

# A Combined Nissen Plus Hill Hybrid Repair for Paraesophageal Hernia Improves Clinical Outcomes and Reduces Long-Term Recurrences Compared with Laparoscopic Nissen Alone

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## Abstract

**Introduction** We compared clinical and objective outcomes of combined Nissen-Hill hybrid (HYB) to Nissen fundoplication (LNF) for repair of paraesophageal hernia (PEH).

**Methods** This study is a single-institution retrospective chart review of prospectively collected data for consecutive patients undergoing PEH repair from 2006 to 2015 with at least 6 months of follow-up. Quality of life metrics (QOLRAD, HRQL, and dysphagia), manometry, radiographic imaging, and pH testing were administered pre- and postoperatively.

**Results** With 319 repairs (HYB = 141, LNF = 178), the groups were comparable in age and gender, but HYB had a higher BMI (30.95 vs 29.27,  $p < 0.05$ ), larger hernia (6 vs 5 cm,  $p < 0.05$ ), and more Barrett's esophagus (42 vs 29,  $p < 0.05$ ). At a median follow-up of 22 months, DeMeester scores were equivalent but PPI use was higher in the LNF group. All three quality of life scores were better for HYB: GERD-HRQL 3.75 vs 7.49,  $p = 0.01$ ; QOLRAD 6.59 vs 6.23,  $p = 0.04$ ; and swallowing 40.71 vs 36.47,  $p = 0.01$ . At a median follow-up of 60 months (HYB = 39, LNF = 31), anatomic recurrences and reoperations were lower for HYB: 5 vs 45 % ( $p < 0.05$ ), 2.6 vs 9.7 % ( $p = 0.2$ ).

**Conclusion** Combining Nissen and Hill for PEH repair appears to result in better quality of life and fewer recurrences compared to LNF.

**Keywords** Antireflux surgery · Paraesophageal hernia · Laparoscopic · Fundoplication

## Introduction

Paraesophageal hernia represents a major failure in the anatomy and structural integrity of the gastroesophageal (GE) junction and the esophageal hiatus. Complete disruption of the

phrenoesophageal ligament is typically combined with substantial or massive enlargement of the hiatus. Repair must be able to resist heightened cephalad axial forces directed against the GE junction as well as radial tension directed against closure of the hiatus. To date, long-term anatomic recurrence following traditional laparoscopic repair has been high, with rates of 55–66 % in experienced hands.<sup>1–3</sup>

In a recent multi-institution randomized trial with patients entered from 2003 to 2007 to compare laparoscopic Hill repair (LHR) to laparoscopic Nissen fundoplication LNF for uncomplicated reflux disease/sliding hiatal hernia, the repairs were shown to be equivalent in clinical and objective outcomes. However, the causes for failure in this trial highlighted strengths and weaknesses of each repair, with 2/46 LNF failures due to mediastinal herniation of the fundoplication and 2/56 LHR failures due to loosening of the anterior collar sling sutures without herniation.<sup>4</sup> This suggested a strategy which might be effective in repair of paraesophageal hernia (PEH). It was reasoned that critical features of the two repairs might be combined, using the strength of one to offset the weakness of

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the other. The combined Nissen-Hill hybrid (HYB) repair was tested first in complex patients with PEH and/or Barrett's esophagus because of the known high failure in these groups with traditional repairs. A feasibility trial from 2006 to 2008 of 20 patients showed it to be feasible and safe with a low side effect profile, including dysphagia.<sup>5</sup> Expansion of the trial to 50 patients completed in 2010 with a 25-month follow-up assessing clinical outcomes showed improved postoperative quality of life and a 2 % clinical recurrence requiring surgical revision.<sup>6</sup>

From the outset, the primary goal in combining the two repairs was to address the high anatomic recurrence rate following traditional repairs for PEH. The aim of this current study is to compare outcomes for HYB versus LNF for the repair of PEH, including a subset of patients with long-term follow-up to compare anatomic recurrences.

## Materials and Methods

We performed a retrospective review of prospectively collected data for consecutive patients with PEH undergoing primary repair at a single institution over a 10-year period, and with at least 6 months of follow-up. The operations were performed by one of the three thoracic surgeons skilled in the procedures. The choice of procedure was made by the surgeon with two surgeons routinely performing LNF and one surgeon routinely performing HYB. PEH was defined as a hiatal hernia with fundus herniated superior to the GE junction and at least 5 cm axial height of fundus above the hiatus as seen on upper endoscopy (EGD) and/or upper GI radiography (UGI). Patients were excluded if <18 years of age, had poor esophageal motility (<70 % peristaltic waves, distal amplitude <30 mmHg), had presence of esophageal stricture or short esophagus determined intraoperatively (defined as esophageal intra-abdominal length <2 cm from the anterior rim of the hiatus after high mediastinal dissection), use of Collis gastroplasty, had a history of previous antireflux surgery, active malignancy, or medical contraindications to surgery.

The primary outcome measures were clinical, defined by quality of life metrics and recurrent reflux determined by pH testing. Secondary outcomes were adverse outcomes, as well as long-term recurrence defined as hernia >2 cm on imaging or having symptomatology requiring operative revision. We used the Ottawa Thoracic Morbidity and Mortality (TM&M) classification system for complications. This ranks complications according to their impact on resource utilization and re-interventions, according to their level of care.<sup>7</sup>

Operative technique of the HYB was performed as previously described with two of the usual four nonabsorbable Hill sutures passed sequentially through the anterior and then the posterior collar sling musculature of the GE junction and then through the pre-aortic fascia, tied down over a 56–58 bougie

after completion of a full Nissen wrap, oriented at the 9:00 position. In relation to LHR, these would be considered the lower two anchoring sutures (Fig. 1).<sup>5</sup> At the discretion of the surgeon, Surgicel (Ethicon, Johnson and Johnson, New Brunswick, NJ) was placed to repair hiatus in the HYB group when primary repair was under tension whereas Bio-A (GORE, Flagstaff, Arizona) was used for the hiatus in the LNF group.

Patient evaluation included investigational studies performed postoperatively at 6 months as well as 1–3 yearly follow-up. Our standard practice is to encourage all patients to undergo routine testing at 6–12 months because of the high recurrence rates following PEH repair and because postoperative symptoms may be unreliable. Some patients underwent testing at a later date to follow identified abnormalities or for recurrence of symptoms. Studies included UGI, EGD, high-resolution manometry, and selective wireless pH analysis. Self-administered quality of life metrics for GERD and dysphagia were measured pre- and postoperatively and included the Quality of Life in Reflux and Dyspepsia Questionnaire (QOLRAD), the Gastroesophageal Reflux Disease Health-Related Quality of Life (GERD-HRQL) metric, and the Dysphagia Severity Score Index, calculated as previously described.<sup>7</sup> For patients who were unable to complete quality of life metrics in person, they were interviewed by phone by a physician utilizing a scripted interview format. Postoperative proton pump inhibitor use was defined as daily or almost daily. A subset of patients with a >24-month follow-up were analyzed for long-term anatomic recurrence and failure requiring reoperation.

The study and database were both approved by the Institutional Review Board of Swedish Medical Center. Individual patient consent was waived due to the retrospective nature of the study. Postoperative quality of life data were completed in person during clinic visit or by phone interview.



**Fig. 1** Nissen wrap sits above the placed Hill sutures: in the hybrid procedure the Nissen wrap sits above the previously placed Hill sutures that are clipped and placed in the abdomen

Statistical analysis was performed with continuous variables analyzed using Student’s *t* test and chi-squared comparisons for categorical values. Statistical significance was defined as a *p* value <0.05.

**Results**

Between 2006 and 2015, laparoscopic PEH repairs were performed on a total of 474 patients with at least 6 months of follow-up. After excluding previous antireflux surgery and short esophagus, there were 141 patients in the HYB group and 178 in the LNF group (Fig. 2). The median follow-up and age were equivalent between the groups; BMI and average hiatal hernia size were slightly higher in the HYB group, and Barrett’s esophagus was significantly more frequent (29.7 vs 16.3 %, *p* < 0.05). Preoperative objective data were similar between the groups (Table 1).

**Perioperative Findings**

There were no intraoperative or postoperative 30-day mortalities. The rate of intraoperative complications between the two groups was comparable with 14 (10 %) in the HYB group and 20 (11.2 %) in the LNF (*p* = 0.71). These included splenic injury (2/1.4 vs 5/2.8 %, *p* = 0.4), esophageal injury (1/0.7 vs 1/0.56 %, *p* = 0.87), gastric injury (2/1.4 % vs 0, *p* = 0.11), liver injury (2/1.4 vs 4/2.25 %, *p* = 0.58), bowel injury (0 vs 1/0.56 %, *p* = 0.79), and injury to the vena cava (1/0.7 % vs 0, *p* = 0.26). These were all limited intraoperative complications, with no blood loss >200 cc, no postoperative leaks, and no returns to the operating room. The impact on operative time was not assessed.

Using the Ottawa Thoracic Morbidity and Mortality(TM&M) classification system (Table 2), we had one grade IV complication, one grade III, and six grade II complications in the HYB group. There were eight readmissions with only one requiring admission to ICU for 2 days for uncontrolled atrial fibrillation. A total of four were admitted for dehydration; one patient was

**Table 1** Demographics and preoperative data

	HYB N = 141 (%)	LNF N = 178 (%)	<i>P</i> value
Gender (F)	96 (68)	117 (66)	0.44
Median f/u (months)	28	20.5	
Mean age	64	63	0.22
BMI	30.95	29.27	<0.05
Hernia (cm)	6	5	0.01
Barrett’s	42 (29.7)	29 (16.3)	<0.05
LESP	20.5	18.4	0.43
rLESP	7.1	6.5	0.23
DeMeester	39.69	38.53	0.30

*LESP* lower esophageal sphincter pressure. *rLESP* residual lower esophageal sphincter pressure

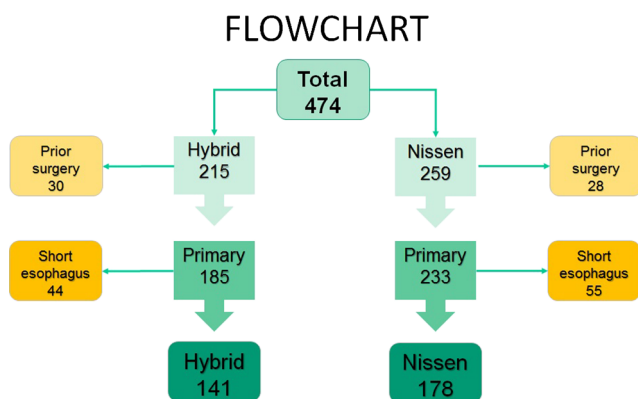
admitted with a PE on postop day 27. One patient was readmitted for pleural effusions not requiring thoracentesis and one on postop day 7 for a non-ST elevation MI.

In the LNF group, there were also a total of eight readmissions within 30 days. There was one grade IIIb complication requiring reoperation of a patient admitted with gastric herniation through a relaxing incision requiring reoperation on postop day 27. Two grade IIIa patients required intervention; one with bilateral pleural effusions required thoracentesis and one required thoracostomy for a pneumothorax. Five patients were classified as grade II, three with dehydration, one with aspiration pneumonitis, and one with bilateral shoulder pain from the mediastinal dissection.

**Quality of Life and Objective Outcomes—Overall Group**

The median follow-up was 28 months for HYB and 20.5 months for LNF. Quality of life data were collected in 90 (64 %) patients in the HYB group and 89 (50 %) patients in the LNF group. All three quality of life scores were better for HYB than for LNF (Table 3).

Objective testing was available for 99 (70 %) patients in the HYB group and 95 (53 %) patients in the LNF group. This included pH testing in 70 (70 %) patients in the HYB group and 63 (66 %) patients in the LNF group. Manometry was obtained in 43 (43 %) and 38 (40 %), endoscopy in 67



**Fig. 2** Flowchart

**Table 2** Ottawa Thoracic Morbidity and Mortality classification

	HYB N = 141 (%)	LNF N = 178 (%)	<i>P</i> value
Grade IV	1	0	0.26
Grade IIIb	0	1	0.37
Grade IIIa	1	2	0.7
Grade II	6	5	0.56
Grade I	0	0	

**Table 3** Postoperative results

	HYB N (%)	LNF N (%)	P value
LESP	23.32	20.83	0.14
rLESP	13.05	10.49	0.05
DeMeester	9.6	14.99	0.13
PPI	2 (2 %)	15 (16 %)	<0.05
QOLRAD	6.59	6.23	0.04
GERD-HRQL	3.75	7.49	0.01
Swallow function	40.71	36.47	0.01

LESP lower esophageal sphincter pressure, rLESP residual lower esophageal sphincter pressure, DM DeMeester score

(68 %) and 86 (91 %), and upper GI in 64 (65 %) and 49 (52 %) of patients in the HYB and LNF groups. DeMeester scores were normalized in the HYB group and essentially normalized in the LNF group, though scores trended higher (9.6 vs 14.99,  $p = 0.13$ ); PPI usage was higher in the LNF group as well (2 vs 15,  $p < 0.05$ ) (Table 3).

### Long-Term Outcomes

Seventy patients had follow-up of greater than 24 months, with a median of 61 months for 39 patients in the HYB and 62 months for 31 patients in the LNF. There were 3 (7.7 %) deaths in the HYB and 4 (12.9 %) deaths in the LNF groups unrelated to the surgeries. Regarding PPI usage, there were 2 (5 %) patients in the HYB group resuming PPIs compared with 7 (23 %) patients in the LNF group ( $p = 0.03$ ) (Table 4). Regarding anatomic recurrences, there were 2 (5 %) in the HYB group versus 13 (45 %) in the LNF group ( $p = 0.002$ ). Of those with anatomic recurrence, 7 (54 %) were symptomatic and 3 of these (9.7 %) underwent surgical revision. The remaining four were no longer surgical candidates for revision due to age or comorbidities. Of the two recurrences in the HYB group, 1 (2.6 %) required reoperation due to complete breakdown of the hiatus ( $p = 0.20$ ). The other patient presented with symptoms of early satiety and bloating almost 2 years after initial surgery and is being managed symptomatically (Table 4).

**Table 4** Long-term follow-up

	HYB N = 39 (%)	LNF N = 31 (%)	P value
Median f/u	61 months	62 months	
PPI	2 (5 %)	7 (23 %)	0.03
Anatomic recurrence*	2 (5 %)	13 (42 %)	0.002
Surgical revision	1 (2.6 %)	3 (9.7 %)	0.2

PPI proton pump inhibitor

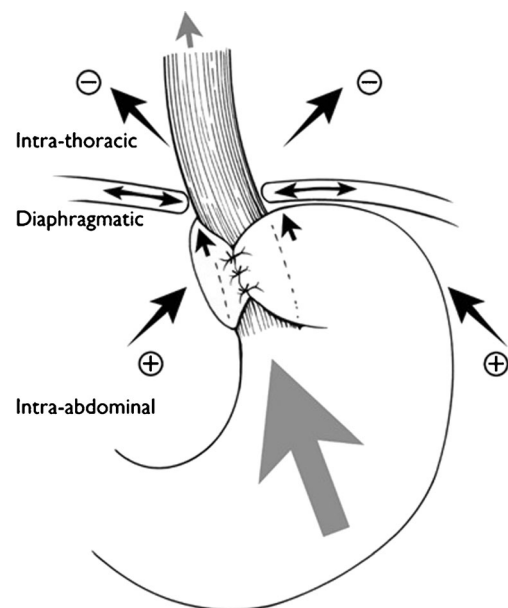
\* hernia > 2cm

### Discussion

The primary finding in this study was the superiority of the combined hybrid (HYB) repair in all three quality of life measures and postoperative proton pump inhibitor use. In addition, the subgroup with median 5-year follow-up showed substantially lower recurrence rates in the HYB group—5 versus 45 %—and there were fewer reoperations for failure.

Multiple studies have shown improvement of quality of life following laparoscopic repair of PEH, and our data are consistent with those findings.<sup>8,9</sup> Dysphagia for HYB was statistically lower than for LNF. This may be because the upper edge of the fundoplication is kept from impacting on the rim of the hiatus and the intra-diaphragmatic portion of the esophagus by the Hill sutures.

The anatomic recurrence results of the combined hybrid repair also appear to be superior when compared to other studies documenting long-term anatomic recurrence rates following traditional repairs for PEH at over 50 %, <sup>2,4</sup> and while some may argue that anatomic recurrences may often be asymptomatic or minimally symptomatic, progression is likely to lead to further trouble, and anatomic recurrence represents a failure of surgical strategy.<sup>9</sup> These recurrences happen despite adhering to the well-known tenets of a successful repair, including high mediastinal mobilization of the esophagus to obtain adequate intra-abdominal length, secure closure of the hiatus, and selective use of biologic mesh, intra-abdominal fixation of the fundus, esophageal lengthening procedures, and diaphragmatic relaxing incisions. What is unique about the HYB repair is that the GEJ itself is fixed to the pre-aortic fascia, rather than the outward aspect of the fundus. This firm

**Fig. 3** Forces on the GE junction

fixation internal to the wrap may have greater ability to resist the axial forces directed upward against the GE junction and the wrap.

The idea of combining aspects of both Nissen and Hill repairs was a result of analyzing the failures seen in the randomized trial comparing laparoscopic Nissen and Hill repairs.<sup>4</sup> In that study, even though Nissen circumferential integrity remained intact and maintained control of reflux, lack of adequate intra-abdominal fixation led to herniation and migration of the GE junction and the wrap into the mediastinum. Conversely, the Hill repair fixed the GE junction securely to the pre-aortic tissue just above the celiac axis where the GEJ is maintained. However, the Hill sutures appear to pull through their fixation in the anterior collar sling, which leads to a loss of circumferential integrity of the angle of His reconstruction, leading to loosening and recurrent reflux. We reasoned that by adding the Hill sutures to the Nissen fundoplication, the Nissen wrap is permitted to maintain its correct position around the lower esophageal sphincter and function without being forced upward against the rim of the hiatus, since the GE junction is maintained in its correct intra-abdominal position by Hill sutures rather than the wrap.

A closer look at the recurrences in this study suggests that our initial idea of combining aspects of both repairs does seem to offset the weaknesses. The majority of recurrences in the LNF group occurred due to herniation of the wrap into the mediastinum and resulted in symptomatology in 7 of the 13 patients with recurrence. Recurrence in the HYB group was infrequent, though one patient had complete failure of the diaphragmatic closure. In the other patient, while the fundus had herniated into the mediastinum, the valve configuration remained intact, with the GE junction remaining anchored in position, presumably due to Hill suture fixation. The only weakness that is not mitigated by this repair is radial forces on the hiatal closure (Fig. 3).

There are several limitations to this study. First, it is retrospective, with its inherent limitations, and follow-up was incomplete. Second, operations were chosen by the surgeon, and there may have been unrecognized differences in the performance of the repairs aside from the ones focused upon. Third, the two groups are not perfectly matched, though the differences appear to favor the LNF rather than the HYB. Fourth, postoperative testing was somewhat more frequent in the hybrid group. While it is our routine to encourage all patients to undergo postoperative testing, the hybrid group may have been more receptive to testing because of awareness that the procedure was new. Lastly, long-term follow-up was with fewer patients, and there was a potential bias toward greater follow-up for symptomatic patients.

## Conclusion

In this retrospective study, the combined Nissen-Hill hybrid repair appeared to compare favorably with laparoscopic Nissen fundoplication for the repair of PEH, with superior quality of life outcomes and resumption of PPIs. In particular, in a subgroup of 70 patients with a long-term median follow-up of 60 months, anatomic recurrence was 5 % for HYB versus 45 % for LNF. There was no increase in complications or side effects compared to the LNF. A randomized trial may be helpful in validating these results.

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