [21]. There are some concerns that TIF relies on specific technique and careful patient selection to be effective and may result in gradual resumption of PPI's in the long term in some patients [22]. Finally, there have been a few reports of complications such as perforations and the need for additional anti-reflux surgeries [22]. More studies are needed comparing the cost, limitations, efficacy, side-effect profile, and longer-term durability of the partial fundoplication to the TIF with hiatal hernia repair.

One limitation of our study is that 24-h pH monitoring was not repeated post-procedure. However, pH scores are an imperfect measurement of success in the treatment of GERD when regurgitation is the predominant symptom. Impaired acid clearance and increased frequency of reflux events due to mechanical compromise of the gastroesophageal valve due to hernias, for example, contribute to the pathophysiology of refractory GERD [11]. We argue that patient satisfaction and symptom control are practical and valid measures of the efficacy of this combined procedure because they account for a broader spectrum of reflux disease not necessarily related to low pH and acid itself. Other limitations include that this was a single-center, non-randomized, retrospective study using a non-validated satisfaction survey. Another limitation is that pre-procedural symptoms were gathered retrospectively; initially, focus was only placed on patient satisfaction and additional symptom data were gathered upon follow-up.

Overall, we found that the HH + TIF procedure is convenient and efficient for patients in the short term. Patients only have to undergo one session of anesthesia. Further studies are needed to investigate the financial and logistical advantages of performing single-session versus two-session HH + TIF procedure.

Author contributions CG involved in data collection, manuscript writing, and data interpretation. KW participated in data collection, manuscript editing, and project administration. FK collected the data. SR and LH involved in manuscript editing and project design. CF and JS performed data collection and project design.

VE involved in data collection, manuscript editing, project design, analysis, and interpretation of the data.

Funding There was no grant support for this study.

Compliance with ethical standards

Disclosures The authors have no relevant disclosures or conflicts of interest.

References

1. Richter JE, Rubenstein JH (2018) Presentation and epidemiology of gastroesophageal reflux disease. *Gastroenterology* 154(2):267–276. <https://doi.org/10.1053/j.gastro.2017.07.045>
2. Mermelstein J, Mermelstein AC, Chait MM (2018) Proton pump inhibitor-refractory gastroesophageal reflux disease: challenges and solutions. *Clin Exp Gastroenterol* 11:119–134. <https://doi.org/10.2147/ceg.s121056>
3. Rabach L, Saad AR, Velanovich V (2019) How to choose among fundoplication, magnetic sphincter augmentation or transoral incisionless fundoplication. *Curr Opin Gastroenterol*. <https://doi.org/10.1097/mog.0000000000000550>
4. Che F, Nguyen B, Cohen A, Nguyen NT (2013) Prevalence of hiatal hernia in the morbidly obese. *Surg Obes Relat Dis* 9(6):920–924. <https://doi.org/10.1016/j.soard.2013.03.013>
5. Trad KS, Simoni G, Barnes WE, Shughoury AB, Raza M, Heise JA, Mavrelis PG (2014) Efficacy of transoral fundoplication for treatment of chronic gastroesophageal reflux disease incompletely controlled with high-dose proton-pump inhibitors therapy: a randomized, multicenter, open label, crossover study. *BMC Gastroenterol*. <https://doi.org/10.1186/1471-230x-14-174>
6. Håkanson BS, Lundell L, Bylund A, Thorell A (2019) Comparison of laparoscopic 270° posterior partial fundoplication vs total fundoplication for the treatment of gastroesophageal reflux disease. *JAMA Surg* 154(6):479. <https://doi.org/10.1001/jamasurg.2019.0047>
7. Hopkins RJ, Irvine T, Jamieson GG, Devitt PG, Watson DI (2019) Long-term follow-up of two randomized trials comparing laparoscopic Nissen 360° with anterior 90° partial fundoplication. *BJS*. <https://doi.org/10.1002/bjs.11327>
8. Broeders JA, Roks DJ, Jamieson GG, Devitt PG, Baigerie RJ, Watson DI (2012) Five-year outcome after laparoscopic anterior partial versus Nissen fundoplication. *Ann Surg* 255(4):637–642. <https://doi.org/10.1097/sla.0b013e31824b31ad>
9. Trad KS, Barnes WE, Prevou ER, Simoni G, Steffen JA, Shughoury AB, Mavrelis PG (2018) The TEMPO trial at 5 years: transoral fundoplication (TIF 20) is safe, durable, and cost-effective. *Surg Innov* 25(2):149–157
10. Trad KS (2016) Transoral incisionless fundoplication. *Curr Opin Gastroenterol* 32(4):338–343. <https://doi.org/10.1097/mog.0000000000000275>
11. Ihde GM, Pena C, Scitern C, Brewer S (2019) PH scores in hiatal repair with transoral incisionless fundoplication. *JSLs J Soc Laparoendosc Surg*. <https://doi.org/10.4293/jsls.2018.00087>
12. Janu P, Shughoury AB, Venkat K, Hurwich D, Galouzis T, Siatras J, Mavrelis P (2019) Laparoscopic hiatal hernia repair followed by transoral incisionless fundoplication with esophyX device (HH TIF): efficacy and safety in two community hospitals. *Surg Innov*. <https://doi.org/10.1177/1553350619869449>
13. Ihde GM, Besancon K, Deljkich E (2011) Short-term safety and symptomatic outcomes of transoral incisionless fundoplication with or without hiatal hernia repair in patients with chronic gastroesophageal reflux disease. *Am J Surg* 202(6):740–747. <https://doi.org/10.1016/j.amjsurg.2011.06.035>
14. Bazerbachi F, Krishnan K, Dayyeh BKA (2019) Endoscopic GERD therapy: a primer for the transoral incisionless

- fundoplication procedure. *Gastrointest Endosc* 90(3):370–383. <https://doi.org/10.1016/j.gie.2019.05.028>
15. Velanovich V (2007) The development of the GERD-HRQL symptom severity instrument. *Dis Esophagus* 20(2):130–134. <https://doi.org/10.1111/j.1442-2050.2007.00658.x>
 16. Allen CJ, Parameswaran K, Belda J, Anvari M (2008) Reproducibility, validity, and responsiveness of a disease-specific symptom questionnaire for gastroesophageal reflux disease. *Dis Esophagus* 13(4):265–270. <https://doi.org/10.1111/j.1442-2050.2000.00129.x>
 17. Belafsky PC, Postma GN, Koufman JA (2002) Validity and reliability of the reflux symptom index (RSI). *J Voice* 16(2):274–277. [https://doi.org/10.1016/s0892-1997\(02\)00097-8](https://doi.org/10.1016/s0892-1997(02)00097-8)
 18. Broeders JA, Roks DJ, Jamieson GG, Devitt PG, Baigrie RJ, Watson DI (2012) Five-year outcome after laparoscopic anterior partial versus Nissen fundoplication. *Ann Surg* 255(4):637–642
 19. Orlando RC, Liu S, Illueca M (2010) Relationship between esomeprazole dose and timing to heartburn resolution in selected patients with gastroesophageal reflux disease. *Clin Exp Gastroenterol*. <https://doi.org/10.2147/ceg.s12333>
 20. Bell R, Lipham J, Louie B, Williams V, Luketich J, Hill M et al (2019) Laparoscopic magnetic sphincter augmentation versus double-dose proton pump inhibitors for management of moderate-to-severe regurgitation in GERD: a randomized controlled trial. *Gastrointest Endosc* 89(1):14–22. <https://doi.org/10.1016/j.gie.2018.07.007>
 21. Trad KS, Barnes WE, Prevou ER, Simoni G, Steffen JA, Shug-houry AB et al (2018) The TEMPO trial at 5 years: transoral fundoplication (TIF 20) is safe, durable, and cost-effective. *Surg Innov* 25(2):149–157. <https://doi.org/10.1177/1553350618755214>
 22. Edriss H, El-Bakush A, Nugent K (2014) Esophageal perforation and bilateral empyema following endoscopic esophyX transoral incisionless fundoplication. *Clin Endosc* 47(6):560. <https://doi.org/10.5946/ce.2014.47.6.560>

Publisher's Note Springer Nature remains neutral with regard to jurisdictional claims in published maps and institutional affiliations.