



and Other Interventional Techniques

## Clinical results of laparoscopic fundoplication at ten years after surgery

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### Abstract

**Background:** Several studies have demonstrated laparoscopic antireflux surgery (LAS) for the treatment of gastroesophageal reflux disease (GERD) to be efficient at short- and midterm follow-up evaluations. The aim of this study was to evaluate the results for LAS 10 years after surgery.

**Methods:** The 100 consecutive patients who underwent LAS by a single surgeon in 1993 were entered into a prospective database. Nissen fundoplication was performed for 68 patients, and partial posterior fundoplication (modified Toupet procedure) was performed for 32 patients. Evaluations of the outcome were made 5 and 10 years after surgery. A structured symptom questionnaire and upper gastrointestinal barium series were used at 5 years. The same questionnaire and an added quality-of-life questionnaire (the Gastrointestinal Quality of Life Index [GIQLI]) were used at 10 years.

**Results:** Seven patients died of unrelated causes during the 10-year period. Four patients underwent revision surgery: one patient for persistent dysphagia and three patients for recurrent reflux symptoms. Three patients were lost to any follow-up study. At 5 years, 93% of the patients were free of significant reflux symptoms. At 10 years, 89.5% of the patients still were free of significant reflux (93.3% after Nissen, 81.8% after Toupet). Major side effects (flatulence and abdominal distension) were related to “wind” problems. The GIQLI scores at 10 years were significantly better than the preoperative scores of the patients under medical therapy with proton pump inhibitors.

**Conclusions:** Elimination of GERD symptoms improved quality of life and eliminated the need for daily acid suppression in most patients. These results, apparent 5 years after the operation, still were valid at 10 years.

**Key words:** Gastroesophageal reflux disease — (GERD) — Laparoscopic antireflux surgery (LAS) — Nissen fundoplication — Toupet procedure

Since our initial report on the laparoscopic approach for Nissen fundoplication in 1991, there has been a large acceptance of the technique in the surgical community [1]. Numerous papers have been published, reactivating the long-standing debate about the place of surgery in the therapy for gastroesophageal reflux disease (GERD), and about the best type of procedure to perform.

However, during this same period, alarming reports were published concerning the outcome and usefulness of the antireflux operations. For instance, the long-term follow-up evaluation of an open randomized trial demonstrated that more than 60% of the patients who underwent surgery were again taking antacid medications after a certain period [2]. The current study aimed to evaluate the outcome of laparoscopic antireflux surgery 10 years after the procedure.

### Patients and methods

#### Patient selection

Between 1991 and 2003, 1,528 patients undergoing a laparoscopic fundoplication were entered into a prospective database. To avoid operator and learning curve issues, we chose to study a group of patients who underwent surgery by a single surgeon with experience from performing more than 100 laparoscopic fundoplications. Out of respect for these requirements, we selected the year 1993. During this period, 165 patients underwent either a Nissen or a Toupet (partial posterior) fundoplication in our department. Of these, 100 consecutive patients who had undergone surgery by the single surgeon constituted the studied cohort (Table 1).

The 100 patients comprised 38 women and 62 men with a mean age of 52 years (range, 10–78 years). For all the patients, the primary symptom indicating surgery was heartburn, associated with regurgitation in 54% and dysphagia in 8% of the patients. Atypical symptoms of GERD, including asthma, cough, and chest pain, also

**Table 1.** Patient population

No. of patients	100
No. of operations	100
No. of operations completed laparoscopically	100
Nissen fundoplication	68
Toupet fundoplication	32
Age (years): range (mean)	10–78 (52)
Male:female ratio	62:38
GERD symptoms (%)	
Heartburn	100
Regurgitations	54
Dysphagia	8
Atypical symptoms	40

GERD, gastroesophageal reflux disease

were experienced by 40 patients. All the patients were taking proton pump inhibitors (PPIs) for acid suppression.

### Preoperative investigations

All the patients underwent gastrointestinal endoscopy, and esophagitis was scored using the Savary–Miller classification. The classification identified 12 patients with grade 1, 67 patients with grade 2, and 6 patients with grade 3 esophagitis. Also, 15 patients presented with Barrett's esophagus.

Preoperative 24-h ambulatory pH monitoring was performed for 60 patients. Abnormal DeMeester values were scored for 53 patients and normal scores for 7 patients. Surgery was indicated by positive PPI therapeutic test results for 40 patients who did not have pH testing.

All but one (10-year-old) patient underwent a standard esophageal manometry. Residual pressure (>6 mmHg) in the lower esophageal sphincter (LES) was found in 19 patients. At presentation, 80 patients had an LES pressure lower than 6 mmHg. Normal esophageal motility was present in 73 patients, and impaired esophageal peristalsis in 26 patients. Esophageal peristalsis was considered weak if the amplitude in the distal esophagus was less than 40 mmHg. Impaired esophageal peristalsis was considered severe if the reduced amplitude was associated with more than 50% nonpropulsive (<20 mmHg) waves. All the patients underwent upper gastrointestinal series before surgery, and a hiatal hernia was demonstrated in 71 of them. The hernia was reducible in 81% of the patients.

### Operatives techniques

Two types of fundoplication were used in our series. A laparoscopic Nissen fundoplication was performed for 68 patients by tailoring a floppy 360° wrap with routine division of the short gastric vessels and crural repair. This allowed creation of a short (<2 cm) wrap with nonabsorbable sutures. The wrap was not anchored to the crura.

A laparoscopic partial posterior fundoplication (Toupet fundoplication) was performed for 32 patients by tailoring a 270° posterior wrap with routine division of the short gastric vessels and crural repair. This 4-cm wrap was anchored to the right and left crux muscles.

After an initial learning curve (before 1993), in which fundoplications were performed with a calibrating bougie in place, this series of patients was treated without a bougie. The choice between the two fundoplications was based on the results of esophageal manometry and perioperative anatomic factors such as the size and shape of the gastric fundus. Therefore, a partial wrap was chosen because of severe motility disorders ( $n = 14$ ) or a normotonic LES ( $n = 9$ ), or because of a small gastric fundus ( $n = 8$ ), which was found in one young patient who did not undergo a preoperative manometry (Table 2).

### Postoperative assessment

The current series of 100 patients was analyzed after a first period of 5 years (mean follow-up period,  $63.2 \pm 3.2$  months, unpublished data).

**Table 2.** Patient's manometric characteristics and operative procedure

	Patients ( <i>n</i> )	Type of fundoplication	
		Nissen ( <i>n</i> )	Toupet ( <i>n</i> )
LESP > 6 mmHg			
Normal esophageal peristalsis	19	10	9
Impaired esophageal peristalsis	0	0	0
LESP < 6 mmHg			
Normal esophageal peristalsis	54	46	8
Weak esophageal peristalsis	26	12	
Severe esophageal dysmotility			14

LESP, lower esophageal sphincter pressure

The patient symptom information was obtained using a standardized symptom questionnaire. The patients were asked to grade the following symptoms on a 4-point scale: heartburn, regurgitation, dysphagia, chest pain, nausea, belching, abdominal distension, and flatulence. The medication received was noted. Images of the fundoplication were obtained with a barium swallow. Symptoms and x-rays were correlated.

The same cohort of patients was reanalyzed 10 years after surgery (mean follow-up period,  $123.3 \pm 7.3$  months) using the same symptom questionnaire, with the addition of a quality-of-life questionnaire, the Gastrointestinal Quality of Life (GIQLI), developed by Eypasch et al. [3, 4]. The GIQLI contains up to 36 items scored on a 5-point Likert scale (range, 0–144). The higher the score on the GIQLI, the better the quality of life. The scores for each item are used to calculate a score between 0 and 4 for each of the five subdivisions: gastrointestinal symptoms, emotional status, physical functions, social functions, and stress by medical treatment. Unfortunately, this index was not in use 10 years ago. We had to compare the results of this evaluation with the scores of healthy controls, the scores of patients with GERD, and the scores of patients with GERD using PPIs. Our referral scores are equivalent to those reported in other studies [5–8].

### Statistical analysis

The incidence of symptoms are expressed as percentages of the corresponding group. The GIQLI results are expressed as mean  $\pm$  standard deviation. The two-tailed Mann–Whitney *U* test and the Wilcoxon test were used to assess the significance of non-parametric data sets. The significance level was set at a *p* value less than 0.05. Cumulative recurrence-free follow-up data were calculated using the Kaplan–Meier method and compared using the log-rank test.

### Results

There was no death related to surgery and no conversion to open surgery. The postfundoplication history for this group of patients is schematized in Table 3. Seven patients died during the follow-up period. The causes of death were car accident, ( $n = 1$ ), cardiac episode ( $n = 1$ ), pulmonary episode ( $n = 1$ ), cancer ( $n = 2$ ), and unknown cause ( $n = 2$ ). Two deaths occurred during the first 5-year period, and five deaths occurred during the second period. Four patients underwent remedial antireflux surgery, and two patients had gastric surgery. The total responses for the 5- and 10-year questionnaires show that only three patients were lost to all follow-up evaluation.

**Table 3.** Postfundoplication history of 100 patients

1993		1998		2004	
100 patients		Response: 86 of 95 patients (90.5%)		Response: 69 of 87 patients (79.3%)	
68 Nissen fundopl.	1 death 1 redo 1 gastrectomy	58/65 Nissen	5 deaths 1 bariatric surgery	49/59 Nissen	
32 Toupet fundopl.	1 death 1 redo	28/30 Toupet Symptom questionnaire barium swallow	2 redo	20/28 Toupet Symptom questionnaire GIQLI	

fundopl., fundoplication; GIQLI, gastrointestinal quality of life index

**Table 4.** Heartburn, regurgitation, and dysphagia scores 5 years after laparoscopic fundoplication

	Toupet ( <i>n</i> = 28) 5 years <i>n</i> (%)	Nissen ( <i>n</i> = 58) 5 years <i>n</i> (%)	
<b>Heartburn (score)</b>			
None (0)	18 (64.2)	44 (75.8)	
Occasional (1)	6 (21.4%)	13 (22.4%)	NS
Moderate, therapy (2)	4 (14.2%)	1 (1.7%)	
Severe, constant (3)	0	0	
<b>Regurgitations (score)</b>			
None (0)	20 (71.4)	51 (88)	
Occasional (meal) (1)	8 (28.5)	7 (12)	NS
Moderate (supine) (2)	0	0	
Severe, constant (3)	0	0	
<b>Dysphagia (score)</b>			
None (0)	18 (64.2)	36 (62)	
Occasional, coarse food (1)	10 (35.7)	19 (32.7)	NS
Cleared with liquids (2)	0	3 (5.1)	
Severe, solids and liquids (3)	0	0	

### Symptomatic assessment

At 5 years, the primary symptom responsible for surgery (heartburn) was relieved in 94% of the patients (Nissen 98% and Toupet: 86%) available for follow-up evaluation. There was no significant difference between the two groups (Table 4).

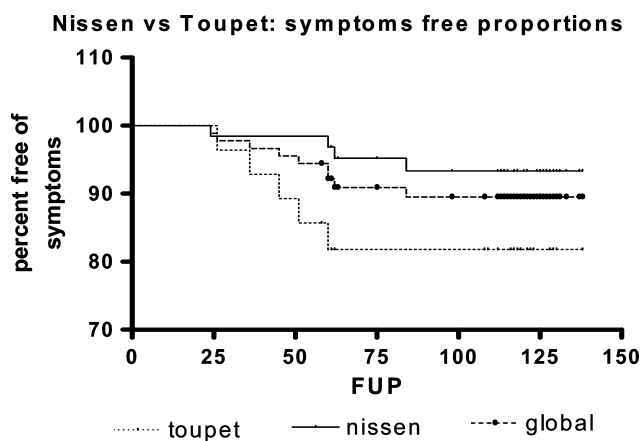
Two patients had required revision surgery: one for persistent dysphagia after a Nissen procedure and one for recurrent symptoms after a Toupet procedure. Between the 5- and 10-year follow-up periods, one woman had a bariatric operation. Two patients from the Toupet group required a reoperation for recurrence. The major reflux symptom 10 years after surgery (heartburn) still was controlled in 94.2% of the responders (Nissen: 96%; Toupet: 90%).

The patients who completed the 5- and 10-year investigations represented 20 Toupet and 45 Nissen fundoplications (Table 5). Only one Nissen patient downgraded from a heartburn score of 0 to a score of 2 in the interval between 5 and 10 years. Four patients who responded only to the 10-year analysis had a heartburn score of 0.

Kaplan–Meier estimates of recurrence-free proportions are shown in Fig. 1. Control of reflux still obtained in 89.5% of the patients at 10 years (Nissen, 93.3%; Toupet, 81.8%, log-rank test;  $p = 0.1714$ ).

**Table 5.** Heartburn score for 65 patients who completed the 5- and 10-year follow-up studies

Score	Nissen ( <i>n</i> = 45)		Toupet ( <i>n</i> = 20)	
	5 years	10 years	5 years	10 years
0	35	28	14	12
1	9	3	4	1
2	1	1	2	2
3	0	0	0	0

**Fig. 1.** Cumulative recurrence-free follow-up: Toupet versus Nissen fundoplication.

### Barium swallow

A radiologic evaluation of the fundoplication was obtained 5 years after surgery for 57 of 86 patients. It demonstrated a well-positioned and competent valve in 36 of the 36 Nissen patients and an intrathoracic migration of the wrap in 33% of the Toupet patients, leading to recurrence for 2 of them (Table 6). At 10 years, the patients who had normal barium swallow at 5 years and responded to the 10-year enquiry remained free of reflux symptoms. Of the seven patients with an intrathoracic partial fundoplication at 5 years, one had redo surgery, and only one is under medical therapy at this writing.

**Table 6.** Impact of anatomic wrap position on the outcome after fundoplication

Heartburn score and barium swallow 5 years after surgery ( <i>n</i> = 57)		
Heartburn (score)	Toupet ( <i>n</i> = 21)	Nissen ( <i>n</i> = 36)
None (0)	3/14 intrathoracic migration	29/29 valve OK
Occasional (1)	2/4 intrathoracic migration	7/7 valve OK
Needing therapy (2)	2/3 intrathoracic migration	0
Severe (3)	0	0

### Side effects of the procedure

One patient had undergone remedial surgery (conversion of Nissen fundoplication to Toupet) for persistent dysphagia. At 10 years, one patient reported significant dysphagia (score, 2) after Nissen fundoplication. Disturbing “wind”-related problems (abdominal distension and flatulence scores exceeding 1) were reported by more than 40% of the patients after Toupet and Nissen fundoplication. There was no significant difference between the two groups. Table 7 shows the heartburn scores and the side effects of fundoplication for the 5- and 10-year follow-up periods.

Analysis of paired data at 5 and 10 years demonstrated a significant reduction in the incidence of dysphagia and flatulence, in contrast to the results for abdominal bloating. There was no significant difference in the incidence of side effects between partial and total fundoplication. The incidence of postoperative dysphagia in patients with preoperative impaired esophageal motility was not different after partial or total fundoplication.

### Antacid drugs

Proton pump inhibitors were being taken by nine patients (10.4%) 5 years after surgery, and by six patients (8.4%) 10 years after surgery. Between the 5- and 10-year follow-up assessments, one patient stopped his medication, two patients underwent reoperation, and two patients were lost to follow-up evaluation.

### Quality-of-life analysis

Figure 2 shows the GIQLI scores of patients on medical therapy and at 10 years after fundoplication. The mean postoperative global score for the available patients was  $113.5 \pm 20.7$ . The mean GIQLI score was  $115.5 \pm 20.75$  for the Nissen group and  $108.5 \pm 27.9$  for the Toupet group (nonsignificant difference). This result must be compared with the mean GIQLI score in the normal population ( $122.6 \pm 8.5$ , nonsignificant difference), with our referral preoperative scores for patients with GERD ( $86 \pm 16$ ), and with the scores of GERD patients receiving PPI medical therapy ( $96.4 \pm 10.2$ ,  $p = 0.01$  vs Toupet,  $p = 0.0001$  vs Nissen).

The difference between good (score, > 100) and less good results (score, < 100) resulted from differences in all subdivisions of the index. Within the gastrointestinal subdivision, a significant difference was observed for all the items except reflux symptoms.

## Discussion

It seems that antireflux surgery has a well-established place in the armamentarium for GERD treatment. The goal of the surgical approach is resolution of the GERD symptoms with as few side effects as possible and no further need for medical treatment. Above all, this should be easily reproducible and able to stand the test of time.

Numerous long-term studies of open-surgery fundoplications have been published. The reported success rates vary from 76% in one 20-year follow-up study to 91% in an extrapolated actuarial analysis [9–12]. Spechler et al. [2] reported a 62% use of antireflux medications 10 years after surgical fundoplication in a randomized controlled trial comparing open fundoplication and medical treatment (anti-H<sup>2</sup>). Despite this fact, 86% of the surgical patients were satisfied with the results of their surgery.

The past decade has seen major changes. Since its introduction in 1991, the laparoscopic approach is appearing as the method of choice, as compared with the open approach. As advantages, it claims less surgical trauma, reduced pain, shorter hospital stay and sick leave, and finally, cosmetically more acceptable scars. It is assumed that laparoscopic fundoplication will give results at least equal to those of open procedures. Several studies have reported excellent short-term results after laparoscopic antireflux surgery [13–21]. Some randomized control trials have published equal short-term results for the laparoscopic and open approaches [22, 26].

On the other hand, some reports have emphasized the high incidence of early postlaparoscopic complications and reoperations [27–30]. The long learning curve for the all-laparoscopic technique has been identified as a confounding factor [31–33].

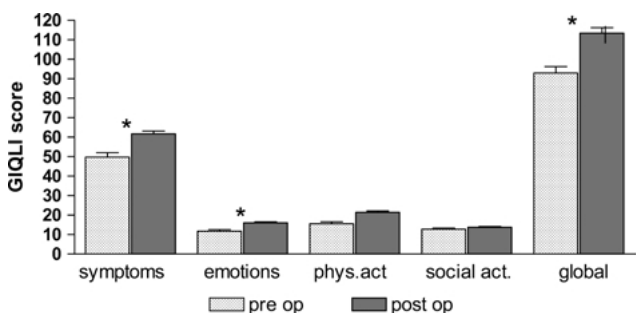
As compared with some long-term series, we did not experience the same incidence of a typical laparoscopic early postoperative complication (i.e., acute paraesophageal migration of the wrap or stomach). We believe this probably is related to the surgical technique, which involved a systematic crural repair.

Few follow-up evaluations of this appealing technique have been reported. Good to excellent results after a follow-up period longer than 5 years are obtained for about 90% of patients, taking into account that the reoperation rate varies between 4% and 13% [16, 34–38].

Our results compare favorably with reports on open and laparoscopic operations. About 90% of patients with 5 and 10 years of follow-up evaluation seemed to be controlled in terms of reflux symptoms. Nissen patients do better than Toupet patients, although the difference is not statistically significant. Reoperation was necessary for four patients within the first 5 years. The analysis of paired data at 5 and 10 years showed a relative stabilization of the results. Fewer than 10% of the patients were found to be receiving antacid medication again. Some of them were being treated without typical recurrent reflux symptoms, for example, in the context of a Barrett’s esophagus or gastritis.

**Table 7.** Heartburn and side effects scores 5 and 10 years after laparoscopic fundoplication

	Toupet		Nissen	
	5 years ( <i>n</i> = 28) <i>n</i> (%)	10 years ( <i>n</i> = 20) <i>n</i> (%)	5 years ( <i>n</i> = 58) <i>n</i> (%)	10 years ( <i>n</i> = 49) <i>n</i> (%)
Dysphagia (score)				
None (0)	18 (64.2)	15 (75)	36 (62)	38 (77.5)
Occasional, coarse food (1)	10 (35.7)	5 (25)	19 (32.7)	10 (20.4)
Cleared with liquids (2)	0	0	3 (5.1)	1 (2)
Severe, solids and liquids (3)	0	0	0	0
Gaz (score)				
None (0)	0	5 (25)	4 (6.8)	17 (34.6)
Occasional (1)	10 (35.7)	9 (45)	19 (32.7)	16 (32.6)
Frequently (2)	14 (50)	2 (10)	27 (46.5)	12 (24.4)
Continuously (3)	4 (14.2)	4 (20)	8 (13.7)	4 (8.1)
Abdominal bloating				
None (0)	6 (21.4)	6 (30)	17 (29.3)	9 (18.3)
Occasional (1)	11 (39.2)	5 (25)	24 (41.3)	16 (32.6)
Frequently (2)	8 (28.5)	4 (20)	9 (15.5)	9 (19.3)
Continuously (3)	3 (10.7)	5 (25)	8 (13.7)	15 (30.6)
Heartburn (score)				
None (0)	18 (64.2)	13 (65)	44 (75.8)	35 (71.4)
Occasional (1)	6 (21.4)	5 (25)	13 (22.4)	13 (26.5)
Moderate, therapy (2)	4 (14.2)	2 (10)	1 (1.7)	1 (2)
Severe, constant (3)	0	0	0	0

**Fig. 2.** Gastrointestinal Quality of Life Index scores before (control group under medical therapy) and after laparoscopic antireflux surgery (data are mean  $\pm$  SD). \*Significant difference.

Concerning the anatomic appearance of the fundoplications, barium swallow studies performed at 5 years demonstrated a well-shaped and positioned valve in all patients after a Nissen fundoplication, but an intrathoracic migration of the posterior partial fundoplication in 7 of 19 patients. Of these, only two patients required therapy for recurrent symptoms. One of these patients underwent reoperation only a few months after the first survey. Five of these patients were free of symptoms at 10 years.

The results of this anatomic study differ from reports in which the anatomic failure rate for fundoplication is as high as 55% [39].

The commonly reported side effects of fundoplications are dysphagia, inability to belch, gas bloating, abdominal distension, and flatulence.

One of our patients presenting with Barrett's esophagus underwent reoperation for a persistent dysphagia. Unfortunately, conversion from a total fundoplication to a partial posterior wrap did not solve the problem because of primary esophageal motility disorders. Our low rate of long-term persistent dysphagia could be related to the

construction of a very floppy wrap, thanks to a systematic gastric fundus mobilization. However, several randomized trials failed to confirm this technical point, although there may be significant differences in the way the mobilization was performed [40–44].

More than 40% of the patients reported “wind”-related problems at 5 years. This incidence was comparable between partial and total fundoplication. Interestingly, the rate of flatulence decreased significantly with time, but the feeling of abdominal distension-bloating increased with time. We do not have an explanation for this observation. Unfortunately, in our study, these symptoms were not systematically scored preoperatively and cannot be evaluated properly. Some studies have demonstrated that the incidence of these side effects does not differ significantly from that found in the preoperative evaluation [45, 46].

Quality-of-life assessment as an outcome variable has become an important feature in clinical research [47]. Currently, the GIQLI is validated, well established, and used in several studies [3, 4]. Our scores 10 years after surgery are comparable with those obtained in other studies during a shorter follow-up period [8, 45, 48, 49]. The global score remains inferior to the score for a control group of healthy patients. But it is increased significantly in comparison with the preoperative score for a control group of patients receiving medical therapy. The major difference is found in the “gastrointestinal symptoms” subdivision of the index.

Fewer than 10% of patients use PPIs 10 years after surgery. This number is much lower than the 60% reported in the Spechler et al. [2] study. This may be related to the quality and reproducibility of the performed antireflux operations (multicentric study vs single dedicated center study), and to the more liberal accessibility of PPI drugs in United States than in Belgium.

## Conclusions

The findings from long-term evaluation lead us to believe that laparoscopic fundoplication can reproduce the results of open fundoplication, as demonstrated in some studies. After open operations, there are statistically more complaints about scars. The other parameters (control of symptoms and side effects) seem to be equivalent: [50]. However, we must keep in mind that these results are obtained in the laparoscopic group, with a reduced mortality and morbidity rate, shorter hospital stay and sick leave, and a lower incidence of incisional complications. There also is a substantial reduction in the rate of incidental splenectomies, as compared with those reported for the open series (0–8%) [51, 52].

Concerning the recommended type of antireflux operation, we have observed more recurrences after partial posterior fundoplication (Toupet) than after Nissen fundoplication. A lower incidence of side effects after the former was not confirmed in our study.

In summary, if other long-term series confirm the results obtained in dedicated centers, laparoscopic fundoplication should become the “gold standard” of treatment for gastroesophageal reflux disease among appropriately investigated and selected patients.

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