

Belsey Mark IV Repair for Recurrent Hiatal Hernia and Failed Fundoplication: An Analysis of Outcomes in 206 Patients

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How to cite this paper: Gharagozloo, F., Meyer, M. and Redan, J. (2022) Belsey Mark IV Repair for Recurrent Hiatal Hernia and Failed Fundoplication: An Analysis of Outcomes in 206 Patients. *World Journal of Cardiovascular Surgery*, **12**, 105-117. https://doi.org/10.4236/wjcs.2022.125008

Received: April 20, 2022 **Accepted:** May 27, 2022 **Published:** May 30, 2022

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Background: With the increasing number of laparoscopic fundoplications, many more patients with a failed primary antireflux operation are being referred for complex redo procedures. The objective of this study was to evaluate our results of redo antireflux surgery using the Belsey Mark IV (BMIV) Repair. Methods: A retrospective analysis of the patients who underwent BMIV repair following a failed fundoplication was performed. The primary endpoint was failure of the redo procedure and recurrent hiatal hernia. Secondary endpoints were assessment of the functional results of the redo fundoplication and quality of life with a Dysphagia Score, and Gastroesophageal Reflux Disease-Health-Related Quality of Life (GERD-HRQOL) questionnaire. Results: 206 patients underwent surgery for failed primary fundoplication. Most patients had one prior antireflux surgery 148/206 (71.8%). The most common primary failed fundoplication was the Nissen procedure (189/206, 91.7%). The median time from the prior operation to the redo operation was 34 months. Median follow-up was 25.6 months. The Dysphagia score decreased from 3.6 ± 0.5 preoperatively to 1.0 ± 0.4 postoperatively (p < 0.0001). At the time of follow-up, the Median GERD-HRQL score was 4 (range 0 - 9), classified as excellent, compared to a preoperative Median GERD-HRQL score of 43 (range 41 - 50) which was classified as poor. (p < 0.0001). There was no recurrence of the hiatal hernia. Conclusion: Complete takedown and reestablishment of the normal anatomy, recognition of a short esophagus, and proper placement of the wrap are essential components of a redo antireflux procedure. The BMIV repair as the choice of reopertaive procedure results in excellent symptom relief, significant improvement in quality of life, and is associated with excellent medium-term durability in terms of recurrence of the hiatal hernia.

Keywords

Redo Fundoplication, Failed Nissen, Belsey Repair

1. Introduction

Laparoscopic fundoplication is the most common surgical approach to hiatal hernia (HH) repair. The failure rates for primary fundoplication range from 2% to 30% [1] [2] [3] [4]. Failure rates are usually underestimated due to the variety of definitions of failure, and the tendency to treat the patients symptomatically [4]. Although many patients with mild recurrent symptoms can be managed nonoperatively, 3% to 6% of primary antireflux procedures will require a reoperative intervention [5] [6] [7]. Failed fundoplication leads to esophageal obstruction, progressive esophageal dilation and dysfunction, as well as cardiac and pulmonary symptoms from compression of the left atrium. In addition to providing symptom relief, the main goal of reoperation in a patient with benign esophageal disease is the preservation of the esophageal function. Surgical options for reconstructive antireflux surgery include redo fundoplication, Roux-en-Y esophagojejunostomy, or even esophagectomy. Although redo fundoplication is a complex operation, in most patients it represents the most physiologically acceptable option. However, the success rates for reoperative antireflux surgery are not equal to those of primary antireflux operations. Results of remedial operations for persistent or recurrent symptoms following anti-reflux surgery are generally less satisfactory compared to the primary procedure, especially after multiple failed surgical attempts [8] [9] [10]. Little and colleagues reported that only 84% of patients undergoing reoperative antireflux surgery through a thoracotomy achieved a satisfactory result and the percentage of patients with satisfactory results declined to 42% in patients who had undergone three or more operations [1]. In a systematic review of laparoscopic redo fundoplication in over 1000 patients, van Beek reported intraoperative and postoperative complication rates of 18.6% and 16.9%, respectively, and success rate of only 81% [11]. The success of redo fundoplication is related to the difficulties in recognizing the pattern of failure and to the inherent technical difficulties due to adhesions and gross anatomical distortion from the previous operation. Complete takedown and reestablishment of the normal anatomy, recognition of a short esophagus, and proper selection of the fundoplication are essential components of a successful redo procedure. Our fundoplication of choice in a patient with a recurrent hiatal hernia, and a failed fundoplication with secondary esophageal dysmotility is the Belsey Mark IV repair through a left thoracotomy. The main objective of this study was to evaluate our experience with reoperative surgery for failed primary fundoplication using this technique.

2. Materials and Methods

We retrospectively reviewed our experience with patients who underwent reo-

perative transthoracic Belsey Mark IV fundoplication from 2013 to 2020.

Preoperatively patients underwent a comprehensive evaluation, with a complete history and physical examination. Investigations performed included barium esophagogram, esophagogastroduodenoscopy, esophageal manometry, pH testing, and gastric emptying studies. In addition, the previous operative procedure was reviewed in detail prior to the reoperation. Data on preoperative variables, including gender, age, symptoms, type of surgery, and the pattern of failure, were collected.

Assessment:

Pre and postoperatively the patients' quality of life was assessed with the Gastroesophageal Reflux Disease-Health-Related Quality of Life (GERD-HRQOL) questionnaire [12]. The questionnaire consists of 10 questions with a maximum score of 50. 6 questions relate to gastroesophageal reflux disease, 2 questions relate to swallowing, 1 question relates to bloating, and 1 for medication use. A greater score indicates a worse symptom severity. The best possible score (no symptoms) is 0 and the worst possible score (most severe symptoms) is 50. HRQOL scores are classified as excellent (0 - 9), satisfactory (10 - 15), or poor (16 - 50) [13].

Dysphagia was assessed using the Dysphagia Score Scale. This previously validated scale ranges from 1 = no dysphagia to 5 = unable to swallow saliva [3].

Surgical Technique:

An on-table endoscopy is performed to assess anatomic abnormalities or the presence of a short esophagus, and also to rule out esophageal mucosal lesions, such as high-grade dysplasia or cancer, which may change our operative approach.

Double lumen intubation and single lung ventilation is used. The patient is placed in the right lateral decubitus position, and a "shoulder" roll is placed an arm's length below the axilla to prevent injury to the brachial plexus. The table is flexed to widen the intercostal spaces and lower the ipsilateral hip out of the way. Reverse Trendelenburg tilting of the table is performed until the axis of the upper spine is parallel to the floor. The Belsey Mark IV Repair (BMIV) is approached via the left-sided posterolateral thoracotomy through the sixth intercostal space. This approach provides the best access to both the esophagus and the esophageal diaphragmatic hiatus. Many times adhesions are encountered which usually result from previous aspiration and lung infections. After the lung is freed, it is protected with a wet sponge and retracted into the apex with a cloth-covered retractor. The mediastinal pleura overlying the esophagus is incised beginning at the esophageal hiatus and extending up to the level of the inferior pulmonary vein. The inferior pulmonary ligament is divided with cautery to the level of the inferior pulmonary vein. The lower esophagus and vagus nerves are mobilized with an encircling maneuver using the index finger a finger. The left and right vagus nerves are identified, but care is taken not to separate the nerves from the body of the esophagus. The esophagus is encircled with a Penrose drain.

Dissection of the previous fundoplication:

In order to gain access to the upper abdomen, the diaphragm is opened with an 8 - 10 cm circumferential incision taking care to preserve the branches of the phrenic nerve. Stay sutures of 0 Ethibond are placed on the edges of the diaphragm and fixed onto the drapes. This maneuver allows the surgeon to approach the area of the previous fundoplication from above and below. Intrabdominal adhesions are taken down using electrocautery, and the left lateral segment of the liver is separated from the fundoplication. The key is to separate the fundoplication from the adherent structures which include, spleen, liver and the aorta. Upward traction on the esophagus with the Penrose drain and elevation of the fundoplication with the left hand facilitates the safe dissection, and decreases the risk of injury to these organs or the esophagus and stomach. The left index finger is used to elevate the wrap from the body of the stomach and using the index finger and the thumb in the left hand, the surgeon squeezes the tissues and identifies the fundoplication sutures. All sutures, pledgets and foreign material are removed. Next the fundus of the stomach is separated from the posterior aspect of the esophagus and the aorta and rotated into its natural position. Any serosal defects are repaired with interrupted 4 - 0 silk suture. The key is to completely takedown the fundoplication and any adhesions which may be twisting the distal esophagus.

Next using a combination of endoscopic visualization and external physical examination of the esophagus, the length of the esophagus and the ability to position of the GE junction under the diaphragm are assessed. In case of a short esophagus, a Collis gastroplasty is performed.

Belsey Mark IV Fundoplication:

Three interrupted 0 Ethibond sutures are placed posterior to the esophagus from the medial to lateral crus of the diaphragm approximately 1 cm apart to permit subsequent closure of the posterior esophageal hiatus after completion of the fundoplication. The sutures are left untied until the end of the procedure. A Maloney dilator of 50 French is introduced orally by the anesthesiologist and guided by the surgeon across the GE Junction (GEJ) into the stomach. The modified BMIV fundoplication is performed by placing 3 interrupted mattress 2 - 0 Ethibond sutures through the sermuscular layer of the stomach, 2 cm below the GEJ, and through the esophagus 2 cm above the GEJ, reversed mattressed, and finally through the diaphragm. The sutures are tied to complete the 270° intussusception of the hiatal crus. The anterior portion of the diaphragm is closed with interrupted 0 Ethibond sutures placed in a mattress fashion using 1cm square pledgets of absorbable vicryl mesh (Ethicon New Jersey, USA).

Using the 50 French bougie as a sizing guide, the posterior crural sutures are tied such that the posterior crural opening can admit the index finger of the surgeon's hand. At the completion of the repair, the bougie is removed and a nasogastric tube is passed through the repair into the stomach with manual guidance. The integrity of the fundoplication and the resultant gastroesophgeal valve is assessed by endoscopy. Any unsatisfactory technical shortcomings are corrected immediately.

Closure and Pain Control:

A single posterior 28 French chest tube is placed for drainage of the pleural space. Two on-Q soaker catheters are inserted into a subpleural tunnel that extends from the second to the eighth intercostal spaces and encompasses the area of the incision. The resultant transient neurolysis of intercostal nerves 2 through 8 is achieved by the infusion of approximately 4 mL/h (2 mL per catheter) of 0.125 bupivacaine from two sequentially connected 400 mL on-Q reservoirs. This system is used even after the patient is discharged from the hospital, giving the patient 10 days of local pain control [14].

The lung is reinflated, and the chest is closed. Prior to transfer to the recovery room, as part of the "fast tracking" protocols, the patient is placed in a supine position, the double lumen endotracheal tube is replaced with a single lumen endotracheal tube and bronchoscopy is performed in order to remove secretions from the collapsed lung and to decrease the risk of postoperative atelectasis [15].

Statistical Analysis:

Data were exported into Excel (Microsoft Corp., Redmond, WA.). Information was obtained through hospital databases, medical records, and our prospective database. The data was prospectively accrued and retrospectively analyzed. Individual consent was waived for inclusion in this study; however, it was required and obtained to enter patient data in the prospective database. This study was determined to be exempt under 45 CFR 46.101 (b).

Descriptive statistics are reported as Median with range or Mean \pm Standard Deviation for continuous variables and as number (percentage) for discrete variables.

The primary outcome variable was failure of the redo procedure requiring reoperation and secondary endpoints included the quality-of-life measures after redo surgery.

3. Results

There were 206 patients who underwent surgery for failed primary fundoplication. Their median age was 46 years (range, 39 to 88 years). There were 78 (37.8%) men and 128 women (62.1%). The majority of patients had one prior antireflux surgery 148/206 (71.8%). 58/206 patients (28.1%) had more than one prior antireflux procedure. The most common primary failed fundoplication was the Nissen procedure (189/206, 91.7%). The remaining patients (17, 8.3%) had a Toupet procedure.

The median time from the prior operation to the redo operation was 34 months.

A recurrent hiatal Hernia with migration of the fundoplication into the mediastinum was seen in 197/206 (95.6%) of patients and was the most common cause of failure of the prior antireflux operation. A short esophagus was noted in 9/206 (4.4%) patients. There was no perioperative mortality. Complications were seen in 45/206 (21.8%) and included atrial fibrillation in 38/206 (18.4%) patients, *Clostridium difficile* colitis in 6/206 (2.9%) patients, and pulmonary embolism in 1/206 (0.5%) patient.

The median length of hospitalization was 6 days (range 5 - 18 days).

Clinical follow-up was complete in all patients. Median length of follow-up was 25.6 months (range 1 to 5 years).

Quality of Life:

The Dysphagia score decreased from 3.6 ± 0.5 preoperatively, to 1.0 ± 0.4 postoperatively (p < 0.0001).

At the time of follow-up, the Median GERD-HRQL score was 4 (range 0 - 9), classified as excellent, compared to a preoperative Median GERD-HRQL score of 43 (range 41 - 50) which was classified as poor (p < 0.0001).

Recurrent Hiatal Hernia and failure of redo fundoplication:

During the medium-term follow-up period there was no recurrence of hiatal hernia.

4. Discussion

For many decades, laparoscopic Nissen fundoplication has been the gold standard surgical procedure for GERD. It is a safe, effective, and durable anti-reflux procedure when performed in specialized centers. However, over the past decade, a negative trend in the utilization of laparoscopic surgical fundoplication has been reported in the United States [5] [16]. This has been due primarily to the perception of long-term side effects and fear of failure [8]. In addition, a variability in clinical outcomes related to surgical expertise and non-standardized technical modifications have restricted the adoption of laparoscopic fundoplication mainly to patients with severe long-lasting disease and large hiatal hernia [17].

Results of remedial operations for persistent or recurrent symptoms following anti-reflux surgery are generally less satisfactory compared to the primary procedure, especially after multiple failed surgical attempts. This is related to the difficulties in recognizing the pattern of failure and to the inherent technical difficulties due to adhesions and gross anatomical distortion from the previous operation. It has been shown that the cause of failure has been properly identified and addressed by an appropriate surgical technique, the majority of patients can benefit from a reoperation [18] [19].

Indications to reoperation should be based on the patient's physiological state, the severity of symptoms, and the response to conservative therapy. In most patients with refractory reflux or dysphagia combined with mechanical outflow resistance, a reoperation is mandatory due to the risk of respiratory complications and even pulmonary fibrosis secondary to aspiration [20].

Dysphagia after primary antireflux surgery can be multifactorial and includes both anatomic problems with the repair (tight wrap, long wrap, twisted fundoplication, recurrent hernia) and esophageal dysfunction. In addition, persistent stagnation in the distal esophagus can cause damage that leads to functional and anatomic impairment of the esophagus. This, coupled with possible vagal dysfunction from the prior procedure, adds to the complexities of evaluating patients for a redo antireflux operation.

Reoperative antireflux surgery is a complex operation and preoperative evaluation should be comprehensive. A barium esophagogram and esophagogastroscopy, and a CT scan of the chest and abdomen with oral contrast are very useful and provide a good delineation of the anatomic abnormalities. These investigations were utilized in all the patients in our series. Esophageal and gastric function tests (manometry, pH testing, gastric emptying) also provide useful information, however, these tests are not absolutely necessary when there is a clear defect noted on the anatomic studies.

The most common cause of failure of fundoplication in our series was a recurrent hiatal hernia and migration of the fundoplication into the mediastinum. These findings are consistent with other large reoperative experiences [14] [21]. Herniation of the wrap in the mediastinum with an intact fundoplication occurs as a result of excessive longitudinal tension or inadequate closure of the hiatus. Other factors are a too long and/or tight fundoplication and a twisted fundoplication that can cause severe postoperative dysphagia, which is usually refractory to dilatation. The mechanism of esophageal obstruction appears to be the recurrence of hiatal hernia, and migration of the normally placed wrap into the chest resulting in tightening of the wrap and strangulation of the esophagus. Failure to adequately mobilize the distal esophagus and fundus, failure to properly repair the hiatus, and failure to properly construct the fundoplication may be the reason for recurrence. Inadequate esophageal mobilization can lead to misidentification of the gastroesophageal junction and placement of the fundoplication around the proximal stomach rather than at the gastroesophageal junction. Although this is often called a "slipped Nissen," it should be considered a misplaced rather than a slipped wrap. Recognition of the fat pad around the angle of His and liberal use of intraoperative endoscopy can help to identify the true gastroesophageal junction.

In this series, a short esophagus was present in only 4% of patients.

Maziak and colleagues reported that they performed a Collis gastroplasty for short esophagus in 91 of 94 patients with giant paraesophageal hernia with a very low rate of recurrent hernia [22]. Others have not routinely added a Collis gastroplasty in the management of large hiatal hernias [19], and asserted that in the majority of patients extensive dissection of the esophagus in the mediastinum results in straightening of the esophagus and obviates the need for a Collis procedure [23]. In patients with reoperative antireflux surgery, Collis gastroplasty has been reported from 0% - 62% of patients.Some authors have suggested the routine addition of a Collis gastroplasty after two failures [24]. In this series, if we were unable to achieve 2.5 to 3 cm of tension-free intraabdominal esophagus after complete mobilization in the mediastinum, we added a Collis gastroplasty to the BMIV repair.

It has been suggested that injury to the vagus nerve could be the cause of delayed gastric emptying in patients with failed fundoplication. It has been shown that in general, laparoscopic fundoplication affects vagus nerve integrity in 10% of patients [25]. In this series, we did not observe disruption of the vagus nerve in any patient. Rather, in all patients with wrap migration and tightening of the fundoplication, the posterior vagus nerve appeared to be strangulated by the wrap. It is unclear to what extent the strangulated vagus nerve contributed to gastric emptying and the patient's symptoms. The significant decrease in the GERD-HRQOL after the reoperation is an indirect indication that freeing the vagus nerve may play a role in improving the patients symptoms. A study which compares gastric emptying before and after the reoperation is under way and may shed light on this question.

The reoperation should be tailored to the individual patient by considering a number of factors: reasons for failure of the first operation, esophageal length, peristaltic reserve, presence of Barrett's esophagus, and concomitant gastric pathology. Esophageal resection should only be considered as a last resort in patients with multiple previous repairs, extensive fibrosis with stricture refractory to multiple endoscopic dilatations, and evidence of dysplasia on Barrett's esophagus [1]. Although revision by laparoscopic techniques is feasible, the procedure is generally expected to be long and tedious due to the adhesions of a previous laparotomy and the difficulties that may be encountered in the takedown of the fundoplication. Excellent results from specialized centers have been reported using laparoscopic reopertive techniques. A systematic review and meta-analysis of laparoscopic revisional anti-reflux surgery, including 19 case series and one case-control study, reported on 922 patients [26]. The overall complication rate was 14% (0% - 44%). A satisfactory to excellent result was reported in 84% of patients, while 5% - 11.3% of patients experienced failure and required reoperation.

On the other hand, one of the classical approaches to reoperative antireflux surgery has been transthoracic [1] [27] [28]. The potential advantages of a transthoracic approach are its applicability in patients with multiple prior abdominal operations, "hostile" abdomen, and when a BMIV fundoplication is chosen by the surgeon as in this series. In the 1950's concurrent with Nissen's work, Sir Ronald Belsey developed an intrathoracic fundoplication, the Belsey procedure. Over the course of 20 years, Belsey made 3 key modifications involving the degree of fundoplication of the stomach. His final procedure was termed the "Belsey Mark IV fundoplication" to signify this stepwise development. In patients with a foreshortened esophagus, an esophageal lengthening procedure (Collis gastroplasty) was added as an option to both procedures due to contributions by J. Leigh Collis and later Griffith Pearson, Robert Henderson, and Mark Orringer [29]. Wide adoption of the BM-IV procedure occurred primarily after a report by Skinner and Belsey that showed an 85% success rate in a review of 600 patients in 1961 [30] [31]. Reported advantages to the BM-IV are many: It

allows a barrier to reflux while maintaining normal swallowing, belching, and vomiting, extensive mobilization of the esophagus, and concomitant procedures to the chest wall, lung, and esophagus. In the laparoscopic era, however, this procedure has fallen out of favor because it can only be performed transthoracically. Although the BM-IV is not widely performed, it is a favorable choice in patients with extreme obesity, large hiatal hernias, previous abdominal surgery, redo surgery, esophageal dysmotility, and extreme esophageal shortening [32]. The noted benefits of a BM-IV repair are challenged by the increased morbidity of a thoracotomy, single lung isolation, and a longer length of stay.

In our view, all redo procedures should be considered complex and should be scheduled as the first case of the day. On-table endoscopy is routinely performed after induction of anesthesia, and the scope is left in the esophagus for intraoperative evaluation. Lysis of adhesions between the stomach and the liver and around the hiatus should be very careful to avoid visceral perforations and injury to the vagal trunks. Full mobilization of the fundoplication is performed by removing the crural sutures and by taking down residual short gastric vessels. The sutures holding the wrap should be removed and the fundus should be rotated counterclockwise and be returned to its normal position. We do not favor the use of a stapler for dividing the two halves of the wrap. The fat pad should be routinely excised to identify the true gastroesophageal junction and a 3-cm tension-free intra-abdominal esophageal segment should be obtained. Care should be taken to minimize tension on the crural repair by clearing the entire surface of the two crural limbs and the peritoneal cover of the crura should be preserved. If a short esophagus is suspected, a modified Collis gastroplasty procedure can be performed in conjunction with the BMIV procedure.

One of the difficulties in follow-up of patients is the systematic assessment and standardized reporting of postoperative symptomatic improvement. We utilized a standardized disease-specific instrument, the GERD-HRQOL questionnaire, to assess symptomatic improvement. Based on the Dysphagia Score and GERD-HRQOL score, following reoperative fundoplication, patients had no dysphagia, and the quality of life of patients returned to the excellent range. These results are better than what has been reported with other series of reoperative surgery either by thoracotomy, laparotomy or laparoscopy.

At medium term follow-up, there were no failures or reoperations.

The excellent results in this series are attributed to 4 key factors:

1) Patient Selection: Most surgical failures can be prevented if patients are properly selected, and procedures are properly performed. It is important to make sure that preoperative symptoms are clearly related to gastroesophageal reflux and not to achalasia, gallstones, irritable esophagus, myocardial ischemia, etc.

2) Choice of operative procedure: Following failed fundoplication and long-standing esophageal obstruction, the esophagus dilates and results in decreased esophageal emptying and motility. The BMIV fundoplication is less obstructive and better tolerated by these patients.

3) Surgical technique: The thoracotomy approach allows the surgeon to accomplish the important steps of the procedure without technical compromise: the nature of the failure is clearly understood, the previous fundoplication is taken down completely, and the reconstruction of the hiatus and the redo fundoplication are performed under direct vision and with absolute technical perfection. Failure to adequately mobilize the distal esophagus and fundus to recognize a true shortened esophagus, to properly repair the hiatus, and to properly construct the fundoplication may be the reason for recurrence. Esophageal shortening may result in misidentification of the gastroesophageal junction and placement of the fundoplication around the proximal stomach rather than at the gastroesophageal junction. Intraoperative confirmation of a true short esophagus should alert the surgeon to perform a Collis lengthening procedure instead of a standard fundoplication.

4) Postoperative management: Immediate surgical failures are commonly the result of uncontrolled postoperative nausea and vomiting causing abrupt rises in intra-abdominal pressure and subsequent mediastinal migration of the wrap. Early failures can occur also as a result of sentinel events such as heavy lifting, abdominal straining, or trauma. Control of early retching and vomiting is critical after anti-reflux surgery. It has been found that about one-third of patients with early retching developed mediastinal herniation of the wrap requiring revisional surgery [33]. Two other significant factors in the postoperative period are the avoidance of lung collapse and its sequelae, and excellent pain control. The former is addressed with the use of postoperative bronchoscopy and strict attention to lung inflation. The latter is addressed by the use of subpleural intercostal catheters that provide prolonged chest wall analgesia for a period of ten days.

5. Strengths and Limitations

This series is one of the largest experiences of redo surgery with esophageal preservation after failed fundoplication. A unique feature of this experience is that a standard procedure, BMIV fundoplication, was performed by a single surgical group in all patients. Limitations include those common to retrospective studies, such as selection bias of treatment and limitations in data collection in a retrospective study. In addition, longer follow up is required for greater maturity of time-to-event data to allow for a more complete evaluation of failure of the redo operation.

6. Conclusion

Revisional surgery after fundoplication is complex, requires good judgment and expertise on the part of the surgeon. Accurate preoperative and intraoperative assessment is necessary to identify the cause of the failure and to tailor the procedure to the individual patient. The present series illustrated that by following these principles excellent results are achieved in terms of quality of life and preservation of esophageal organ function. With the rising epidemic of gastroesophageal reflux disease, reoperative hiatus surgery remains a challenge the complexity of which and volume is expected to remain to increase in the future.

Conflicts of Interest

Authors have no conflict of interest to report.

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