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Influence of wrap length on the effectiveness of Nissen and Toupet fundoplications: 5-year results of prospective, randomized study

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Abstract
Background Long-term results in antireflux surgery may depend on fundoplication type and wrap length. We compared the outcome of two different wrap lengths among the patients undergoing partial or total fundoplications. This study is the next part of a prospective 5-year follow-up assessment.
Methods A total of 153 patients were randomized to Nissen or Toupet 1.5- or 3-cm wrap laparoscopic fundoplication. The primary endpoint—treatment failure rate was defined as a recurrent GERD or persistent dysphagia. Intensity of heartburn, dysphagia, gas-bloating, presence of esophagitis were assessed as a secondary outcome at 1-year and 5-year follow-up.
Results At 5-year follow-up, data were collected from 129 (85 %) patients. At 1-year follow-up, 17 (11 %) treatment failures were detected. At the end of the fifth year, the numbers reached 23 (15 %). The failures were more common in the 1.5-cm Toupet (25 %) and the 3-cm Nissen group (18.2 %). The significant difference in failure rates was found between 1.5-cm and 3-cm Toupet groups ($P < 0.05$). Dysphagia remained low during the follow-up in all of the groups. The prevalence of higher scores of heartburn after 5 years was detected in Nissen 1.5-cm group (20.8 %). The lowest scores were observed in Toupet 3-cm group. Bloating symptoms were more prevalent among Nissen and Toupet 3-cm group patients at 5-year follow-up. At the end of the fifth year, the prevalence of esophagitis was lower in Nissen 1.5-cm (19.3 %) and Toupet 3-cm (13.3 %) groups. The highest prevalence of esophagitis—32.4 %—was found in Toupet 1.5-cm group.
Conclusions Nissen and Toupet fundoplication achieved sufficient control of reflux with success rate of 85 % at 5-year follow-up. There were no significant differences in the postoperative dysphagia, esophagitis, and bloating rates. However, the distribution of treatment failures leads us to conclude that 1.5-cm wrap length is insufficient in cases of posterior partial fundoplication.

Keywords GERD (gastro-oesophageal reflux disease) · Antireflux surgery · Fundoplication

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The antireflux surgery is a well-established treatment method for pathological gastroesophageal reflux disease (GERD). Nissen fundoplication is considered to be the standard procedure for GERD and is recommended by European and American associations of surgeons [1, 2]. Original Nissen fundoplication consisted of 6-cm-long wrap from the fundus of the stomach that had effectively increased the tone of the lower esophageal sphincter (LES) [3]. However, high rate of postoperative side effects, such as bloating, inability to belch and vomit, and dysphagia, were observed.

To reduce side effects, partial fundoplications were introduced [4, 5]. After introduction, the concept of partial fundoplication was harshly criticized, and later several, randomized, controlled trials were designed to compare total and partial posterior fundoplications [6]. Most of these

studies made "floppy" fundic wrap and investigated the influence of total or partial fundic wrap on LES and the postoperative side effects. The question what influence fundic wrap length itself could have had on postoperative side effects was not addressed in these studies. Some of them have not described the length of the partial posterior fundoplication wrap [7–10] or performed rather long (3- to 4-cm) Nissen fundoplication wrap [6, 8–11]. Two studies on the length of Nissen fundoplication wrap showed that a loose wrap of just 1–2 cm was sufficient for reflux suppression and reduced the incidence of troublesome postoperative bloating and dysphagia [12, 13].

To determine whether the length of partial or total fundoplication wrap has influence on clinical GERD symptoms, healing of esophagitis, resolution of postoperative side effects, and recurrence rate, we performed the randomized, controlled study. This trial started in 2000; the patient's recruitment was closed in 2003. Operative results as well as 6-month and 1-year follow-up data have been reported in a previous publication [14]. The purpose of current article was to present the 5-year follow-up results.

Patients and methods

Inclusion criteria was age from 18 to 80 years, typical GERD symptoms, esophagitis, hiatal hernia, conservative treatment with PPI for at least 2 months before surgery, and signed informed consent. A total of 153 patients met inclusion criteria and were randomized to either Nissen (1.5-cm or 3-cm wrap) or Toupet (1.5-cm or 3-cm wrap) groups. Full details of the trial protocol were reported previously [14]. Three patients refused to participate in the study, and in all of these cases Nissen fundoplication was performed. They were excluded from further analysis.

Briefly, heartburn, dysphagia, and gas-bloating were evaluated using a 6-point Likert scale. The severity of esophagitis was assessed according to Los Angeles classification [15]. Postoperative barium swallow was performed only if GERD relapse was suspected.

Ambulatory 24-h pH monitoring was performed before the operation, during the follow-up assessment at 12 months, and later if GERD symptoms occurred. All postoperative endoscopic, clinical, and instrumental examinations were performed by an independent investigator blinded to the details of the surgical procedure.

All procedures were performed using the laparoscopic approach. Short gastric vessels were divided. The crura were closed posteriorly with a three to four 3-0 Ethibond sutures to reestablish a normal diameter of the hiatus. A 52-Fr bougie was used for calibration. The Toupet semifundoplication encircled 200–270° and Nissen 360° of the esophageal circumference and the ruler was used to measure the length of the fundoplication wrap according to the data of the randomization (1.5 or 3 cm).

The 1-year follow-up method was reported previously [14]. At 5 years, follow-up was defined as follows: the presence of symptoms was assessed at clinic visits by filling the questionnaire. Any positive reflux-related, dysphagia, gas-bloating symptoms, or PPI dependency led to further investigations: upper GI endoscopy, barium swallow, 24-hour pH-metry.

The primary endpoint of the study was treatment failure. It was defined if at least one of these features was present: (1) persistent reflux esophagitis on endoscopic examination that required continuous PPI treatment or redo surgery; (2) dysphagia occurring every day; (3) GERD symptoms occurring every day with pathologic reflux detected during 24-hour pH-metry; and (4) dysphagia or GERD symptoms with relapse of the hiatal hernia confirmed by barium swallow. Secondary objectives were: intensity of heartburn, dysphagia, gas-bloating, presence of esophagitis.

Statistical analysis

The normal distribution of values was tested by Shapiro–Wilk's test. If normal distribution was present, Student's *t* test was used to compare mean values. In cases with an abnormal distribution, nonparametric statistics assessment was used. Mann–Whitney *U* test and Wilcoxon's test were used to assess the significance of nonparametric data sets. Fisher's exact test was used to assess the primary endpoint due to the low frequency of the variable (treatment failure rate). Significance was defined as $P < 0.05$.

Results

Seventy-six patients had Nissen total fundoplication (38 patients in the 1.5-cm group, and 38 in the 3-cm group) and 77 Toupet partial fundoplication (40 patients in the 1.5-cm group, and 37 in the 3-cm group). At 5-year follow-up, data were collected from 129 (85 %) patients.

Main characteristic of the enrolled patients are presented in Table 1. No statistically significant differences were found between the study groups in terms of sex, age, body mass index (BMI), or duration of the disease. The groups did not differ concerning the duration of surgery or the length of hospital stay. Preoperative data, immediate postoperative, and short-term follow-up results have been reported [14].

The primary endpoint of the study was treatment failure. The total number of treatment failures was evaluated 1 and 5 years after surgery. After the first postoperative year, 17 (11 %) treatment failures were detected. At the end of the fifth year, the numbers of defined treatment failures have reached 23 (15 %). The overall outcome was similar between Nissen

Table 1 General characteristics of patients who entered the study

Indication	Groups of patients			
	Nissen		Toupet	
	1.5 cm	3 cm	1.5 cm	3 cm
Men	17	17	23	17
Women	21	21	17	20
Age (year), mean age (SD)	53.7 (14.6)	49.2 (14.4)	52.4 (12.7)	54.8 (12.6)
Body mass index, mean value (SD)	29.3 (4)	27.7 (4.6)	28.3 (3.3)	29.3 (3.2)
GERD history, mean duration (year), (SD)	6.8 (7.9)	7.2 (7.7)	7.1 (7.6)	7 (7.2)

and Toupet groups in general. The failures were more common in the 1.5-cm Toupet (25 %) and the 3-cm Nissen group (18.2 %; Table 2). The lowest failure rate was observed in 3-cm Toupet group (5.4 %) followed by 1.5-cm Nissen group (10.4 %). The only significant difference in failure rates was found between 1.5-cm and 3-cm Toupet groups ($P < 0.05$). After the detection of treatment failure, redo surgery (5 patients) or permanent PPI treatment (18 patients) was applied. Further analyses of clinical symptoms or objective findings are presented on intention-to-treat basis.

The intensity of dysphagia in groups is presented in Table 3. At 1-year after surgery, patients reported lower dysphagia grade in all the groups comparing to preoperative level, but the differences did not reach statistical significance. It remained nearly unchanged at 5-year follow-up. The rate of grade ≥2 dysphagia was lowest in Toupet 1.5- and 3-cm groups (2.9 and 3.3 %, respectively). Dysphagia of the same grades was three times more common after Nissen fundoplication (9.7 % in 1.5-cm and 10.4 % in 3-cm groups).

Scores of heartburn have decreased dramatically after surgery and remained nearly at the same level among the patients up to 5 years after surgery. The prevalence of higher scores after 5 years was detected in Nissen 1.5-cm group (20.8 %). The lowest scores were observed in Toupet 3-cm group (grade ≥2 6.5 % after 1 year and 6.6 % after 5 years). However, these differences have not reached significant level (Table 4).

Gas-bloating symptoms were more prevalent among Nissen and Toupet 3-cm group patients (Table 5), although there were no significant differences between Nissen and Toupet groups at 5-year follow-up. All patients included in this study had esophagitis. The degree of esophagitis before and after surgery is presented in Table 6. There were no statistically significant differences in degrees of esophagitis before surgery among the groups. At the end of the fifth year, the prevalence of esophagitis was lower in Nissen-1.5 cm and Toupet 3-cm groups (19.3 and 13.3 %, respectively). The highest prevalence of esophagitis—32.4 %—were found in Toupet 1.5-cm group.

Discussion

The goal of antireflux surgery is to control reflux with least impairment in the function of esophagus and stomach. The procedure should produce as few side effects as possible. Chronic dysphagia, inability to belch and vomit, and gas-bloating could have substantial effects on quality of life after antireflux procedures.

After introduction into clinical practice, Nissen fundoplication have undergone some technical modifications, which had the goal to reduce the rate of side effects. DeMeester et al. [12] understood physiologic mechanism of Nissen's fundoplication and added to it division of short gastric vessels with creation of loose floppy wrap. Further studies did not prove that division of short gastric vessels had some influence on reduction of long-term dysphagia [16–18]; however, many surgeons continue to divide short gastric vessels in their routine clinical practice, because they found it easier to create a floppy wrap.

Apart from division of short gastric vessels, two other modifications of Nissen fundoplication were suggested. Thor and Silander [10] in a randomized, controlled study found that introduction of large calibration bougie, when constructing fundoplication, substantially reduced the incidence of long-term dysphagia. Another modification involved shortening the fundoplication wrap from 4 to 1 cm, which decreased the incidence of persistent dysphagia from 21 to 3 % in the study by DeMeester et al.

Table 2 Treatment failures

Treatment failures	Nissen 1 year		Toupet 1 year		Nissen 5 years		Toupet 5 years	
	1.5 cm	3 cm	1.5 cm	3 cm	1.5 cm	3 cm	1.5 cm	3 cm
Relapse of hiatal hernia with persistent esophagitis, *N* (%)	2 (5.2)	2 (5.2)	1 (2.5)	0	2 (5.2)	2 (5.2)	3 (7.5)	1 (2.7)
Persistent esophagitis, PPI treatment, *N* (%)	1 (2.6)	4 (10.4)	6 (15)	1 (2.7)	2 (5.2)	5 (13)	7 (17.5)	1 (2.7)
Total *N* (%)	3 (7.8)	6 (15.6)	7 (17.5)[a]	1 (2.7)[a]	4 (10.4)	7 (18.2)	10 (25)[b]	2 (5.4)[b]

[a] Statistically significant differences in Toupet group at 1-year follow-up ($P < 0.05$)

[b] Statistically significant differences in Toupet group at 5-year follow-up ($P < 0.05$)

Table 3 Dysphagia grades preoperatively, 1 year, and 5 years after surgery

	Nissen		Toupet	
	1.5 cm	3 cm	1.5 cm	3 cm
Before operation (%)	$N = 38$	$N = 38$	$N = 40$	$N = 37$
Grade 0–1	73.7	65.9	80	75.7
Grade 2	13.2	21.0	15	21.6
Grade 3	10.5	7.9	5	2.7
Grade 4–5	2.6	5.2	0	0
12 months after operation (%)	$N = 34$	$N = 33$	$N = 36$	$N = 31$
Grade 0–1	91.2	75.7	86.1	90.3
Grade 2	8.8	21.2	13.9	9.7
Grade 3	0	3.1	0	0
Grade 4–5	0	0	0	0
5 years after operation (%)	$N = 31$	$N = 29$	$N = 34$	$N = 30$
Grade 0–1	90.3	89.6	97.1	96.7
Grade 2	9.7	7	2.9	3.3
Grade 3	0	3.4	0	0
Grade 4–5	0	0	0	0

Table 4 Heartburn intensity preoperatively, 1 year, and 5 years after surgery

	Nissen		Toupet	
	1.5 cm	3 cm	1.5 cm	3 cm
Before operation (%)	$N = 38$	$N = 38$	$N = 40$	$N = 37$
Grade 0–1	7.9	15.8	7.5	2.7
Grade 2	42.1	39.5	52.5	40.5
Grade 3	31.6	26.3	35	40.5
Grade 4–5	18.4	18.4	5	16.3
1 year after operation (%)	$N = 34$	$N = 33$	$N = 36$	$N = 31$
Grade 0–1	94.2	81.8	80.6	93.5
Grade 2	2.8	9.1	11.1	6.5
Grade 3	2.8	9.1	2.8	0
Grade 4–5	0	0	5.6	0
5 years after operation (%)	$N = 31$	$N = 29$	$N = 34$	$N = 30$
Grade 0–1	77.4	86.2	88.2	93.4
Grade 2	9.7	6.9	8.8	3.3
Grade 3	3.2	3.4	0	3.3
Grade 4–5	7.9	3.4	2.9	0

[12]. The physiological effect of shortening of total fundoplication wrap was investigated by del Pino Porres et al. [13]. In a nonrandomized study, they have compared manometric data of conventional 4- to 5-cm-long total wrap with short 1- to 1.5-cm total wrap. No differences were found in the pressure and length of lower esophageal sphincter between the groups. The study limitations were absence of the clinical data, such as heartburn, dysphagia, esophagitis, and failure rate.

Table 5 Bloating grades after operation

	Nissen		Toupet	
	1.5 cm	3 cm	1.5 cm	3 cm
Bloating 1 year postop (%)	$N = 34$	$N = 33$	$N = 36$	$N = 31$
Grade 0–1	73.6	63.6	75	70.9
Grade 2	17.6	15.2	16.7	25.8
Grade 3	8.8	18.2	5.6	3.2
Grade 4–5	0	3	2.8	0
Bloating 5 years postop (%)	$N = 31$	$N = 29$	$N = 34$	$N = 28$
Grade 0–1	64.6	72.4	79.4	67.9
Grade 2	12.9	13.8	11.8	21.4
Grade 3	12.9	13.8	5.9	10.7
Grade 4–5	9.7	0	2.9	0

Table 6 Manifestation of esophagitis in groups before and after surgery

Presence of esophagitis (%)	Nissen		Toupet	
	1.5 cm	3 cm	1.5 cm	3 cm
Before operation	$N = 38$	$N = 38$	$N = 40$	$N = 37$
No esophagitis	0	0	0	0
A	55.3	60.6	45	54.1
B	31.6	28.9	45	32.4
C	10.5	7.9	5	10.8
D	2.6	2.6	5	2.7
12 months after operation	$N = 34$	$N = 33$	$N = 36$	$N = 31$
No esophagitis	94.1	81.8	80.6	96.7
Esophagitis	5.9	18.2	19.4	3.3
5 years after operation	$N = 31$	$N = 29$	$N = 34$	$N = 28$
No esophagitis	80.7	72.4	67.6	86.7
Esophagitis	19.3	27.6	32.4	13.3

Together with modifications of Nissen fundoplication, the concept of partial fundoplication was developed. There are several randomized, controlled studies and recent meta-analyses in the literature that have compared posterior partial to total fundoplication [6, 8, 11, 19–21]. The data from these reports support the hypothesis about similar outcomes in terms of reflux control, whereas less dysphagia and gas-bloating events following posterior partial fundoplication. At 5-year follow-up, we found that grade 2 and higher dysphagia rate was observed three times more often in Nissen compared with Toupet fundoplication group (10 vs. 3.1 %). This difference in our study did not reach a statistically significant level because of small sample size. In the meta-analysis by Shan et al. [21] where the dysphagia rate was compared among 3,365 patients with Nissen and 1,482 with Toupet fundoplications, significantly higher dysphagia rate was observed after Nissen fundoplication (14.3 vs. 11 %; $P < 0.01$).

In our study 12 months after surgery, there was a tendency toward a two times higher mild dysphagia rate in Nissen 3-cm group compared with Nissen 1.5-cm group. The difference in mild dysphagia between Nissen foundoplication groups have disapeared after 5-year follow-up. It also is worth mentioning that in our study no one was classified as treatment failure because of dysphagia and no one had to undergo reoperation or endoscopic dilatation due to persistent dysphagia.

Recent meta-analysis has found nearly equal, more than 30 % prevalence of heartburn after Toupet and Nissen fundoplications [21]. In our study, grade 2 and higher severity of heartburn was most common in 1.5-cm Nissen fundoplication group (20.8 %), followed by 3-cm Nissen (13.7 %) and 1.5-cm Toupet (11.7 %) groups. The lowest rates of heartburn and esophagitis (6.6 and 13.3 %, respectively) were observed after 3-cm Toupet operation. It seems that longer posterior fundoplication wrap has good control of gastroesophageal reflux with minimal impairment of esophageal function.

Postfundoplication gas-bloating rates after 3-cm Toupet fundoplication was similar to those after Nissen fundoplication. It could be explained by the fact that all patients in our study had extensive mobilization of fundus with division of short gastric vessels. Mobilization of the greater curvature seems to result in an increased rate of bloating as demonstrated by Wykypiel et al. [22]. In their study, there was no gas bloating symptoms observed in 20 patients after Toupet fundoplication without division of short gastric vessels.

The results of our study show that both laparoscopic Nissen and Toupet fundoplication achieved sufficient control of reflux symptoms with surgery success rate of 85 % at 5-year follow-up. In addition, there were no significant differences in the postoperative dysphagia, esophagitis, and gas-bloating rate. However, the distribution of treatment failures inside the Toupet group (25 % in 1.5-cm group vs. 5.4 % in 3-cm group) led us to conclude that 1.5-cm wrap length is insufficient in cases of posterior partial fundoplication. In 3-cm Toupet fundoplication group, we observed the lowest dysphagia, heartburn, and esophagitis rates with no difference in gas-bloating symptoms. It could be reasonable to compare 3-cm Toupet fundoplication without division of short gastric vessels with 1.5-cm Nissen fundoplication in future studies.

Disclosures Antanas Mickevičius, Žilvinas Endzinas, Mindaugas Kiudelis, Laimas Jonaitis, Limas Kupčinskas, Juozas Pundzius, and Almantas Maleckas have no conflicts of interest or financial ties to disclose.

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