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SURGICAL ENDOSCOPY
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Dysphagia and quality of life after laparoscopic Nissen fundoplication in patients with and without prostetic reinforcement of the hiatal crura

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Abstract
Background: Recurrent hiatal hernia with or without intrathoracic wrap migration ("slipping Nissen") is one of the most common complications after laparoscopic Nissen fundoplication (LNF). Therefore, we decided to reinforce the hiatal crura using a prostetic mesh prothesis in an attempt to reduce recurrent hiatal hernia.
Methods: The current nonrandomized study compares the surgical outcome, including quality of life data [Gastrointestinal Quality of Life Index (GIQLI)] and subjective degree of dysphagia, in a total of 200 patients with (n = 100) or without (n = 100) mesh prothesis for a follow-up for at least 1 year.
Results: There are no significant differences between groups in postoperative DeMeester score or lower esophageal sphincter pressure. In the group without mesh prothesis, in 6 cases laparoscopic redo surgery was necessary due to severe and persistent dysphagia (n = 2) or a slipping Nissen (n = 4). Additionally, in 5 patients we found recurrent hiatal hernia, but patients have been without symptoms for at least 1 year. In the group with mesh prothesis, laparoscopic refundoplication was performed in only 1 patient due to a slipping Nissen. In this group, recurrent hiatal hernia was not found in endoscopy. After laparoscopic antireflux surgery, GIQLI showed an equal improvement in both groups with an outcome comparable to that for healthy individuals. Postoperative dysphagia was significantly higher in the group with mesh prothesis within the 3 first months after surgery. One year after surgery no differences could be found.
Conclusions: Our findings suggest that LNF with reinforcement of the hiatal crura reduces the risk of recurrent hiatal hernia with or without wrap migration. In addition, LNF with mesh prothesis improves patient's quality of life significantly to the same level as that in patients without mesh prothesis. Postoperative dysphagia is higher in the early period after surgery, but this is only temporary. Long-term results of a randomized trial must be obtained before a general standardization can be discussed.

Key words: Laparoscopic antireflux surgery — Nissen fundoplication — GERD — Hiatal hernia — Quality of life

Within the past 10 years, laparoscopic antireflux surgery (LARS) has been established as an effective, safe, and quality of life-improving treatment option of gastroesophageal reflux disease (GERD). Long-term results of LARS have shown an equally good if not better surgical outcome with corresponding, patient satisfaction as those of the open approach [2, 7, 24, 29, 30, 36]. The procedure most frequently performed is the Nissen fundoplication. During the last decade, in addition to the possibility of performing this procedure laparoscopically, various modifications regarding operative technique and the intrathoracic wrap have resulted in a better surgical outcome and a quality of life improvement [1, 8, 10]. Despite all surgical modifications and new pathophysiological findings, the success rate in centers of LARS is about 85–95%.

At the symptom level temporary but especially persistent and severe dysphagia is the major problem after laparoscopic Nissen fundoplication. In the past few years, numerous clinical factors have been evaluated as predictive factors for possible postoperative dysphagia and therefore to reduce this potential side effect [15, 18, 19, 21].

One of the most frequent anatomical technical failures after LARS is recurrent hiatal hernia with or without an intrathoracic wrap migration ("slipping

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Fig. 1. Conventional closure of the hiatus with interrupted and non absorable sutures.

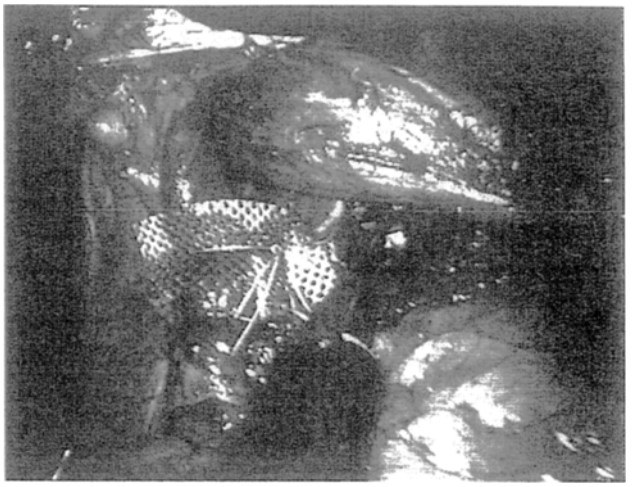

Fig. 2. Closure of the hiatus using a polypropylene mesh prothesis in addition to conventional closure.

Nissen"). This recurrent hiatal hernia with corresponding symptoms occurs in approximately 10% of cases [5, 26, 31, 37]. Analyses after LARS indicate that the supply of the hiatus is one of the most important factors for an efficient operation [27].

The current nonrandomized study presents the surgical outcome, including quality of life data and the subjective degree of postoperative dysphagia, in 100 patients with prostetic reinforcement of the hiatal crura during laparoscopic. "floppy" Nissen fundoplication. A comparison with the results of 100 patients who underwent the traditional procedure with a simple hiatus supply is given.

Materials and methods

Due to our experience and results reported in the literature, the standard surgical procedure of laparoscopic Nissen fundoplication was modified in our surgical department in December 1998. In an attempt to prevent recurrent hiatal hernia we employed a 1 × 3-cm polypropylene mesh prothesis that was cut out of a 10 × 15-cm polypropylene mesh (Tyco Healthcare, Vienna, Austria) normally used for TEPP hernia repair. This mesh has been used in addition to conventional primary closure of the hiatus with interrupted and nonabsorbable sutures. No further changes were introduced at primary intervention. This also applies to the indication for a 360° fundoplication and the complete preoperative diagnostics [3]. In both the traditional procedure and the procedure with mesh prothesis, the short gastric vessels are divided and crural closure is routinely performed. The length of the wrap is always between 2 and 3 cm, sutured to the esophagus, and procedures are performed without using a bougie. Detailed descriptions of both surgical interventions have previously been published [3, 17], and different crural closures are shown in Figs. 1 and 2. All procedures were performed by two surgeons who had performed more than 250 procedures prior to this study.

From December 1998 to February 2000, such a prosthetic reinforcement during laparoscopic Nissen fundoplication was employed in 100 consecutive patients. Surgical outcome of the previous 100 patients without such a reinforcement in the base for our current comparison. Basic requirements before surgery included an evaluation of GERD symptoms and quality of life, esophagogastroduodenoscopy with biopsy and histological examination, esophageal manometry, and 24-h pH monitoring. The following conditions determined the indication for surgery in our patients: persistent or recurrent GERD-related symptoms despite adequate medical treatment (20–80 mg omeprazole/day), persistent or recurrent complications of GERD, a reduced quality of life owing to an increased esophageal exposure to gastric contents, and a pathological LES pressure (< 6 mmHg). The clinical and demographic data of both groups are shown in Table 1. Only patients with primary intervention are included in this study. Patients with a laparoscopically performed refundoplication or patients who required Toupet fundoplication are excluded.

In addition to traditional surgical outcome, we included quality of life data as well as the subjective extent of postoperative dysphagia. Quality of life was evaluated using the German Gastrointestinal Quality of Life Index (GIQLI) [12] and presented to the patients before as well as 3 months and 1 year after surgery, with esophageal manometry and 24-h pH monitoring performed as well. The GIQLI is well established and validated, and an English and French version have been published [11, 33]. The inventory is recommended by the European Study Group for Antireflux Surgery [14]. The subjective degree of dysphagia has been evaluated using a simple verbal rating scale with the description "swallowing difficulties: none, mild, moderate, severe." This scale was presented to all patients before surgery as well as 1 week, 3 months, and 1 year after surgical intervention.

The SPSS program was used for statistical analysis comparing baseline differences between both surgical groups and treatment results using tests as appropriate. A p value < 0.05 was considered statistically significant. Data are reported as mean ± standard deviation or percentage.

Results

Traditional surgical outcome

There were no differences in the operation time of both interventional groups, with an average time of 70 min (range, 45–90 min). There were no operative complications in either groups. Rate of conversion and that of mortality were 0%. Also, there were no immediate postoperative complications. The results of the postoperative control examinations (esophageal manometry and 24-h pH monitoring) are presented for both surgical groups in Table 2 and show no significant differences. In two patients in each group, pathological values in postoperative manometry were found regarding esophageal motility.

In the group of patients without mesh prothesis, six patients had to undergo a laparoscopic refundoplication. Two patients suffered from severe dysphagia

Table 1. Preoperative clinical and demographic data of patients with (n = 100) and without (n = 100) mesh prothesis

	Without mesh prothesis	With mesh prothesis
Age	49.6 ± 12.3	48.2 ± 13.5
Gender	37 female/63 men	42 female/58 male
Mean period of GERD symptoms (years)	6.8 ± 2.9	6.3 ± 2.5
Mean period of omeprazole (20–80 mg/daily) (months)	14.1 ± 7.9	14.7 ± 8.3
Lower esophageal sphicter pressure (mmHg)	2.9 ± 2.3	2.4 ± 2.8
Mean Demeester score	61.8 ± 18.7	63.1 ± 19.9
Endoscopic classification (Savary–Miller)		
0	6	9
1	11	14
2	19	14
3	28	22
4	36	41
No. of Barrett's esophagus	36	40

All data are mean ± standard deviation or absoulte number

Table 2. Mean pre- and postoperative lower esophageal sphincter pressure (LESP) and DeMeester score in patients with (n = 100) and without (n = 100) mesh prothesis

	Before LARS		3 months after LARS		1 year after LARS	
	Without mesh	With mesh	Without mesh	With mesh	Without mesh	With mesh
LESP (mmHg)	2.9 ± 2.3	2.4 ± 2.8	12.8 ± 3.2	13.1 ± 3.9	12.4 ± 3.6	13.7 ± 3.3
DeMeester score	61.8 ± 18.7	63.1 ± 19.9	14.7 ± 11.4	11.2 ± 8.3	13.4 ± 10.9	10.5 ± 11.3

because of a too tight wrap. In both cases, dilatation could not decrease the swallowing problems. In the remaining four cases a recurrent hiatal hernia with an intrathoracic migration of the wrap ("slipping Nissen") was the reason for redo surgery. In five additional cases we found a recurrent hiatal hernia, but all these patients were, subjectively as well as objectively without any symptoms. All these complications appeared within the first postoperative year. In comparison, in the group of patients with a mesh prothesis, only one patient had to undergo laparoscopic redo surgery. This patient suffered from acute and severe dysphagia a few weeks after primary intervention due to a slipping Nissen above mesh prothesis caused by inadequate placement of the mesh. Acute laparoscopic reintervention proved to be technically very difficult. Intraoperatively, a gastric perforation occured that could be managed laparoscopically. Postoperative controls in this patient yielded, for both objective and subjective parameters, no differences compared to those of primary successfully treated patients. In another two patients a single dilatation had to be carried out to treat continuous swallowing problems. One of these patients was also one of the four cases with a pathological esophageal motility after LARS. Recurrent hiatal hernia has not be found in the group with additional mesh prothesis.

Quality of life evaluation

Before LARS, patients of both groups showed an almost identical impairment of quality of life, with an average index of 91.3 ± 10.7 (group without mesh prothesis) and 90.8 ± 11.1 (group with mesh prothesis). The mean preoperative index of both groups was significantly impaired when compared with data of healthy individuals (mean, 122.6 ± 8.5; $p < 0.01$). Three months and 1 year postoperatively, quality of life evaluation yielded almost identical average values for both surgical groups. In comparison to the preoperative results, a significant increase ($p < 0.05$) was calculated for both postoperative controls. The 1-year follow-up index was about 123.4 ± 9.0 and 122.9 ± 8.8, respectively. When compared with normative data, there were no significant differences. General scores (as well as the results of all single subdimensions) of the GIQLI are presented for both groups in Table 3.

Evaluation of dysphagia

Preoperatively, 95% of the patients in both surgical groups had no dysphagia. Also, none of the 200 patients had severe dysphagia. One week after LARS, more than 50% of the patients without mesh prothesis had no subjective swallowing difficulties. In the group with an additional mesh prothesis, 44% had no swallowing difficulties. At the same time, 9% of the patients without mesh and 13% of the patients with mesh prothesis suffered subjectively from severe dysphagia. Three months after surgery there was a significant increase in the number of dyspagia-free patients; in the group without mesh prothesis almost 80% had no swallowing difficulties, and in the group with mesh prothesis almost 65% had no swallowing difficulties. There was significant difference ($p < 0.05$) regarding the number of patients without any swallowing problems. Additionally, a significant difference ($p < 0.05$) was found regarding the

Table 3. Gastrointestinal Quality of Life Index (GIQLI) before and after LARS in patients with (n = 100) and without (n = 100) mesh prothesis

	Normative data	Before LARS		3 months after LARS		1 years after LARS	
GIQLI	( )	Without mesh	With mesh	Without mesh	With mesh	Without mesh	With mesh
General score	122 ± 8.5	91.3 ± 10.7	90.8 ± 11.1	123.8 ± 8.6	123.1 ± 8.4	122.9 ± 8.7	123.4 ± 9.0
Symptoms	62.0 ± 6.3	46.6 ± 8.6	47.1 ± 8.3	64.3 ± 5.6	63.9 ± 7.1	64.6 ± 6.3	64.4 ± 6.0
Emotional	18.5 ± 2.2	12.9 ± 3.9	12.2 ± 4.4	17.9 ± 2.3	17.5 ± 1.9	17.3 ± 2.5	17.7 ± 2.1
Physical	23.5 ± 3.1	17.0 ± 4.1	16.4 ± 3.8	23.2 ± 2.9	23.6 ± 3.2	23.0 ± 3.1	23.1 ± 2.8
Social	14.8 ± 1.8	12.2 ± 1.8	12.4 ± 2.2	14.5 ± 2.1	14.3 ± 1.4	14.2 ± 1.8	14.4 ± 1.7
Medical treatment	3.8 ± 0.4	2.8 ± 1.1	2.7 ± 0.9	3.9 ± 0.2	3.9 ± 0.2	3.8 ± 0.2	3.8 ± 0.1

Data as mean ± standard deviation

Table 4. Subjective degree of dysphagia before and after LARS in patients with (n = 100) and without (n = 100) mesh prothesis

	Before LARS		1 weak after LARS		3 months after LARS		1 year after LARS	
Degree of dysphagia	Without mesh (%)	With mesh (%)	Without mesh (%)	With mesh (%)	Without mesh (%)	With mesh (%)	Without mesh (%)	With mesh (%)
None	96	95	51	44	79.2	64.6	94.7	95.2
Mild	3	5	22	31	9.4	14.1	4.3	3.6
Moderate	1	0	18	24	7.3	18.2	1.1	1.2
Severe	0	0	9	13	4.2	3.0	0	0

number of patients with a subjective degree of moderate dysphagia. About 7% of patients without prothesis and 18% of patients with such a prothesis described their swallowing problems as moderate. One year after successful LARS, about 95% of all patients were subjectively free of any swallowing difficulties and none were suffering from severe dysphagia. Significant differences cannot be calculated at this time. The different degrees of dysphagia are shown in Table 4.

Discussion

The efficacy of LARS as a causal treatment option of GERD can be exemplified by numerous studies. Based on the goal of an effective surgical outcome—safety aspects such as mortality or morbidity, objective data regarding restoration of an antireflux barrier to inhibit progress of disease and factors such as patient satisfaction with therapy and quality of life assessment, as well as cost-utility factors—LARS has proves to be better or equal to corresponding medical treatment with modern acid-suppressive drugs [25, 34]. The following are factors for an excellent or good surgical outcome; (1) a thorough discussion of GERD pathophysiology as well as preoperative diagnostic testing of the functional disturbance, (2) a clearly defined selection of patients, and (3) the exact operative procedure of an experienced surgeon.

Undoubtedly, the good short-term results of LARS have led not only to a rapid increase in the number of interventions carried out but also to a greater amount of failed procedures with a comperatively poor surgical outcome. In relation to this, Rantanen et al. [29] found that only in centers specialized for antireflux surgery an exellent outcome for the surgeon and patient be obtained.

The current study shows our first experiences and short-term results of laparoscopic "floppy Nissen" fundoplication with additional mesh prothesis. Several studies [4, 6, 32] have shown that additional tension-free hiatoplasty in the crural closure has a protective character in regard to the appearance of recurrent hiatal or paraesophageal hernia. For the period of the first postoperative year, there were no significant differences in esophageal manometry and 24-h pH monitoring. In both surgical groups, a total of five patients had a pathological DeMeester score. Despite this result, all patients were subjectively free of symptoms and endoscopy did not show any signs of esophagitis. Recurrent hiatal hernia was not provable in any of these patients and lower esophageal sphincter pressure showed normal values. Before surgery, none of these patients had a Barrett's esophagus, but nevertheless annual endoscopic control was recommended.

Regarding recurrent hernia, mesh prosthesis proved to be a protective factor. In comparison to the group without prothesis, with a total of nine recurrent hernias, there were none in the group with tension-free hiatoplasty. In four cases, a planned laparoscopic reintervention was necessary due to a recurrent hernia and a slipping Nissen. Redo surgery proved to be without any complications. Postoperatively, all patients showed normal surgical outcome, including quality of life data. In contrast, only in one patient in the group with prothesis did a hiatal- or mesh-related problem occur. However, acute surgical intervention proved to have more complications and problems than a planned reoperation. This has also been reported in the literature [9].

An essential factor in the assessment of medical interventions is a change in quality of life. It is well-known that laparoscopic fundoplication can significantly improve patients' long-term quality of life [16, 22, 25, 35]. A comperative quality of life improvement can also be obtained in patients with a mesh prothesis for the duration of 1 year. There were no significant differences between the two interventional groups. Therefore, mesh prothesis has neither a negative nor a positive influence on quality of life. An evaluation of quality of life 4–6 weeks after surgery would have possibly yielded differences. At this time, there was a larger number of patients with mesh prothesis suffering from swallowing difficulties whose eating and drinking habits were also affected.

Postoperative dysphagia appears to be side effects of antireflux surgery. Immediately after surgery, up to 100% of the operated patients suffered from temporary dysphagia to different degrees. Usually, this ablated within the first 3 postoperative months and was not mentioned by the patients again. Intensity and duration of temporary dysphagia are caused by several factors. On the other hand, severe and persistent dysphagia is a complication of antireflux surgery that occurs in up to 20% of the cases. Redo procedure is necessary in 3–6% of these cases [13] and can be performed laparoscopically, including prostetic reinforcement of the hiatal crura, with an comparable outcome to that of successfully performed primary interventions [20, 28].

A comparison of both surgical groups significant differences in the extent of dysphagia after LARS. For the first 3 months the number of patients with swallowing difficulties was significantly higher in the group with mesh compared to the group without mesh. Patients with mesh prothesis judged these swallowing problems to be more intense. One year after successful Nissen fundoplication, early existing differences were not evaluated anymore between both groups. In each group, two patients (2%) had to be treated due to severe dysphagia. In both patients of the mesh prothesis group, a single dilatation successfully eliminated swallowing problems. In the other group, both patients had to undergo laparoscopic redo surgery. Additionally, in both groups there were several patients with subjective moderate or severe swallowing problems but without any objective correlation (e.g., kinematographic x-ray). In these patients a psychological intervention was successful in eliminating these problems [23].

Despite all intensive efforts, in centers of LARS a 100% success rate cannot be guaranteed. Further improvements are necessary in the complete diagnostic and surgical procedure to obtain optimal outcomes for all patients. Such an attempt could include a mesh prothesis at the hiatus. Although our data present a nonrandomized comparison, short-term results support reinforcement of the hiatus, which leads to a reduction of hiatal-related problems after antireflux surgery. In addition, quality of life data show no negative consequences after such an operative expansion. Initial postoperative dysphagia is possibly increased in intensity, but only temporary. Long-term results of a randomized trial must be obtained before a general standardization can be discussed.

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