

# pH Scores in Hiatal Repair with Transoral Incisionless Fundoplication

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## ABSTRACT

**Background and Objectives:** Transoral incisionless fundoplication is an alternative to traditional laparoscopic fundoplications. Recently, hiatal hernia repair combined with transoral incisionless fundoplication has become an accepted modification of the original procedure; however, outcomes information, particularly objective pH monitoring, has been sparse. We retrospectively review the subjective and objective outcomes of transoral incisionless fundoplication combined with hiatal hernia repair.

**Methods:** Ninety-seven consecutive patients presenting for reflux evaluation were reviewed for outcomes after evaluation and treatment. Fifty-five patients proceeded to hiatal hernia repair with transoral incisionless fundoplication. Twenty-nine patients (53%) were found to have matched preoperative and postoperative validated surveys and pH evaluations.

**Results:** There were no serious complications. The mean followup was 296 days (SD, 117 days). The mean Gastroesophageal Reflux Disease Health Related Quality of Life score improved from 33.7 (SD, 22.0) to 9.07 (SD, 13.95),  $P < .001$ . The mean Reflux Symptom Index score improved from 20.32 (SD, 13) to 8.07 (SD, 9.77),  $P < .001$ . The mean pH score improved from 35.3 (SD, 2.27) to 10.9 (SD, 11.5),  $P < .001$ . Twenty-two of the 29 patients were judged to have an intact hiatal repair with transoral incisionless fundoplication (76%). Of the 22 patients with an intact hiatal repair and intact fundoplication, 21 (95%) had normalized their pH exposure.

**Conclusions:** In this retrospective review, hiatal hernia repair combined with transoral incisionless fundoplication significantly improved outcomes in patients with gastroesophageal reflux disease in both subjective Gastroesophageal Reflux Disease Health Related Quality of Life and Reflux Symptom Index measurements as well as in objective pH scores.

**Key Words:** TIF 2.0, Transoral incisionless fundoplication, pH study, Hiatal hernia, Gastroesophageal reflux disease (GERD), Reflux.

## INTRODUCTION

Gastroesophageal reflux disease (GERD) is a common malady that affects nearly 20% of the adults in the United States on a weekly basis. Transoral incisionless fundoplication (TIF 2.0) has become an alternative to the use of traditional fundoplications for the treatment of GERD but does not address the hiatal hernia component of GERD. Two approaches to the use of the TIF 2.0 procedure have developed. Those who only use TIF 2.0 if the hiatus shows a greatest transverse diameter  $< 2$  cm (cm) or an axial displacement of the Z-line  $< 2$  cm have continued to report increasingly improved symptom control data in level 1 and level 2 studies.<sup>1-9</sup> Another group of physicians have been performing laparoscopic hiatal repair with either delayed or immediate transoral incisionless fundoplication with the TIF 2.0 technique, as this is the most common presentation of patients with GERD and all prior fundoplication procedures have been done only after correction of the hiatal defect.<sup>10-12</sup> In 2017, the US Food and Drug Administration allowed the correction of the hiatal defect just prior to the TIF 2.0 procedure to be added into the device's instruction for use, removing confusion and controversy that has been surrounding the combined approach since it was conceived. This also allows for the publication of data that has not been previously reported. An initial prospective study of the combined laparoscopic hiatal hernia repair with TIF 2.0 was reported by Janu and Mavrelis,<sup>12</sup> showing again excellent symptom control. This retrospective review is

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Informed consent: Dr. Ihde declares that written informed consent was obtained from the patient for publication of this study/report and any accompanying images.

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an initial study of subjective symptoms survey outcomes and objective pH measurement outcomes using a combined laparoscopic hiatal hernia repair with the transoral incisionless fundoplication using the TIF 2.0 procedure.

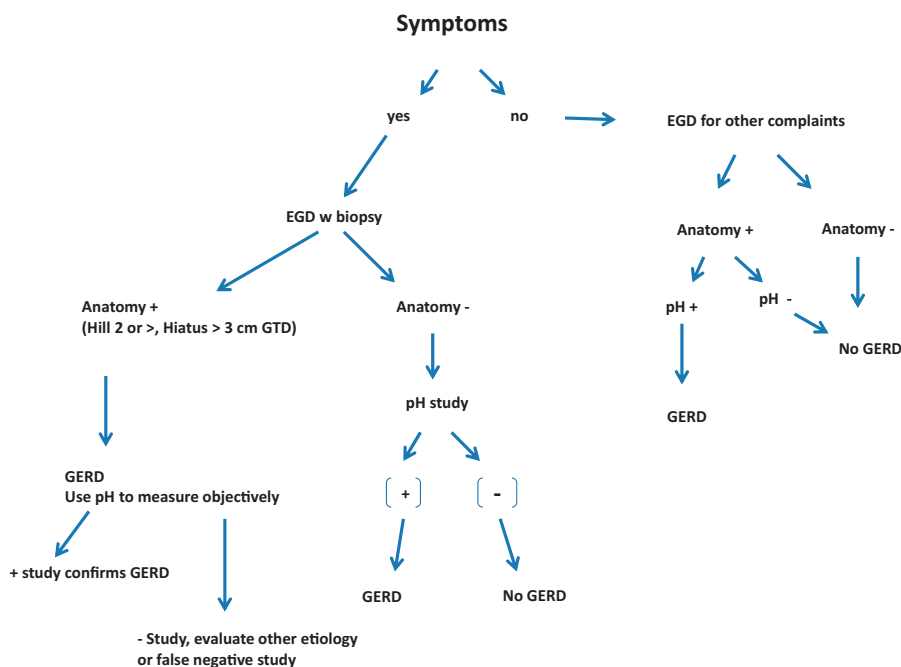
## MATERIALS AND METHODS

Approval for a retrospective study of outcomes data was obtained by the Institutional Review Board at our multi-specialty group. Consent for study was contained in the consent for procedure. A database of patient information was developed from a list of consecutive patients evaluated for reflux disease from October 2015 to December 2017. A routine workup for GERD was performed. Ninety-seven patients were evaluated during this time period. Fifty-five patients proceeded to have hiatal hernia repair with transoral incisionless fundoplication using the TIF 2.0 technique. Thirty patients had no procedure and elected to continue with medical therapy. Eight patients had laparoscopic hiatal hernia repair with laparoscopic fundoplication. Three patients had recurrence of disease symptoms after prior Nissen fundoplication and underwent laparoscopic hiatal repair with transoral incisionless fundoplication to position and fix the wrap on to the esophagus. One patient with known preoperative gastroparesis had previously undergone a hiatal hernia repair with the TIF 2.0 procedure. Postoperatively she continued to have abdomi-

nal pain and bloating. After trying medical therapy she underwent pyloroplasty with resolution of her symptoms.

## Patient Assessment

Patient's diagnosis of reflux disease is obtained using a three-part assessment of symptoms, anatomy, and pH study. A GERD diagnosis decision tree was used to diagnose GERD (**Figure 1**). Disease processes with symptoms that may overlap reflux symptoms were evaluated as well. Patients with complaints of reflux symptoms uncontrolled by medical therapy or concerned about long-term medication cost and side effect were evaluated at an initial visit with validated symptom surveys of GERD Health-Related Quality of Life (HRQL)<sup>13,14</sup> and RSI (Reflux Symptom Index)<sup>15</sup> as well as a complete history and physical. They then underwent further evaluation with upper endoscopy, 48-hour capsule pH monitoring<sup>16-20</sup> (BRAVO™ reflux testing system, Medtronic, Dublin, Ireland), gastric emptying study, hepatobiliary iminodiacetic acid scan with ejection fraction and esophageal manometry (Manoscan, Medtronic, Dublin, Ireland) or barium swallow. Upon completion of the workup, patients had a second office visit and underwent a review and illustration of the results as well as a review of treatment options to include continued medications, laparoscopic hiatal repair with laparoscopic fundoplication, or laparoscopic hiatal repair with transoral incisionless fundoplication. A full review of the history of



**Figure 1.** GERD diagnosis decision tree.

these approaches, risks, benefits, outcomes, and a 6-week recovery diet after surgical procedures was undertaken. Patients with a positive hepatobiliary iminodiacetic acid scan were recommended to have a cholecystectomy at the time of surgical intervention. Patients with a prolonged gastric emptying time were advised of medical treatment options and surgical treatment options but were counseled to not undergo surgical intervention of their gastroparesis at the time of surgical intervention for GERD.

### Endoscopic Evaluation

Patients underwent video endoscopy with intravenous propofol sedation while under the care of an anesthetist. Data recorded included Z line, axial displacement of the Z line from the diaphragmatic pinch, Hill criteria grading,<sup>21</sup> and measurement of the greatest transverse diameter of the hiatal opening by using the retro-flexed tip of the endoscope as a measuring device. The retroflexed tip of the endoscope measures 3 cm across and any patient with a hiatus that would admit the tip of the scope was recommended to undergo hiatal repair at the time of counseling. The omega loop of the retroflexed endoscope measures 4 cm across, allowing for further measurement in larger hiatal defects (**Figure 2**). Biopsy of the gastric antrum for *Helicobacter pylori* and biopsy of the distal esophagus was performed as well. A BRAVO™ pH monitor was placed at the end of the endoscopy. None of the patients evaluated had a hiatus < 3 cm in greatest transverse diameter.



**Figure 2.** Endoscope used to measure hiatus.

### Hiatal Hernia Repair

Laparoscopic hiatal repair was performed with 0-Ethibond Excel® (Ethicon, Cincinnati, OH) figure of eight stitches. One anterior stitch was placed to bring the musculature of the left crural limb over the central tendon and in approximation to the right crural limb. The rest of the defect was closed using 0-Ethibond figure of eight sutures to approximate the posterior right and left crural bundles until the defect approximated the esophagus without impinging upon it. (2–9 sutures) A 58 French bougie was used to dilate the posterior oropharynx and size the hiatal repair to prevent excessive esophageal constriction at the hiatus.

### TIF 2.0 Procedure

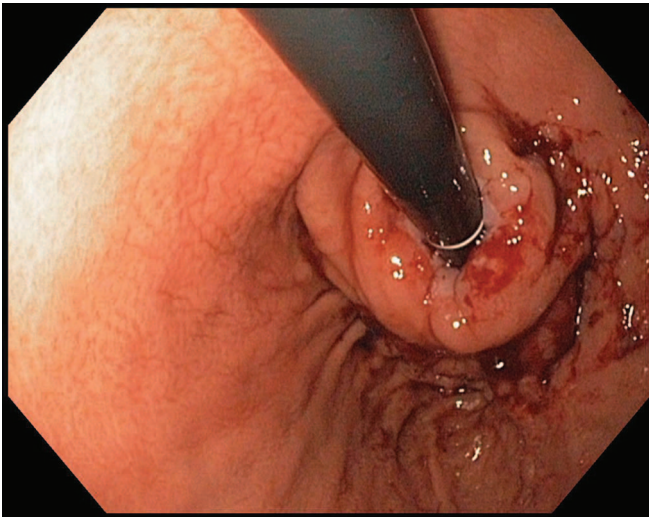
Transoral incisionless fundoplication was performed using the TIF 2.0 technique as described by Bell.<sup>22</sup> This consists of using helical retractor and suction appliance of the EsophyX<sub>2</sub>® device (Endogastric Solutions, Redmond, WA, USA) to stabilize the esophagus with folding fundus over the esophagus using the tissue mold. Then a rotational movement is used to initially pin the 11 o'clock corner with the first 2 Serofuse® fasteners (Endogastric Solutions, Redmond, WA, USA). Then move up the esophagus with 2 more fasteners, then another 2 fasteners further up as tolerated by tension on the tissue. Then we rotate to the 1 o'clock position and in a similar fashion suture the anterior corner with 3 sets of 2 fasteners. Then the 5, 6, and 7 o'clock positions are folded and plicated with 2 fasteners each to try to obtain a 4-cm length fundoplication. Any laxity in either the 11 o'clock or 1 o'clock positions are then tightened up with the remaining 2 fasteners in the 20 fastener cartridge. If needed another cartridge of fasteners can be used to develop the fundoplication to the satisfaction of the surgeon with a goal of developing a 300° 3-cm fundoplication (**Figure 3**).

### Hospital Stay

All patients are monitored overnight and begin a clear liquid, noncarbonated diet when awake and alert from surgery. Patients are discharged home on a 6-week recovery diet in the morning if there is no tachycardia and the white blood cell measurement is less than 15,000 cells per microliter.

### Follow-Up Assessment

Patients are seen again in the office at 2 weeks and if any complaints again at 6 weeks postoperative. Patients are asked to return at 6 months to undergo a survey of their



**Figure 3.** Immediate Post TIF 2.0 procedure.

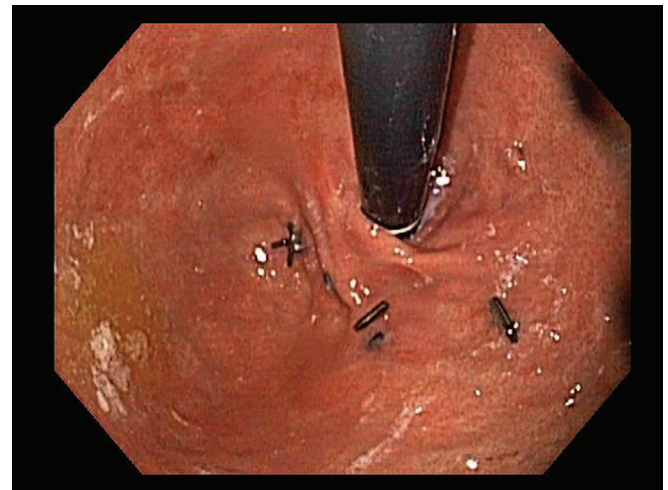
condition, upper endoscopy and repeat 48-hour pH monitoring.

### Treatment Assessment

Patients were evaluated preoperatively with validated surveys, upper endoscopy, and 48-hour pH monitoring. These values are compared to postoperative values at the 6-month follow-up visit. The follow-up endoscopy is performed to assess the hiatal repair, the fundoplication and healing of the esophagus. The GERD-HRQL is a validated symptoms survey consisting of 6 heartburn questions, 2 dysphagia questions, 1 bloating question, and 5 regurgitation questions. An additional question on the use of reflux medication is included. Individual scores  $< 2$  are considered controlled and a reduction of the total score  $> 50\%$  was considered significant. The RSI is a validated measure for laryngopharyngeal symptoms and includes a visual analog scale of 0–5 for 9 items. It is considered positive for a score  $> 13$ . The pH score is a composite measurement of multiple factors in relation to acid exposure to the esophagus and is reported as a DeMeester score. A score  $< 14.72$  is considered normal. Normalization of the pH score was considered significant. This creates a triad for evaluation of symptom survey, pH score and anatomic assessment. The hiatal repair was considered intact if the hiatal opening was graded as Hill I or II with a greatest transverse diameter  $< 3$  cm (**Figure 4**). The fundoplication was considered intact if the wrap was at least  $200^\circ$  in rotation and at least 2 cm in length (**Figure 5**).



**Figure 4.** Recurrent Hiatal Hernia.



**Figure 5.** Failed TIF 2.0 fundoplication.

### Statistical Methods

Data were gathered in a spreadsheet format using Microsoft® Excel (Microsoft, Redmond, CA, USA). Jamovi (<https://www.jamovi.org>) was used to provide statistical analysis. Means and standard deviation are reported with a paired sample *t*-test for two sample means to determine significant changes in the overall group from preoperative baseline to the recommended 6-month followup.

## RESULTS

### Initial Patient Characteristics

Ninety-seven patients were evaluated for reflux. Of the 97 patients reviewed, 61% were female. The median age was

59 years. The mean body mass index was 28 kg/m<sup>2</sup>. Patients were evaluated based initially on complaints of heartburn and/or regurgitation. The patients had a mean 8-year history of proton pump inhibitor use. All had positive indications of GERD using the decision tree of symptoms surveys, pH data, and anatomic assessment. Thirty patients decided to remain on medical therapy. All patients undergoing surgical therapy were found to have a significant hiatal defect on endoscopy, except for one patient who underwent pyloroplasty for gastroparesis. She had undergone a prior hiatal repair with the TIF 2.0 procedure and was known to have significant gastroparesis at the time. She returned to undergo pyloroplasty to relieve symptoms of abdominal pain and bloating after failing medical therapy and had a successful result. Fifty-five patients underwent hiatal repair with transoral incisionless fundoplication using the TIF 2.0 technique. Eight underwent hiatal repair with laparoscopic fundoplication and 3 were hiatal repairs with transoral incisionless fundoplication to repair a failed Nissen fundoplication.

### Follow-Up Assessments

Of the 55 patients who underwent hiatal repair with the TIF 2.0 procedure, 20 (36%) failed to follow up at 6 months. Eight (15%) had no preoperative pH study. Nineteen patients did not return for follow-up assessment, one of whom did not have a preoperative pH study. Twenty-nine patients (53%) were evaluated based on matched preoperative and postoperative assessments. The mean time to repeat assessment was 296 days (SD, 117 days). One of these patients had a pH study elsewhere preoperatively and had reported a pH < 4 for 14% of the time. Postoperatively his pH < 4 was 0.0% of time and so his change is considered significant due to normalization.

Among these 29 patients, the initial mean GERD HRQL score was 33.75 (SD, 22.0) and the mean follow-up score was 9.07 (SD, 13.95);  $t(27) = 6.03$ ,  $P < .01$ ,  $d = 1.14$ . The mean initial RSI score was 20.32 (SD, 13) and the mean follow-up score was 8.07 (SD, 9.77);  $t(27) = 5.80$ ,  $P < .01$ ,  $d = 1.10$ . The mean initial pH score was 35.3 (SD, 22.7) and the mean follow-up score was 10.9 (SD, 11.5);  $t(27) = 5.94$ ,  $P < .01$ ,  $d = 1.12$ . Three of 29 patients (10%) remained on proton pump inhibitor use. One patient had significant gastritis with a pH score of 23.3 (HRQL, 33; RSI, 20) that improved to a pH score of 11.2 after treatment. One patient did not have a preoperative pH score, only a reported percentage of time with pH < 4 statistic and so was not included in the analysis, but postoperatively did normalize the time of pH < 4. Overall, 22 of the 29 patients (76%) normalized their pH exposure.

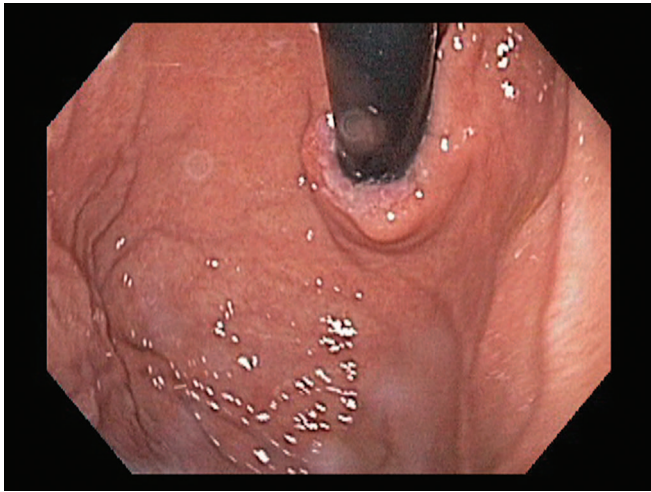
Seven patients (24%) had an elevated pH score. Six of these patients were demonstrated to have defects in their repair. High pH scores were attributed to failure of the hiatal hernia repair in 5 of the 7 patients (71%) and due to poor fundoplication in one (14%). Three patients (11%) were found to have an intact fundoplication but also a recurrent hiatal hernia on an initial follow-up endoscopy, and had pH scores of 23.3 (Health-Related Quality of Life (HRQL), 17; RSI, 16), 34.2 (HRQL, 1; RSI, 4), and 37.8 (HRQL, 60; , 44). Four patients had an abnormal pH score (pH, 40.8; HRQL, 0; RSI, 0), (pH, 22.9; HRQL, 0; RSI, 0) (pH, 37.8; HRQL, 16; RSI, 12) (pH, 18.1; HRQL, 2; RSI, 3) and intact anatomy on initial follow-up endoscopy. Two of these patients underwent repeat endoscopy 3 months later and were found to have a recurrent hiatal hernia (pH, 40.8; HRQL, 0; RSI, 0), (pH, 22.9; HRQL, 0; RSI, 0). One patient had an intact hiatus but the fundoplication was demonstrated to be poor (pH, 18.1; fundoplication, 180°; HRQL, 2; RSI, 1). One patient did not return for repeat assessment after identifying an elevated pH score on follow-up evaluation (pH, 18.8; HRQL, 20; RSI, 18).

Intact hiatal repair with intact transoral incisionless fundoplication lead to normalization of pH scores in 21 of 22 patients (95%).

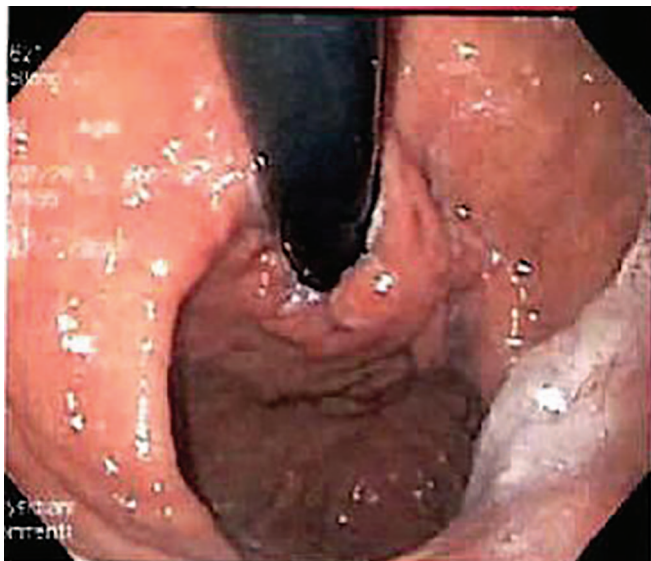
Bloat scores of 0–5 changed from a mean 2.37 (SD, 1.69) to 1.93 (SD, 1.80),  $P = .179$ , and had a Pearson Correlation of 0.55.

### DISCUSSION

In 2007 a tissue manipulation and suturing device called “EsophyX®” (Endogastric Solutions, Redmond, WA, USA) was introduced that would reinvaginate the distal esophagus through the gastric wall to restore the flap valve anatomy (**Figures 6 and 7**). The EsophyX® device was shown to create a transoral incisionless fundoplication that looked remarkably similar to the Nissen fundoplication on endoscopy and showed a similar volume vector profile. Additionally, early reports showed an absence of the post fundoplication bloating syndrome.<sup>23,24</sup> At the same time, concerns have been on the rise over the long-term cost and possible side effects of decades-long use of proton pump inhibitor therapy.<sup>25,26</sup> Transoral incisionless fundoplication demonstrated greater symptom control than medications but pH data was lacking until an initial publication by Bell in 2011.<sup>27</sup> Bell also reported a rotational technique has become the recommended procedure and is referred to as the TIF 2.0 procedure, differentiating any future data set from prior techniques.<sup>22</sup> Additional study indicated that if the hiatal hernia was



**Figure 6.** Normal Anatomy.



**Figure 7.** TIF 2.0 restores normal anatomy.

present and not addressed, approximately half the patients would have early disease control failure.<sup>10</sup> Since the EsophyX® device for endoluminal fundoplication became available in 2007, improvements have been made in the device itself, technique,<sup>22</sup> number of fasteners used and size of the fastener,<sup>28</sup> and overall experience has become substantial among those who have adopted the procedure. Additionally, selection has improved as we have recognized not only the contribution of a hiatal hernia to reflux, but the size at which a hiatal defect will begin to affect outcomes (>2 cm greatest transverse diameter (GTD)).<sup>10–12,22</sup> Improvement in all these factors has improved symptom control from the first prospective regis-

try<sup>6</sup> (70% off proton pump inhibitors (PPI) and 75% esophagitis healed) to the latest prospective trials<sup>3,29</sup> (97% off PPI and 90% healed esophagitis). Durability of the TIF 2.0 procedure has been demonstrated in multiple studies.<sup>3–5,7,9,30–33</sup> However, most reflux patients do present with a hiatal defect > 2 cm. The transoral incisionless fundoplication has advantages over laparoscopic fundoplication due to the avoidance of the bloat syndrome and its reproducibility. This is the compelling argument for using the TIF 2.0 procedure at the time of laparoscopic hiatal repair. Still, only a few research articles<sup>10–12</sup> are available for this technique and although symptom control is good, pH data has not been published using the combined hiatal repair with TIF 2.0 technique.

In this study we show statistically significant improvement in symptom surveys and pH measurement across the group of studied patients with 21 of 29 (72%) of patients normalizing their pH scores. In seven of these patients, pH scores were elevated but the repair was defective (six recurrent hiatal hernias and one poor fundoplication).

In patients with a repair judged to be intact, 21 of the 22 patients had normal pH scores (95%). In the one patient with abnormal pH and intact anatomy on follow up evaluation, one has to consider whether a repeat endoscopy three months later would demonstrate an abnormal anatomy or not. Elevated pH scores on follow-up assessment indicated a defect in the repair in 7 of the 8 patients (88%), whether apparent at the time or discovered at a later endoscopy. Further study with a larger cohort is needed to properly study that relationship. However, these findings further support the importance of hiatal repair and the early effect of even a mildly dilated hiatus on reflux disease (Hill grade >2 or greatest transverse diameter (GTD) > 3 cm) as was demonstrated in an earlier study.<sup>10</sup> It is important to recognize that historically, the durability of reflux control with laparoscopic fundoplication has largely been dependent on the hiatal repair remaining intact as well.<sup>34,35</sup> Unfortunately, no new technique to improve the durability of hiatal hernia repair has been described.<sup>35</sup>

There were no serious adverse events, demonstrating safety in the combined approach. Bloat scores were reduced but not statistically significant, consistent with earlier studies showing no association of increased bloating syndrome with transoral incisionless fundoplication.<sup>6,7</sup>

This retrospective study should provide some groundwork for a further prospective study on outcomes data for the combined hiatal hernia repair and TIF 2.0 fundoplication approach.

## CONCLUSION

In this retrospective review, laparoscopic hiatal hernia repair with transoral incisionless fundoplication using the TIF 2.0 technique is safe and demonstrates an effective means of controlling reflux disease in subjective GERD-HRQL and RSI measurements and objective pH score measurement in this small population of patients with short-term followup. Further, side effects of the bloating syndrome related to traditional laparoscopic fundoplication surgery can be minimized using this technique. Ongoing prospective study is needed to further support these conclusions.

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