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# Nissen Fundoplication for Gastroesophageal Reflux Disease

## *Evaluation of Primary Repair in 100 Consecutive Patients*

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One hundred consecutive patients had a primary Nissen fundoplication for gastroesophageal reflux disease. None of the patients had previous gastaric or esophageal surgery or evidence of esophageal stricture or motility disorder. The primary symptom was persistent heartburn in 89 patients and aspiration in 11. An abnormal pattern of esophageal acid exposure was documented in all patients with 24-hour esophageal pH monitoring. By actuarial analysis, the operation was 91% effective in the control of reflux symptoms over a 10-year period. The incidence of postoperative symptomatic gas bloat and increased flatus was lower in patients with preoperative abnormal manometric measurements of the distal esophageal sphincter ( $p < 0.05$ ). Three modifications in operative technique were made during the course of the study to minimize the side effects of the operation. First, enlarging the caliber of the bougie to size the fundoplication reduced the incidence of temporary swallowing discomfort from 83 to 39% ( $p < 0.01$ ). Second, shortening the length of the fundoplication decreased the incidence of persistent dysphagia from 21 to 3% ( $p < 0.01$ ). Third, mobilizing the gastric fundus for construction of the fundoplication increased the incidence of complete distal esophageal sphincter relaxation on swallowing from 31 to 71% ( $p < 0.05$ ). This was done to prevent the delayed esophageal acid clearance secondary to incomplete sphincter relaxation observed after operation in five of 36 studied patients. It is concluded that by proper patient selection and the incorporation of the above surgical techniques, the Nissen fundoplication can re-establish a competent cardia and provide relief of reflux symptoms with minimal side effects.

**O**VER THE PAST three decades, there has been an increasing interest in the pathophysiology of gastroesophageal reflux disease and its rational surgical management. Recognition of the high failure rates after an anatomical hiatal hernia repair led to the development of procedures designed to re-establish the competency of the cardia by improving its function. In a prospective study, the Nissen fundoplication was shown to be superior to both the Belsey and Hill procedures in the

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control of reflux symptoms and in the restoration of distal esophageal sphincter competence.<sup>1</sup> Despite these excellent early results, concern was expressed regarding the durability and long-term side effects of the Nissen fundoplication. The purpose of this study was to evaluate the results of 100 consecutive primary Nissen fundoplication procedures performed and followed by the same surgeon over a 13-year period. The findings advanced our understanding of the criteria for patient selection and the technique for constructing the fundoplication.

### Population Studied

Between 1972 and 1984, 288 patients had an antireflux procedure performed by the senior author (TRD), of which the Nissen fundoplication was the most common (Fig. 1). The population studied was drawn from the Nissen group and consisted of 100 consecutive patients with gastroesophageal reflux disease and no evidence of an esophageal stricture on endoscopy or a motility disorder on esophageal manometry. The latter includes, in addition to specific motility abnormalities, patients with a mean contraction amplitude of less than 20 mmHg or an incidence of simultaneous and/or repetitive contractions on swallowing greater than 30%. None of the patients had previous esophageal or gastric surgery. There were 52 female patients and 48 male patients, with a mean age of 46 and a range of 11 to 79 years.

In 89 patients, heartburn was the predominant symptom. Aspiration, manifested as chronic cough, asthma and/or recurrent pneumonia, was the predominant symptom in 11 patients. Associated symptoms were: re-

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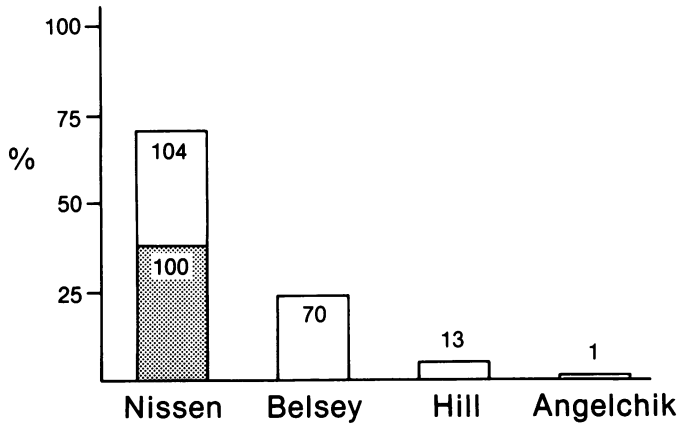


FIG. 1. Distribution of the type of antireflux procedure performed over the study period (1972-1984) (N = 288). The shaded area represents the portion of the population reported in the present study.

gurgitation (62 patients), esophageal dysphagia (33 patients), and cervical dysphagia (8 patients). The mean duration of symptoms was 53 months, with a range of 3 months to 15 years.

On upper gastrointestinal roentgenographic barium studies, 61 patients showed a hiatal hernia, six of whom had a Schatzki ring, and 39 refluxed barium from the stomach into the esophagus in the upright position. Twenty-three patients had a normal study.

The diagnosis of gastroesophageal reflux disease was documented in all patients by measuring an increased esophageal exposure to acid gastric juice on 24-hour esophageal pH monitoring (Fig. 2).<sup>3</sup> The pattern of abnormal esophageal acid exposure is shown in Figure 3.

All patients had at least 3 months of adequate medical treatment, as judged by their referring physician and the senior author. This included a variety of dietary, postural, and drug therapies. The latter consisted of antacids and bethanecol and, more recently, cimetidine and metoclopramide.

The clinical indication for the antireflux repair was the persistence of reflux symptoms. The complication of persistent endoscopic esophagitis was present in 42 patients, four of whom also had Barrett's esophagus.

A control population consisted of 45 asymptomatic subjects with no history of upper gastrointestinal disease and a normal upper gastrointestinal roentgenographic barium study. Their mean age was 35, with a range of 18 to 63 years. All control subjects had a normal esophageal exposure to gastric juice on 24-hour esophageal pH monitoring (Fig. 2). Esophageal manometry was performed on each subject and the values obtained were used for comparison with the pre- and postoperative motility studies obtained in the patient population. A written informed consent was obtained from each control subject.

Methods

Endoscopy

Fiberoptic endoscopic examination was performed by the senior author. Esophagitis was scored as grade one for an erythematous and friable mucosa, grade two for linear erosions, and grade three for deeper and wider linear erosions with islands of edematous mucosa between erosive furrows.<sup>4</sup> When Barrett's esophagus was suspected, multiple mucosal biopsies were performed. The diagnosis was confirmed if a columnar-type epithelium was found 2.0 cm or more above the gastroesophageal junction.<sup>5</sup>

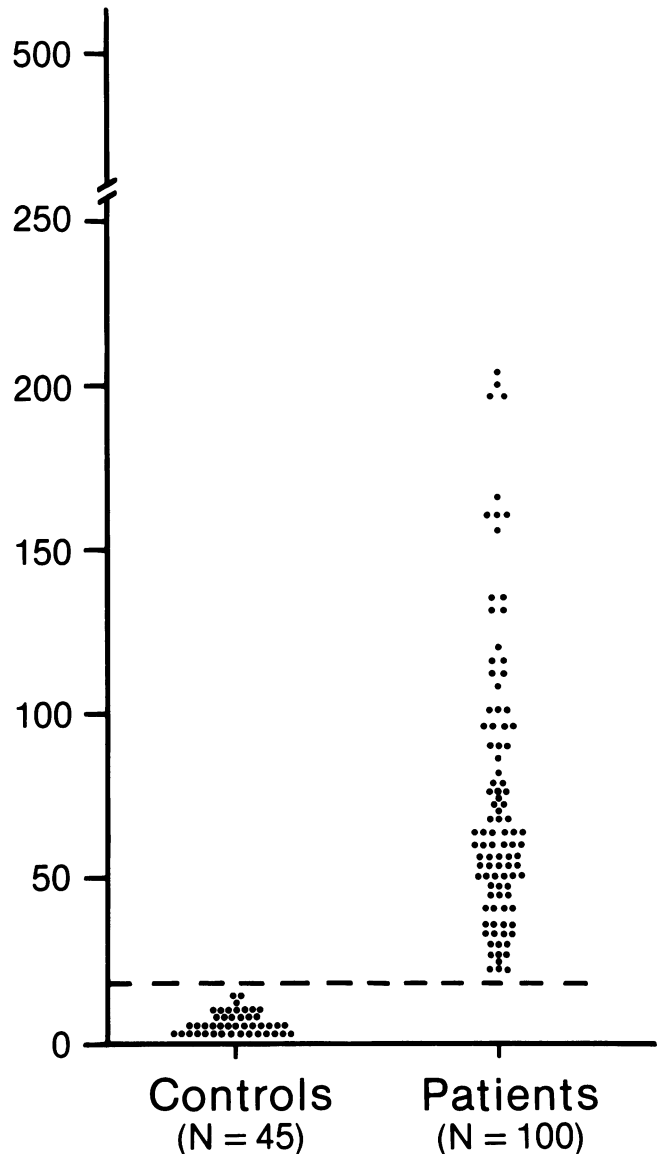


FIG. 2. Preoperative 24-hour esophageal pH test score in the patient population compared to control subjects. Dotted lines represent the upper limit of normal.

### Esophageal Manometry

Esophageal manometry was performed according to the technique described by Winans and Harris,<sup>6</sup> using a single-catheter assembly consisting of three to five fluid-filled polyethylene tubes bonded together with three to five lateral openings placed at 5.0 cm intervals from the distal end of the catheter and radially oriented 72 to 120 degrees apart. The diameter of the lateral openings was 2.0 mm in the three lumen catheter and 0.8 mm in the five lumen catheter. A constant infusion of distilled water was delivered, initially by a Harvard infusion pump (Harvard Bioscience, South Natick, MA) through the three lumen catheter, and subsequently by an Arndorfer pneumohydraulic low compliance system (Arndorfer Medical Specialties, Inc., Greendale, WI) through the five lumen catheter. The rate of infusion was 3.6 ml/min with the former, and 0.6 ml/min with the latter. Studies obtained with the two infusion systems were compared in a group of 14 subjects, and a correction factor was calculated to give uniformity of measurements between the two systems.

The catheter was passed into the stomach and withdrawn in 1.0 cm increments back into the esophagus, and in 0.5 cm increments from the esophagus into the pharynx. The overall length, the abdominal length, that is, the length below the respiratory inversion point, and the mean resting pressure of the distal esophageal sphincter were measured. Sphincter relaxation was considered complete (100%) when sphincter pressure dropped to gastric baseline on swallowing. The mean amplitude of the contractions and the incidence of repetitive and simultaneous contractions in the distal esophageal body were noted during ten dry and ten wet swallows. The length and mean resting pressure of the upper esophageal sphincter and the peak pharyngeal pressure were similarly measured.

### Twenty-Four Hour Esophageal pH Monitoring

Prolonged esophageal pH monitoring was performed according to a technique previously described,<sup>3</sup> with a pH electrode placed 5.0 cm above the upper border of the distal esophageal sphincter as measured by manometry. Acid reflux was defined whenever the pH in the esophagus dropped to four or less. Gastroesophageal reflux was assessed by a composite mathematical score that incorporated six components of the 24-hour record: (1) per cent of time the esophageal pH was four or less for the total 24-hour period, (2) for the time in the upright position, and (3) for the time in the supine position; (4) the total number of reflux episodes, (5) the number of episodes lasting 5 minutes or longer, and (6) the duration of the longest episode. Individuals whose cumulative score exceeded by more than two standard deviations the mean score of previously reported control subjects were considered to have an abnormal esophageal acid exposure.<sup>7</sup>

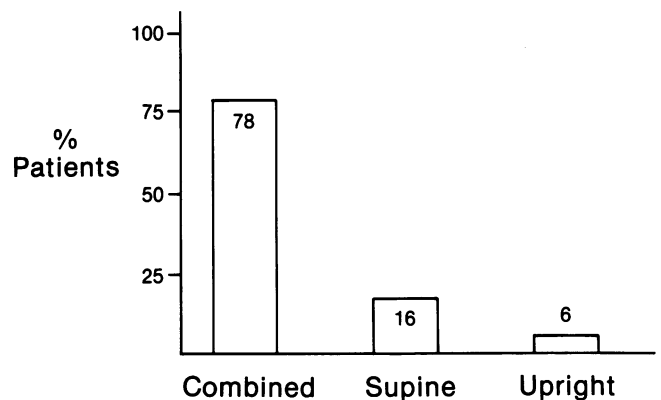


FIG. 3. Patterns of esophageal acid exposure in the patient population.

### Technique of Operation

The fundoplication was initially performed according to the technique described by Nissen.<sup>8-9</sup> Over the course of the study, three modifications were made in the technique of constructing the fundoplication. These were initiated by an analysis of the operative results in the studied patients and other patients not included in the reported group. The modifications were: (1) the caliber of the bougie used to size the diameter of the gastric wrap was increased from 36 to 60 French, (2) the length of the gastric wrap was reduced from 4.0 to 1.0 cm, and (3) the short gastric vessels were divided to allow the gastric fundus to be utilized in the construction of the gastric wrap. Based on these operative modifications, the patients were placed into one of the four periods shown in Table 1.

In 82 patients the operation was done transabdominally, and in 18 a transthoracic approach was used. The operation, as currently performed by the abdominal approach,<sup>10</sup> was facilitated by the use of a special retractor to provide excellent exposure of the esophageal hiatus. For this purpose, we have welded a Weinberg retractor to a Balfour handle that attaches to a bar over the patient's chest (Fig. 4). The operation is begun by dividing the gastrohepatic ligament in the area where it is thin and usually transparent. Care should be taken not to divide the hepatic branch of the anterior vagus nerve. The incision is carried superiorly over the anterior surface of the esophagus, di-

TABLE 1. Modifications in Surgical Technique During the Study Period

Period	No. Patients	Size Bougie (French)	Mobilization Fundus	Length Wrap (cm)
I	24	36	No	4
II	25	60	No	4
III	15	60	Yes	3
IV	36	60	Yes	1

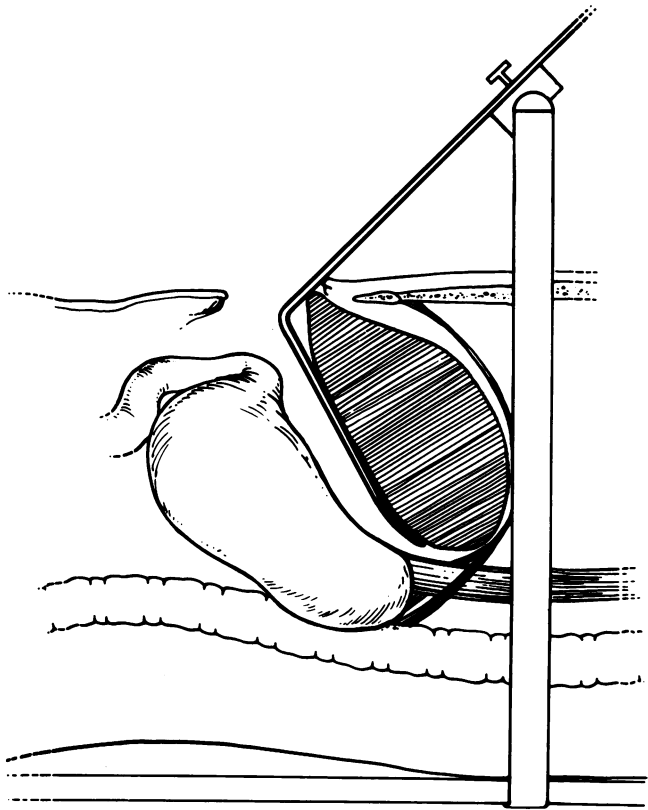


FIG. 4. Position of a modified Weinberg retractor to provide continuous exposure of the esophageal hiatus when performing a transabdominal Nissen fundoplication.

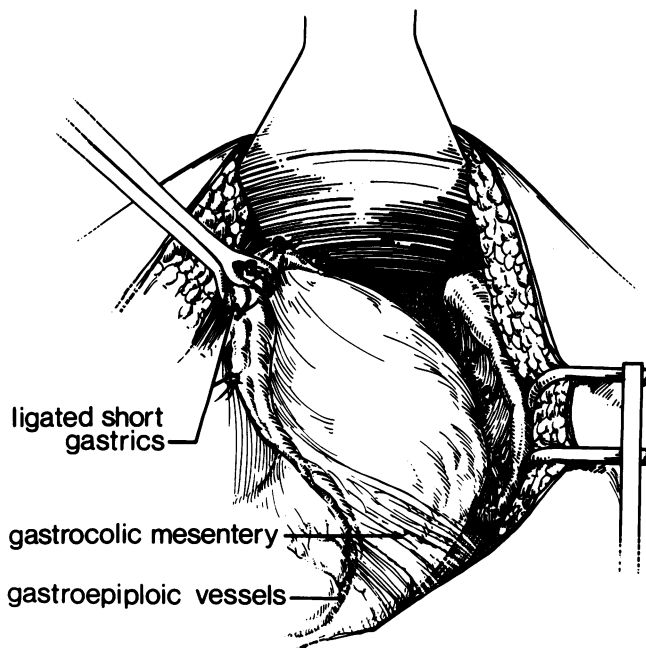


FIG. 5. Division of the short gastric vessels and mobilization of the gastric fundus prior to constructing the fundoplication.

viding the reflection of the parietal peritoneum off the diaphragm onto the esophagus. The incision is continued down the left side of the esophagus until the left crus of the esophageal hiatus is identified. The loose areolar tissue over the superior surface of the esophagus is removed.

The first step of the repair is to isolate the esophagus by circumferential blunt finger dissection within the posterior mediastinum anterior to the aorta, encircling both the right and left vagal trunks with the esophagus. When encircled, the right or posterior vagus is identified and a soft rubber drain is passed around the esophagus, excluding the nerve. While retracting on the rubber drain, the loose fibrous tissue, posterior to the esophagus and cephalad to the branches of the left gastric artery, is divided to identify clearly the right and left crus of the esophageal hiatus when the esophagus is retracted to the left.

The second step of the repair is to mobilize the fundus of the stomach by dividing the short gastric vessels, starting at the point where the veins begin to drain superiorly toward the spleen, rather than inferiorly toward the right gastroepiploic vein (Fig. 5). Usually, at the most superior aspect of the greater curvature, one will find short gastric vessels that take a retroperitoneal course, tethering the fundus of the stomach to the posterior abdominal wall. These vessels, if not divided, force the surgeon to construct the fundoplication with a portion of the body of the stomach rather than the fundus.

The third step of the repair is to close the esophageal hiatus. The esophagus is retracted to the left and the right and left limbs of the crura are approximated with interrupted 0-silk sutures, starting inferiorly where they decussate over the aorta. The sutures are placed at 1.0 cm intervals, advancing the esophageal body anteriorly as the hiatus is closed. Usually six sutures are required to complete the closure. All sutures should be placed within the muscle of the crura and tied with a tension that causes tissue approximation without strangulation. When complete, the hiatus should freely admit a fingertip adjacent to the esophagus. It is better to err in making the closure of the hiatus too loose rather than too tight. The purpose of the crural closure is only to maintain the repair within the abdomen.

The fourth step of the repair is to construct the fundic wrap. A number 60 French bougie is passed by the anesthesiologist down the esophagus and into the stomach to display the gastroesophageal junction. The pad of areolar tissue, which lies on the anterior surface of the gastroesophageal junction, is removed to allow proper identification of the junction and encourage the fusion of the fundic wrap to the esophagus. Care should be taken while removing the fat pad not to injure the anterior vagal nerve. The freed posterior wall of the fundus is pulled with a Babcock clamp between the right or posterior vagal trunk and the esophagus containing the number 60 French

bougie. The anterior wall of the fundus is pulled across the anterior surface of the esophagus. This results in enveloping the distal esophagus between the anterior and posterior fundic wall.

The needles at both ends of a 2-0 polypropylene suture are passed through a 1.5 × 0.5 cm Teflon® felt pledget 1.0 cm apart, and then through the left or anterior lip of the fundic wrap, again 1.0 cm apart. Both ends of the suture are passed through a second pledget sandwiching the lip between the two pledgets. One of the limbs of the suture is then passed through the anterior wall of the esophagus at the gastroesophageal junction, incorporating the tissue down to, but not through, the muscularis mucosa. The second limb is similarly passed through the anterior wall of the esophagus 1.0 cm cephalad to the first stitch. Both ends of the suture are passed through a third Teflon felt pledget, again 1.0 cm apart, and then through the right or posterior lip of the fundic wrap. Both ends of the suture are then passed through a fourth and final Teflon felt pledget. The placement of the horizontal mattress stitch is shown in Figure 6.

A single tie is placed in the suture to approximate the two lips of the fundic wrap around the esophagus containing the number 60 French bougie. The ability for the polypropylene suture to slide through tissue without sawing allows for a test approximation of the fundic wrap without causing tissue damage or hematoma formation. When drawn together, the fundic wrap should be large enough to accept the insertion of the surgeon's index finger alongside the esophagus containing the number 60 French bougie. If the surgeon is unable to insert his finger or feels tight bands over his finger, the wrap is too small and the left or anterior end of the horizontal U-stitch must be replaced more laterally and inferiorly on the anterior wall of the fundus. This enlarges the internal diameter of the wrap. If there is excessive space, the wrap is too loose and the left or anterior end of the U-stitch must be replaced more medially and superiorly on the anterior wall of the fundus. This reduces the internal diameter of the wrap. When the wrap is of proper size, the bougie is removed and the limbs of the U-stitch are tied securely. A transverse section of the completed fundoplication is shown in Figure 7 and illustrates the relationship of the stomach to the esophagus in forming a wrap with a circumference of slightly less than 360 degrees.

The transthoracic approach was used in patients who were obese, had concomitant pulmonary disease that needed definition, or whose roentgenographic hiatal hernia did not reduce when in the upright position. The operation, as currently performed by the thoracic approach,<sup>2</sup> starts by mobilizing the esophagus from the level of the diaphragm to the aortic arch without injuring the vagal nerves. There is sufficient blood supply through the intrinsic arterial plexus of the esophagus, fed by the inferior

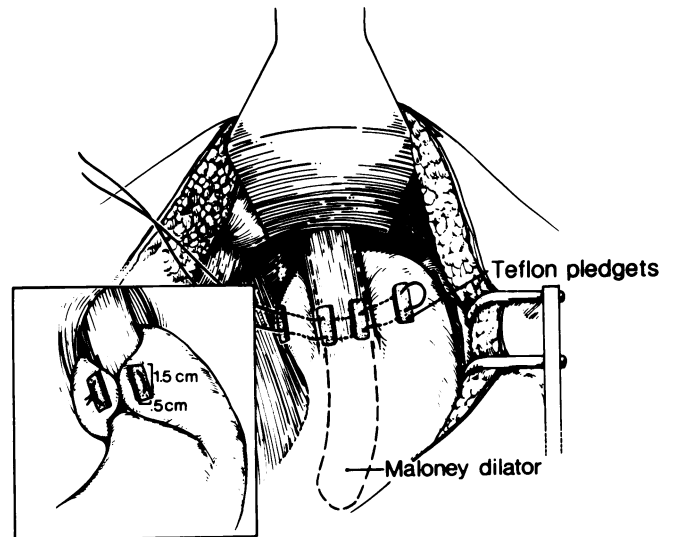


FIG. 6. Construction of the fundoplication. A number 60 French bougie is passed across the gastroesophageal junction and a horizontal mattress suture of 2-0 polypropylene, buttressed with Teflon® felt pledgets, is used to hold the wrap. Insert shows the completed 360 degree fundic wrap and the dimensions of the Teflon pledgets.

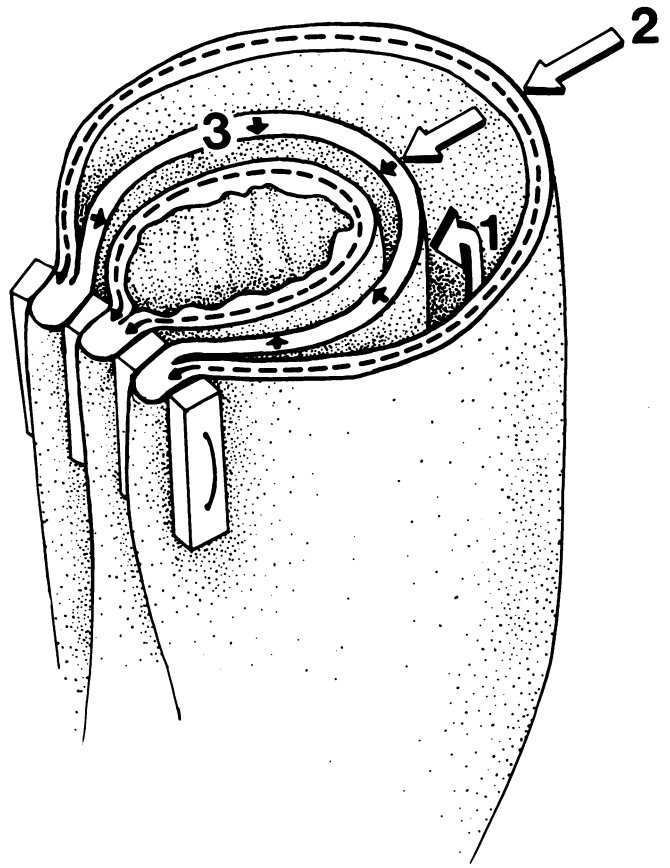


FIG. 7. Schematic cross section of the Nissen fundoplication showing the position of the Teflon® felt pledgets and the relation of the gastric wrap to the esophagus. Arrows illustrate how intragastric pressure (1), intra-abdominal pressure (2), and gastric muscle tone (3) are transmitted to the distal esophageal sphincter.

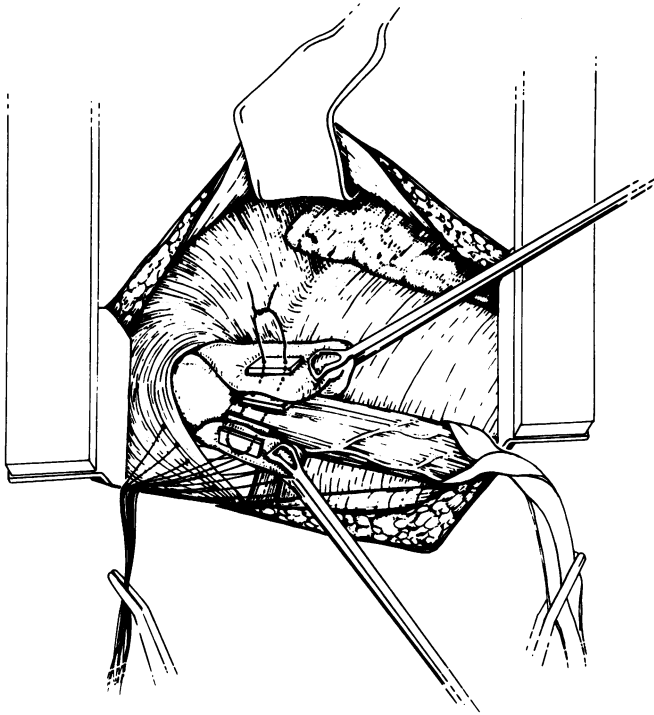


FIG. 8. The posterior position of the Teflon® felt pledgets in performing a transthoracic Nissen fundoplication. The gastric fundus has been brought up through the hiatus and rotated to the right for an easier placement of the holding U-stitch. The complete fundoplication consists of an anterior fundic wrap secured posteriorly by a U-stitch reinforced with Teflon felt pledgets.

thyroid artery in the neck and branches of the right bronchial artery in the thorax, to maintain the integrity of the mucosa and prevent ischemic necrosis of the muscle. This degree of mobilization is usually necessary to place the reconstructed cardia into the abdomen without undue tension.

The second step of the transthoracic repair is to free the cardia from the diaphragm. This can be accomplished through the hiatus, gaining access into the abdominal cavity through the phrenoesophageal membrane. When all the detachments between the cardia and diaphragmatic hiatus are divided, the esophagus is retracted anteriorly in the hiatus and sutures are placed through the right and left crura in preparation for their approximation. About six sutures, placed 1.0 cm apart, are required.

The third step of the transthoracic repair is to envelope the distal esophagus with the anterior and posterior wall of the fundus. The fundus and body of the stomach are withdrawn through the hiatus into the chest. The fundoplication is done over a number of 60 French bougie in a manner similar to that described for the abdominal approach, except that the fundus is anterolateral instead of posterolateral, and the holding suture is placed posterior instead of anterior (Fig. 8). When complete, the fundoplication

is placed into the abdomen by compressing the fundic ball with the hand and manually maneuvering it through the hiatus. Once in the abdomen, the fundoplication should remain there, and a gentle up-and-down motion on the diaphragm should not encourage it to emerge back through the esophageal hiatus into the chest. If the repair remains in the abdomen unaided, the previously placed crural sutures are tied to approximate the crura and reduce the size of the hiatus.

#### *Postoperative Evaluation*

Postoperative morbidity and mortality within the first 30 days after operation were obtained from the patient's office and hospital record. A clinical evaluation was obtained yearly and consisted of a direct interview with the patient in the clinic or by phone. A standard questionnaire was used to collect the data and assure completeness of the yearly clinical evaluation. Questions were directed towards assessing the presence of symptoms indicating the recurrence of reflux (heartburn, regurgitation, and aspiration) and the occurrence of side effects of the operation, that is, the inability to belch or vomit, temporary swallowing discomfort (resolved within 3 months), persistent dysphagia, the need for dilatation, increased flatus, and symptomatic gas bloat. To avoid bias, dysphagia was defined as any discomfort in swallowing. Patients were also asked for their own assessment of the operation. The evaluation obtained at the last patient-physician encounter was used for data analysis except when a symptomatic recurrence occurred. In this situation, the date of recurrence was noted, and no further data were recorded at subsequent encounters from this part of the questionnaire. All patients were contacted at least once during the follow-up period. At the last evaluation, 26 of the initial 100 patients were unable to be contacted. In these patients, their previous evaluation was used for analysis.

Patients were asked to volunteer for postoperative endoscopy and esophageal function studies consisting of manometry and 24-hour esophageal pH monitoring. Thirty-six patients volunteered, 21 between 6 months and 2 years, seven between 2 and 5 years, and eight between 5 and 10 years after the operation. Nine of these patients volunteered for two postoperative studies, the first within 1 year and the second between 3 and 9 years after the operation.

#### *Statistical Analysis*

The standard life table method was used to evaluate the symptomatic recurrence rate. The chi square test, with correction for continuity when appropriate, was used to compare percentages. The two-tailed t-test was used to compare means. Statistical significance was designated at the 0.05 level. Values were expressed as mean  $\pm$  standard

deviation, except in illustrations where the standard error of the mean was used.

### Results

Table 2 lists the operative mortality and morbidity. The one death that occurred in the series was due to an anaphylactoid drug reaction 22 days after the operation and 14 days after the patient was discharged from the hospital. In one patient, dissection around the esophagus produced a 3.0 cm tear. This was closed and buttressed by the fundoplication without consequence. Once incidental splenectomy occurred in the series. One patient developed acute cholecystitis on the fifth postoperative day and required cholecystectomy.

The follow-up period ranged from 1 to 13 years and averaged 45 months. Seven patients died during the follow-up period, including the one operative death. None of the deaths was due to the operation.

There were three symptomatic recurrences of gastroesophageal reflux occurring 6 months, 2 years, and 7 years after operation. Figure 9 shows the actuarial success rate of the operation in controlling reflux symptoms based on the number of patients at risk for each yearly interval of follow-up. This analysis shows that the operation has a 91% success rate in controlling reflux symptoms over a 10-year period. All 33 patients with preoperative esophageal dysphagia, and seven of the eight with cervical dysphagia, were relieved after surgery. A cricopharyngeal myotomy was successfully performed in the one patient with persistent cervical dysphagia.<sup>11</sup>

Thirty-six patients volunteered for postoperative esophageal manometry and 24-hour pH monitoring. Nine patients volunteered for a second postoperative study 3 to 9 years after the operation. All nine patients were normal on their first postoperative 24-hour pH test. On the second study, four of them remained normal and five became abnormal. Overall, the 24-hour pH test was abnormal in six patients, one on the first and five on the second study (Fig. 10).

Two of the three patients with a symptomatic recurrence had postoperative esophageal function studies. Both had an abnormal 24-hour pH monitoring test, one on the first, and the other on a second study. The cause of the recurrence in the former was a defective cardia secondary to breakdown of the repair and, in the latter, delayed acid clearance of physiologic reflux episodes.

Thirty-four asymptomatic patients had postoperative studies and four had an abnormal 24-hour esophageal pH monitoring test. In all four, an initial postoperative 24-hour pH test was normal. In each patient, the abnormal test was due to delayed acid clearance of physiological reflux episodes. Thirty patients had a normal postoperative 24-hour esophageal pH monitoring test. Four patients had two postoperative studies, both of which were normal.

TABLE 2. Operative Mortality and Morbidity

	No. Patients
Death (Unrelated; postdischarge; P.O. day 22)	1
Esophageal tear	1
Splenectomy	1
Pleural effusion (required thoracostomy)	3
Wound infection	1
Deep venous thrombosis	2
Atelectasis (increased hospitalization)	2
Costochondritis	2
Acute cholecystitis	1

Mortality = 1%.  
Morbidity = 13%.

Altogether, there were five patients who after operation had delayed acid clearance of physiological reflux episodes, one symptomatic and four asymptomatic. All five had sequential postoperative pH studies. The first study was done within 1 year of the operation. The second study was done at 3 years in two patients, and 7, 8, and 9 years after the operation in the remaining three patients. In all five patients, the first postoperative 24-hour pH test was normal and the second abnormal. The delayed acid clearance was reflected by an increase in the number of reflux episodes lasting 5 minutes or longer (Fig. 11), while the total number of reflux episodes remained within normal limits. This finding suggested that over time the procedure causes a deterioration of esophageal acid clearance either by affecting propulsive force of the esophageal body or increasing the resistance of the cardia to esophageal emptying.

Table 3 shows the technique of fundoplication used in these five patients. All of them had a fundoplication of 3.0 to 4.0 cm in length, and in two it was performed over

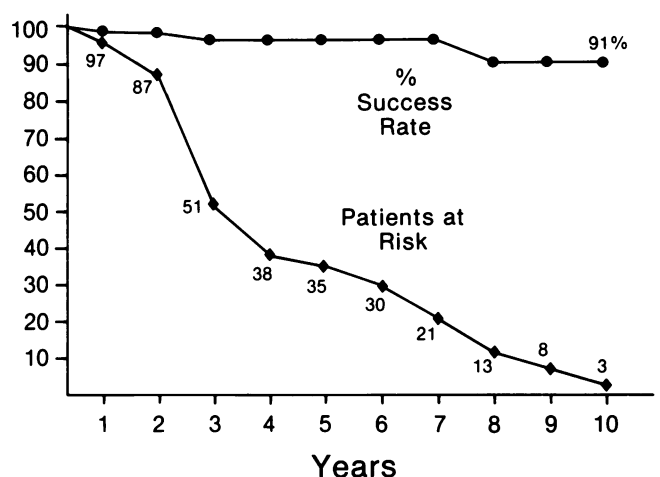


FIG. 9. Actuarial success rate of the Nissen fundoplication in the control of reflux symptoms. The numbers on the lower curve represent the patients at risk for each subsequent yearly interval from which the actuarial curve was calculated.

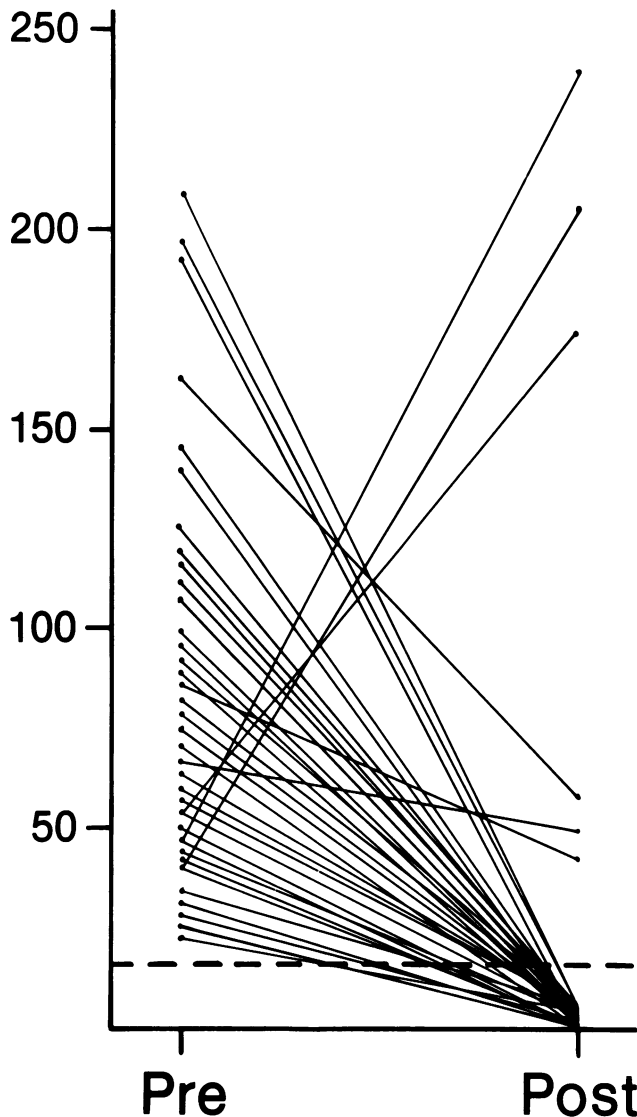


FIG. 10. Pre- and postoperative 24-hour pH score in 36 patients. Six patients had an abnormal postoperative study: two had symptoms of heartburn and regurgitation and four were asymptomatic.

a 36 French bougie. This suggests that such a long and/or narrow fundoplication may have contributed an increased resistance to esophageal emptying. In three patients, the fundus was not mobilized, and, consequently, the body of the stomach was most likely used to construct the fundoplication. This could prevent complete relaxation of the distal esophageal sphincter on swallowing and interfere with acid clearance.<sup>12</sup>

Table 4 shows that, after operation, all of these five patients had an esophageal peristalsis of normal amplitude, but four showed an incomplete relaxation of the distal esophageal sphincter on swallowing. In patients No. 1, 2, and 3, the fundus was not mobilized (Table 3). Patient No. 5, who had complete sphincter relaxation, developed

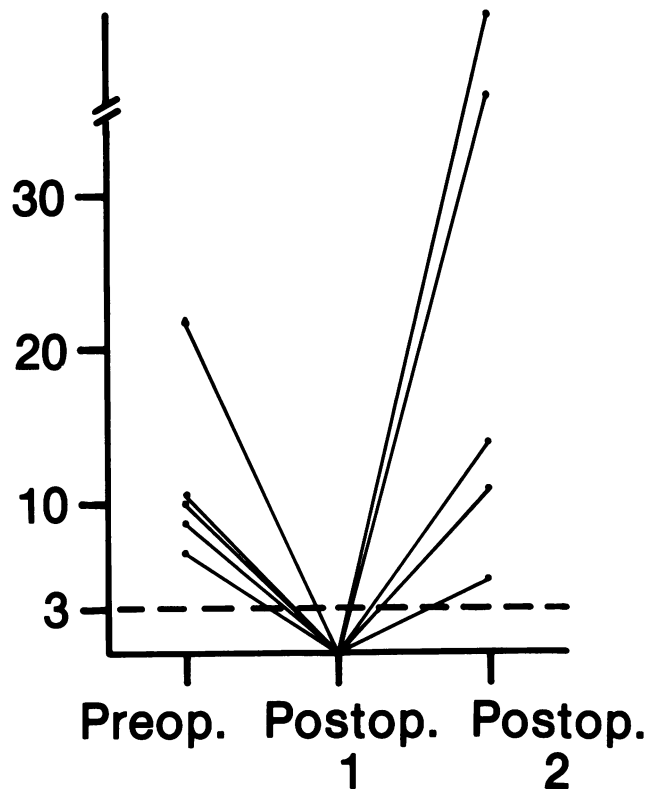


FIG. 11. Number of reflux episodes  $\geq 5$  minutes from sequential 24-hour pH monitoring studies in five patients with an abnormal postoperative 24-hour pH score. In all patients an initial postoperative test was normal and a subsequent test became abnormal. An increase in the number of reflux episodes lasting 5 minutes or longer, while the total number of reflux episodes remained within normal limits, indicates a delayed esophageal clearance of physiologic reflux episodes.

after operation an esophageal motility disorder. In all five patients, the distal esophageal sphincter pressure was increased by the procedure and remained stable during the observation period.

Figure 12 shows that with mobilization of the fundus the likelihood of having complete relaxation of the distal esophageal sphincter on swallowing is significantly increased. This occurred without loss of reflux control, except in one patient, previously mentioned, whose 24-hour pH test became abnormal because of an inability to clear acid due to an esophageal motility disorder induced by surgery.

TABLE 3. Technique of Fundoplication in Patients Who Developed Delayed Esophageal Acid Clearance after Operation

Patient	Length Wrap (cm)	Size Bougie (French)	Mobilization Fundus
1	4	36	No
2	4	36	No
3	4	60	No
4	3	60	Yes
5	3	60	Yes



TABLE 4. Esophageal Manometry in Patients Who Developed Delayed Esophageal Acid Clearance after Operation

Patient	Studies	DES Pressure (mmHg)	DES Overall Length (cm)	DES Abdominal Length (cm)	DES Relaxation (%)	Amplitude Esophageal Contractions (mmHg)
1	Preop	7.0	3.5	1.0	100	40
	Postop 1	14.0	4.5	3.5	0	30
	Postop 2	21.0	2.4	1.4	0	30
2	Preop	17.0	4.0	1.5	100	45
	Postop 1	31.0	3.0	2.0	0	40
	Postop 2	19.0	4.0	3.0	0	45
3	Preop	3.7	3.3	1.0	100	35
	Postop 1	15.0	3.5	2.0	50	30
	Postop 2	14.0	3.6	2.2	50	30
4	Preop	5.3	2.3	0.0	100	50
	Postop 1	13.0	2.4	2.0	30	45
	Postop 2	12.0	2.6	2.0	30	45
5	Preop	6.0	4.7	1.7	100	50
	Postop 1	24.0	3.0	1.5	100	45*
	Postop 2	15.7	2.7	1.3	100	35*

\* >30% simultaneous contractions.

Table 5 shows the side effects of the operation for the whole series (Periods I, II, III, and IV), and compares the incidence of side effects associated with the original operative technique (Period I) to those associated with the currently used technique (Period IV). There was no difference in the incidence of the inability to belch or vomit with the change in technique between Periods I and IV, but it did decrease significantly the postoperative incidence of temporary swallowing discomfort and persistent dysphagia. Figure 13 shows that a reduction in induced temporary swallowing discomfort (resolved within 3 months) was obtained by increasing the caliber of bougie used to size the gastric wrap from 36 to 60 French. Figure 14 shows that a reduction in induced persistent dysphagia was obtained by decreasing the length of the gastric wrap

from 4.0 to 1.0 cm. Only two patients with persistent dysphagia, both from Period II, required dilatation. Neither responded and eventually required a second operation for relief.

Table 6 shows that the postoperative incidence of symptomatic gas bloat and increased flatus was significantly lower in patients whose preoperative distal esophageal sphincter manometrics were more than two standard deviations below the mean measured in the control subjects (Table 7). Similarly, the pure upright refluxers, who are characteristically aerophagic, had a higher postoperative incidence of symptomatic gas bloat (four of six) than the supine (four of 16) or the combined refluxers (seven of 78). All upright refluxers had distal esophageal sphincter manometrics similar to control subjects.

Table 8 shows the evaluation of the operative results from the patient's perspective. Ninety of the 100 patients were satisfied with their surgical results to date, and 92% would have the operation if the decision had to be made over.

Before operation, the patients as a group had a significantly lower mean distal esophageal sphincter pressure (Fig. 15), shorter mean overall sphincter length (Fig. 16),

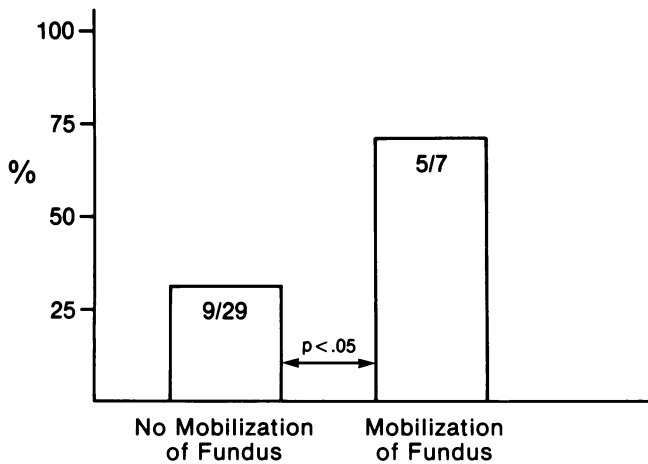


FIG. 12. The relationship of using the mobilized gastric fundus in constructing the fundoplication to the incidence of complete manometric relaxation of the distal esophageal sphincter on swallowing based on 36 postoperative studies.

TABLE 5. Side Effects of the Operation

	Periods I, II, III, IV	Period I	Period IV
Inability to belch	36%	21%	36%
Inability to vomit (if tried)	63%	61%	63%
Temporary swallowing discomfort	50%	83%	39%*
Increased flatus	38%	50%	30%
Symptomatic gas bloat	15%	21%	11%
Persistent dysphagia	14%	21%	3%*

\*  $p < 0.01$ .

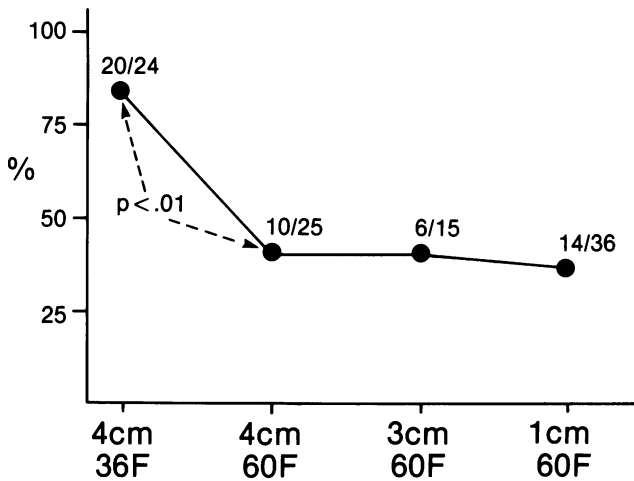


FIG. 13. Incidence of induced temporary swallowing discomfort in relation to the technique used to construct the fundoplication (N = 100). A significant reduction occurred by increasing the caliber of the bougie used to size the gastric wrap to 60 French.

and shorter mean sphincter length exposed to intra-abdominal pressure (Fig. 17) than the control subjects. The operation, which is designed to improve the mechanics of the cardia, corrected these deficiencies, as shown by the mean values for similar manometric measurements made in the 36 patients who volunteered for postoperative studies. Before operation, the patients had a significantly lower mean amplitude of esophageal contractions than did the control subjects. The addition of a fundoplication, regardless of its length or diameter, did not significantly change this measurement (Fig. 18).

On preoperative endoscopy, 42 patients had endoscopic esophagitis: nine of grade one, 20 of grade two, and 13 of grade three. Four patients with grade two esophagitis had associated Barrett's esophagus. Thirteen of the 36 patients who had postoperative studies had esophagitis before op-

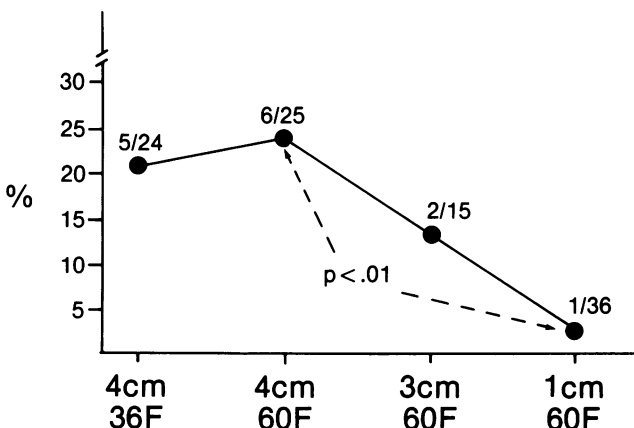


FIG. 14. Incidence of induced persistent dysphagia in relation to the technique used to construct the fundoplication (N = 100). A significant reduction occurred by reducing the length of the gastric wrap to 1.0 cm.

TABLE 6. Incidence of Side Effects of the Operation Related to Preoperative Distal Esophageal Sphincter Manometrics

	Normal D.E.S. (N = 43)	Defective D.E.S. (N = 57)
Symptomatic gas bloat	44%	23%*
Increased flatus	75%	48%*

\* p < 0.05.

eration, one of whom had associated Barrett's esophagus. Healing of the esophagitis occurred after operation in all patients. Complete regression of the columnar-lined epithelium was observed in the patient with Barrett's esophagus 6 years after operation.<sup>13</sup>

### Discussion

This study shows that the Nissen fundoplication is an effective and durable antireflux procedure and can abolish the symptoms and complications associated with gastroesophageal reflux disease. If the diagnosis of gastroesophageal reflux disease is documented by a positive 24-hour pH monitoring test, the operation is able to control reflux symptoms in 91% of the patients over a 10-year period. The study also shows that the major side effects of the procedure can be minimized with further patient selection and attention to technical details in the construction of the fundoplication.

Long-term control of reflux symptoms can be assured only when selection of patients for surgery is based on: (1) the presence of reflux symptoms, with or without persistent esophagitis; (2) an increase in esophageal acid exposure, documented by 24-hour esophageal pH monitoring; and (3) the presence of adequate esophageal contractility. In some patients, the cause of reflux symptoms and increased esophageal acid exposure is not due to a manometrically defective distal esophageal sphincter but to gastric pathology that causes reflux through a manometrically normal sphincter. In such patients, the fundoplication will stop the symptoms and the reflux of gastric contents into the esophagus but may cause other complaints, such as symptomatic gas bloat. These patients should be identified and investigated before operation for gastric pathology or excessive aerophagia as a cause of their reflux. The results in Table 6 show that the incidence of these side effects can be significantly reduced by operating only on patients who have a supine or combined

TABLE 7. Manometric Measurements of the Distal Esophageal Sphincter in Control Subjects (N = 45)

	Mean ± SD	Mean - 2 SD
DES pressure	14.9 ± 4.6 mmHg	5.7 mmHg
DES overall length	4.2 ± 1.1 cm	2.0 cm
DES abdominal length	2.6 ± 0.8 cm	1.0 cm

TABLE 8. Patient's Evaluation of the Operative Results

	%
Cured by operation	83
Improved by operation	10
Worsened by operation	7
	} 100
Satisfied with surgery	90
Would have surgery again	92

pattern of reflux and a manometrically deficient distal esophageal sphincter. The latter are patients whose sphincter manometrics are two standard deviations below the mean measurements in control subjects, that is, a sphincter pressure of 6.0 mmHg or less, an overall sphincter length of 2.0 cm or less, and/or a length of sphincter exposed to intra-abdominal pressure of 1.0 cm or less<sup>14-15</sup> (Table 7).

Technical modifications were made in the construction of the fundoplication because of the high incidence of temporary swallowing discomfort and persistent dysphagia associated with the original procedure. The occurrence of temporary swallowing discomfort (resolved within 3 months) and persistent dysphagia was significantly reduced by increasing the caliber of the bougie used to size the gastric wrap to 60 French and reducing the length of the wrap to 1.0 cm. Two patients with persistent dysphagia required dilatation. Both had a 4.0 cm wrap which had to be taken down for relief. With the current surgical technique, only one patient has complained of occasional postoperative dysphagia. This patient has not required dilatation.

A second reason for a change in operative technique was the fear that the initial method used to reconstruct the cardia was the cause for the gradual deterioration in esophageal acid clearance observed in five of the nine patients who had sequential postoperative studies. Based on our observations, the decrease in acid clearance was thought to be due to a failure of the distal esophageal

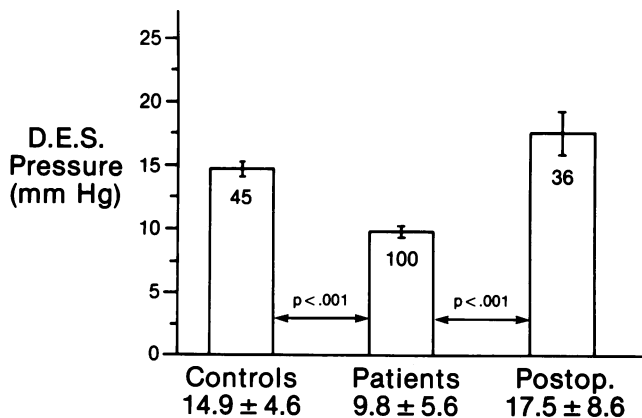


FIG. 15. Comparison of the mean distal esophageal sphincter pressure measured in control subjects, and in patients before and after surgery.

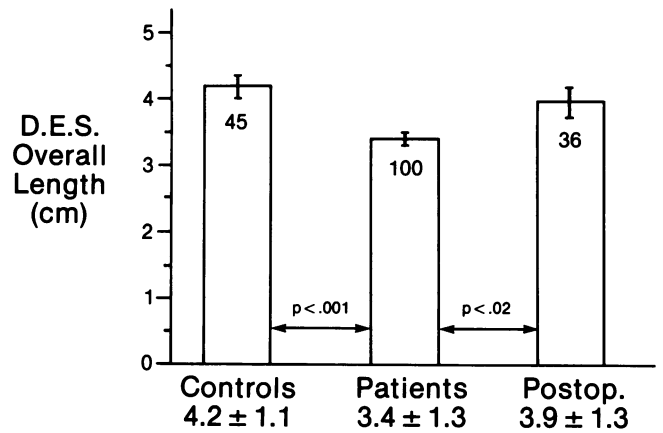


FIG. 16. Comparison of the mean overall length of the distal esophageal sphincter measured in control subjects, and in patients before and after surgery.

sphincter to relax completely on swallowing rather than a deterioration in esophageal contraction or the construction of a too long or narrow fundoplication. The former could not be supported by the postoperative manometric studies and the latter would more likely cause greater resistance to the esophageal emptying of solids than liquids. The fact that increasing the diameter and reducing the length of the fundoplication lowered the incidence of dysphagia supports this concept. Three of the five patients who developed delayed acid clearance after operation did not have mobilization of their fundus when the fundoplication was constructed. In all three, the sphincter did not completely relax on postoperative studies. Consequently, the operative technique was changed and the fundoplication constructed with the mobilized gastric fundus to assure complete relaxation of the reconstructed cardia.<sup>12</sup> This technical change resulted in a higher incidence of complete relaxation of the cardia without loss of reflux control (Fig. 12). We hope that this change in

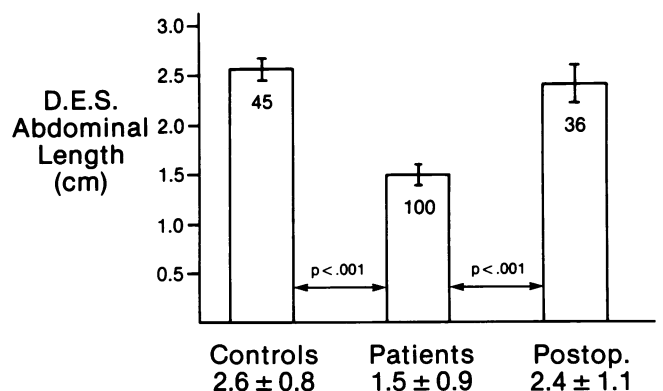


FIG. 17. Comparison of the mean abdominal length of the distal esophageal sphincter measured in control subjects, and in patients before and after surgery.

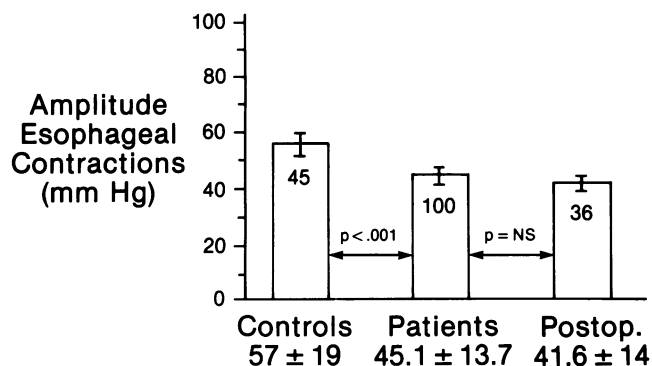


FIG. 18. Comparison of the mean amplitude of esophageal contractions measured in control subjects, and in patients before and after surgery.

technique will prevent the inability of some patients to effectively clear physiological reflux after fundoplication. The observation of the development of delayed esophageal acid clearance after operation probably explains the reported failure of histological improvement in esophageal mucosa biopsies after a Nissen fundoplication.<sup>16</sup>

The characteristics of a mechanically defective distal esophageal sphincter were defined in previous studies relating esophageal manometry to increased esophageal acid exposure on 24-hour pH monitoring.<sup>14-15</sup> The present study shows that the Nissen fundoplication can correct these manometric abnormalities and indicates that the operation is able to restore normal physiology to a mechanically defective sphincter. Furthermore, this can be accomplished without causing a deterioration or augmentation in the esophageal contractility.

On the basis of our experience, we conclude that the Nissen fundoplication, constructed according to the described technical modifications, is an effective and durable antireflux repair and has negligible side effects. The best results are obtained in symptomatic patients who have an abnormal 24-hour esophageal pH monitoring test with supine or combined pattern of reflux, a mechanically defective distal esophageal sphincter, and adequate contractility of the esophageal body.

### Summary

This study shows that the Nissen fundoplication is an effective and durable antireflux repair, providing relief of

reflux symptoms in 91% of patients for up to 10 years. The side effects of the operation can be minimized by proper patient selection and attention to the technical details in constructing the fundoplication. The operation has proven capable of correcting manometric measurements of the distal esophageal sphincter associated with an increased esophageal acid exposure.

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