The Treatment of Gastroesophageal Reflux Disease With Laparoscopic Nissen Fundoplication
Prospective Evaluation of 100 Patients With “Typical” Symptoms

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Objective
To evaluate prospectively the outcome of laparoscopic fundoplication in a large cohort of patients with typical symptoms of gastroesophageal reflux.

Summary Background Data
The development of laparoscopic fundoplication over the past several years has resulted in renewed interest in the surgical treatment of gastroesophageal reflux disease (GERD).

Methods
One hundred patients with typical symptoms of GERD were studied. The study was limited to patients with positive 24-hour pH studies and “typical” symptoms of GERD. Laparoscopic fundoplication was performed when clinical assessment suggested adequate esophageal motility and length. Outcome measures included assessment of the relief of the primary symptom responsible for surgery; the patient’s and the physician’s evaluation of outcome; quality of life evaluation; repeated upper endoscopy in 30 patients with presurgical esophagitis; and postsurgical physiologic studies in 28 unselected patients, consisting of 24-hour esophageal pH and lower esophageal sphincter manometry.

Results
Relief of the primary symptom responsible for surgery was achieved in 96% of patients at a mean follow-up of 21 months. Seventy-one patients were asymptomatic, 24 had minor gastrointestinal symptoms not requiring medical therapy, 3 had gastrointestinal symptoms requiring medical therapy, and 2 were worsened by the procedure. Eighty-three patients considered themselves cured, 11 were improved, and 1 was worse. Occasional difficulty swallowing not present before surgery occurred in 7 patients at 3 months, and decreased to 2 patients by 12 months after surgery. There were no deaths. Clinically significant complications occurred in four patients. Median hospital stay was 3 days, decreasing from 6.3 in the first 10 patients to 2.3 in the last 10 patients. Endoscopic esophagitis healed in 28 of 30 patients who had presurgical esophagitis and returned for follow-up endoscopy. Twenty-four-hour esophageal acid exposure had returned to normal in 26 of 28 patients studied after surgery. Lower esophageal sphincter pressures had also returned to normal in all patients, increasing from a median of 5.1 mmHg to 14.9 mmHg.

Conclusions
Laparoscopic Nissen fundoplication provides an excellent symptomatic and physiologic outcome in patients with proven gastroesophageal reflux and “typical” symptoms. This can be achieved with a hospital stay of 48 hours and a low incidence of postsurgical complications.

The invention of the video laparoscope has forever changed the face of surgery. Complex surgical procedures can now be performed with laparoscopic access, with minimal disruption of the patient’s life and a marked reduction in the pain associated with major surgery. Gastroesophageal reflux, recognized as a clinical entity only in the mid-1930s, is now the most prevalent upper gastrointestinal (GI) disorder in clinical practice. The reason for this is unclear, but it may be related to high-fat, overindulgent Western dietary habits. Significant changes have also occurred in the un-
nderstanding and treatment of gastroesophageal reflux disease (GERD) since it became a recognized abnormality. It is now known to be a chronic disease requiring lifelong treatment in 25% to 50% of patients.\(^2\) Further, recent large-scale population studies have shown that the complications and death rate from GERD have increased in the past decade.\(^3\)

Antireflux surgery emerged only after it was recognized in the 1950s that a hiatal hernia was associated with the gastroesophageal reflux.\(^4\) It assumed a greater role when a defective lower esophageal sphincter (LES) was identified with advanced and difficult-to-control disease.\(^5\)\(^-\)\(^7\) Despite this relatively short history, there has been a gradual advancement in surgical techniques and improvement in outcome.\(^8\) The advent of laparoscopic technology has catalyzed renewed interest in the surgical treatment of GERD. Early clinical studies of laparoscopic Nissen fundoplication documented successful relief of reflux symptoms in >90% of patients.\(^9\)\(^-\)\(^11\) As a result, laparoscopic Nissen fundoplication is positioned to become the standard of surgical care for patients with GERD. Further, its popularity has significantly increased the number of patients referred for surgical therapy. This fact has driven the need for a careful assessment of what can be accomplished with this maturing procedure.

**PATIENTS AND METHODS**

Patients with GERD can be divided into those with “typical” symptoms (heartburn, regurgitation, and dysphagia) and those with “atypical” symptoms (cough, hoarseness, and wheezing). Typical symptoms are a more reliable and precise guide to the presence of disease, and consequently their improvement better reflects the effectiveness of therapy. In contrast, it is more difficult to identify a cause-and-effect relation between atypical symptoms and gastroesophageal reflux. Consequently, their improvement or lack thereof is a less reliable indication of reflux control. For these reasons we have chosen to limit this study to the prospective evaluation of consecutive patients with typical reflux symptoms.

Between December 1991 and April 1996, 225 patients underwent primary antireflux surgery at the University of Southern California. Of these, 143 underwent laparoscopic Nissen fundoplication. The remainder had open procedures: transabdominal Nissen in 21, transthoracic Nissen in 22, Belsey hemifundoplication in 8, and Collis gastroplasty and Belsey hemifundoplication in 31. Open procedures were performed in patients with one or more of the following criteria: previous abdominal procedures, morbid obesity, esophageal shortening, and poor esophageal motility. Patients were selected for surgical therapy based on chronic daily symptoms of gastroesophageal reflux and pathologic esophageal acid exposure on 24-hour esophageal pH study. Most patients (70%) were taking proton pump inhibitors for acid suppression and either had breakthrough symptoms or more commonly desired an alternative to lifelong medication. Failure of medical therapy was not required before fundoplication, and all patients were offered the alternatives of continuing with medical therapy or undergoing antireflux surgery.

The population studied consisted of 100 patients undergoing laparoscopic fundoplication in which the primary symptom driving surgery was heartburn (\(n = 82\), regurgitation (\(n = 10\)), or dysphagia (\(n = 8\)). Forty-three patients were excluded: 23 had atypical symptoms of GERD, including asthma, cough, and chest pain; 17 had negative 24-hour esophageal pH monitoring (many of whom had paraesophageal hiatal hernias); 2 had prior gastroesophageal procedures (one myotomy, one prior antireflux procedure); and 1 had a laparoscopic fundoplication after a lung transplant.

**Diagnostic Studies**

The diagnosis of GERD was confirmed by the presence of increased esophageal acid exposure measured by 24-hour esophageal pH monitoring (Fig. 1). Esophageal acid exposure was quantitated in each patient by a scoring system (previously described) and by calculating the total percentage of time during which the esophageal pH was <4.\(^12\) Seventy-seven patients had nocturnal (i.e., supine) reflux. Of these patients, reflux occurred in both the upright and supine periods in 46 and only in the supine period in 31. Fifteen patients had isolated upright reflux. Thirty-five asymptomatic volunteers underwent esophageal pH and motility testing in the same laboratory during the same time period. These normal values were used for comparison with presurgical and postsurgical motility studies in the patients having laparoscopic fundoplication.

Video barium studies of the upper GI tract and upper endoscopy were performed in all patients. A hiatal hernia was present in 83 patients (<3 cm in 23 patients, 3 to 5 cm
in 49, and >5 cm in 11). Twenty-two patients had a demonstrable lower esophageal mucosal ring, and 22 had radiologic evidence of free reflux of barium from the stomach into the esophagus. On endoscopy, esophagitis was considered to be present if grade II (linear erosions) or grade III (coalescent erosions) changes were seen. Mucosal erythema was not included in the diagnosis of esophagitis. Thirty-eight patients had grade II and eight patients grade III esophagitis. Strictures (defined as difficulty in passing a 9-mm endoscope) were present in 6 patients, and Barrett’s esophagus (defined as any length of endoscopically visible intestinal metaplasia) was present in 35 patients.

Stationary manometry was performed in each patient, and LES pressure (measured at the respiratory inversion point), overall length, and abdominal length were calculated from the mean of the five recordings. A structurally defective sphincter giving rise to incompetence was defined as one or more of the following: resting pressure <6 mmHg, overall length <2 cm, or abdominal length <1 cm.13 By these criteria, 79% of patients had a defective LES. Before surgery, mean values were 5.7 mmHg for sphincter resting pressure, 2.2 cm overall length, and 0.8 cm abdominal length. A deficient abdominal length of the sphincter was the most prevalent abnormality, occurring in 77% of patients. Sixty-seven percent had a deficient LES pressure and 57% had a short overall sphincter length.

**Surgical Technique**

Important technical elements included crural and hiatal dissection, crural closure, and fundic mobilization by dividing the short gastric vessels in all patients. A short (1 to 2 cm), loose fundoplication was constructed over a 60 French bougie by enveloping the distal esophagus with the anterior and posterior wall of the gastric fundus. Based on the clinical and physiologic results of our early patients,14 several modifications were made in the technique of constructing the fundoplication. These included incorporating the posterior vagus nerve in the fundoplication rather than excluding it, as is done in the open procedure; extending the scope of the dissection posterior to the gastroesophageal junction and the degree of fundic mobilization; and paying attention to the geometry of the fundoplication such that the anterior and posterior fundic lips were folded around the esophagus to meet at the 9 o’clock position. Elements of the technique that we believe are particularly important to avoiding complications and achieving a high degree of long-term success are highlighted.

**Hiatal Dissection**

The key to the hiatal dissection is identification of the right crus. Metzenbaum-type scissors and fine grasping forceps are preferred for dissection. In all except the most obese patients, there is a thin portion of the gastrohepatic omentum overlaying the caudate lobe of the liver (Fig. 2). Dissection is begun by incising this portion of the gastro-hepatic omentum above and below the hepatic branch of the anterior vagal nerve, which we routinely spare. A large left hepatic artery arising from the left gastric artery is present in up to 25% of patients. It should be identified and avoided. After incising the gastrohepatic omentum, the lateral surface of the right crus becomes evident. The peritoneum overlying the anterior aspect of the right crus is incised with scissors and electrocautery and the right crus dissected as much as possible from anterior to posterior. The medial surface of the right crus leads into the mediastinum and is entered by blunt dissection with both instruments. At this juncture, the esophagus usually becomes evident. The right crus is retracted laterally and the tissues posterior to the esophagus are dissected. No attempt is made at this point to dissect behind the gastroesophageal junction. Meticulous hemostasis is critical. Blood and fluid tend to pool in the hiatus and are difficult to remove. Irrigation should be kept to a minimum. Care must be taken not to injure the phrenic artery and vein as they course above the hiatus. A large hiatal hernia often makes this portion of the procedure easier because it accentuates the diaphragmatic crura. However, dissection of a large mediastinal hernia sac can be difficult.

After dissection of the right crus, attention is turned toward the anterior crural confluence. The tissues anterior to the esophagus are held upward with the left-handed grasper and the esophagus is swept downward and to the right, separating it from the left crus. The anterior crural tissues are then divided and the left crus is identified. The left crus is dissected as completely as possible, including taking down the angle of His and the attachments of the fundus to the left diaphragm. A complete dissection of the lateral and inferior aspect of the left crus and fundus of the stomach is the key maneuver allowing circumferential mobilization of the esophagus. Failure to do so results in difficulty encircling the esophagus, particularly if approached from the right. Repositioning of the Babcock retractor toward the
fundic side of the stomach facilitates retraction for this portion of the procedure.

The esophagus is mobilized by careful dissection of the anterior and posterior soft tissues within the hiatus. If the crura have been completely exposed, dissection to create a window posterior to the esophagus is not difficult. From the patient’s right side, the esophagus is retracted anteriorly with the surgeon’s left-hand instrument, allowing posterior dissection with the right hand, and vice versa for the left-sided dissection. The posterior vagus nerve is left on the esophagus. The medial surface of the left crus is identified and the dissection is kept caudad to it. There is a tendency to dissect into the mediastinum and left pleura. In the presence of severe esophagitis, transmural inflammation, esophageal shortening, or a large posterior fat pad, this dissection may be particularly difficult. If unduly difficult, it should be abandoned and the hiatus approached from the left side by division of the short gastric vessels. After posterior dissection, a grasper is passed through the surgeon’s left-handed port behind the esophagus and over the left crus. A Penrose drain is placed around the esophagus and is used as an esophageal retractor for the remainder of the procedure.

Crural Closure

The crura are further dissected and the space behind the gastroesophageal junction is enlarged as much as possible. The esophagus is retracted anterior and to the left and the crura are approximated with three or four interrupted 0 silk sutures, starting just above the aortic decussation (Fig. 3). We prefer a large needle (CT1) passed down the left upper 10-mm port to facilitate a durable crural closure. Because the space behind the esophagus is limited, it is often necessary to use the surgeon’s left-handed (nondominant) instrument as a retractor. This maneuver facilitates placement of single bites through each crus with the surgeon’s right hand. We prefer tying the knots extracorporeally, using a standard knot pusher.

Fundic Mobilization

Complete fundic mobilization allows construction of a tension-free fundoplication without distortion of the fundus. Replacing the liver retractor with a second Babcock forceps facilitates retraction of the gastroplenic mesentry during division of the short gastric vessels. The gastroplenic omentum is suspended anteroposteriorly in a clothesline fashion using both Babcock forceps, and the lesser sac is entered approximately one-third the distance down the greater curvature of the stomach (Fig. 4). The short gastric vessels are sequentially divided with the aid of a Harmonic Scalpel (Ethicon Endosurgery, Cincinnati, OH). An anterior-to-posterior rather than medial-to-lateral orientation of the vessels is preferred, except for those close to the spleen. The dissection includes dividing the posterior pancreato-gastric branches posterior to the upper stomach and continues until the right crus and caudate lobe can be seen from the left side (Fig. 5). With caution and meticulous dissection, the fundus can be completely mobilized in almost all patients.

Geometry of the Fundoplication

The fundoplication is created with particular attention to the geometry of the fundus (Fig. 6). To ensure that the posterior fundus is used in the construction of the fundoplication, it is grasped and passed behind the esophagus from left to right rather than pulled from right to left. This is accomplished by placing a Babcock clamp through the left lower port and grasping the midportion of the posterior fundus (Fig. 7). The fundus is passed behind the esophagus to the right side. The Babcock clamp becomes visible on the right side with an upward and clockwise twisting motion. The anterior wall of the fundus is brought over the anterior wall of the esophagus above the supporting Penrose drain. Both posterior and anterior fundic lips are manipulated so
that the esophagus is enveloped without twisting the fundus (Fig. 8). The laparoscopic visualization has a tendency to exaggerate the size of the posterior window. Consequently, the space behind the esophagus may be smaller than thought. This can cause ischemia of the fundus when it is passed behind the esophagus. If the posterior lip of the fundoplication has a bluish discoloration, the stomach should be returned to its original position and the posterior window enlarged. A 60 French bougie is passed into the stomach and the fundoplication is constructed around it to size its diameter properly. The anterior and posterior lips of the fundoplication are sutured together using a single U-stitch of 2-0 Prolene buttressed with felt pledgets.

The most common error in constructing the fundoplication is to grasp the anterior portion of the stomach and pull...
it behind the esophagus. This results in twisting the gastric fundus around the esophagus. Instead, the esophagus should be enveloped by an untwisted fundus before suturing. Two anchoring sutures of 2-0 silk are placed above and below the U-stitch to complete the fixation of the fundoplication. When finished, the stomach should remain in its original plane, with the suture line of the fundoplication facing in the right anterior direction and the greater curvature in the left posterior direction. Before removing the ports, the abdomen is irrigated, hemostasis is ensured, and the bougie is removed.

Outcome Measures

Both symptomatic and functional measures were used to analyze the outcome of the procedure. The symptomatic outcome was assessed by a physician other than the responsible surgeon and was considered excellent if the patient was asymptomatic, good if the symptoms were relieved but minor GI complaints (e.g., bloating or flatulence) persisted, fair if the symptoms were improved but medication was necessary for complete relief, and poor if the symptoms were not improved. Particular attention was taken to determine if the primary symptom responsible for surgical referral was relieved. Patients were asked to make their own assessment of the outcome of the procedure by judging whether they were cured, improved, or worsened by the procedure and whether they would undergo surgery again under similar circumstances. These results were obtained by telephone or personal interview using a standardized questionnaire at a median of 21 months after surgery. Follow-up was complete in 95% of the study group.

Patients who had presurgical erosive esophagitis underwent a second endoscopy procedure to determine if the esophagitis had healed. Post-surgical physiologic studies were performed in 28 unselected patients and consisted of 24-hour esophageal pH monitoring and LES manometry. Quality of life was assessed with the Short Form 36 (SF-36) health survey questionnaire in 46 patients.

Statistical Analysis

Results are reported as mean plus or minus standard error of the mean. Comparison of proportions was made using the Fisher's exact test.

RESULTS

Perioperative Course and Hospital Stay

All patients were admitted to the hospital the day of surgery. Two of the patients (patients 2 and 42) were converted to open laparotomy because of difficulty in fundic mobilization and short gastric division. There were no deaths. Significant complications occurred in four patients (GI bleeding, a partial splenic infarct, heparin-induced hemarthrosis, and pneumonia in one patient each). Hospital stay averaged $3.1 \pm 0.2$ days, decreasing from a mean of 6.3 days in the first 10 patients to 2.3 days in the last 10 patients. Laparoscopic fundoplication took an average of $202 \pm 58.5$ minutes. With experience, surgical time decreased from a mean of 236 minutes in the first 20 patients to 171 minutes in last 10 patients ($p < 0.001$).

Symptomatic Assessment

Ninety-five patients were contacted at a median of 21 months after surgery (range 8 months to 5 years). Follow-up was $>4$ years in 5 patients, 3 to 4 years in 12, 2 to 3 years in 35, 1 to 2 years in 43. All patients had daily symptoms before surgery. The primary symptom responsible for surgery was relieved in 91 of the 95 patients available for follow-up (96%). Four patients had continued heartburn; none had persistent regurgitation or dysphagia.

When all GI symptoms were considered, 67 patients were asymptomatic (Table 1). When asked, 23 patients reported occasional symptoms of bloating, flatulence, or early satiety but required no further therapy. Three patients were improved but had persistent symptoms that required additional therapy (heartburn in two, crampy abdominal pain in one). Two patients were considered failures. In one, heartburn improved, but the patient developed postsurgical regurgitation and dysphagia. The other developed daily dysphagia that persisted $>3$ months after fundoplication.

Table 2 shows the patients' evaluation of their outcome. When asked whether the operation cured, improved, or worsened their symptoms, 99% of patients (94/95) were either cured or improved. Some form of antireflux medica-
tion was taken by 90% of patients before surgery; 47% of them took proton pump inhibitors (Table 3). After surgery, only four patients required any form of acid suppression or prokinetic therapy.

### Side Effects of the Procedure

The most common symptom after surgery was a temporary difficulty in swallowing that lasted <3 months and occurred in 47 patients. Increased flatus occurred in 45 patients and occasional bloating or early satiety in 42 (Table 4). Twenty-four patients reported the inability to vomit, although none of these had discomfort as a result. Most patients (76) could belch after fundoplication. Seven patients had dysphagia >3 months after surgery: in five it was occasional, in one weekly, and in one daily. By 13 months after surgery, dysphagia had resolved in all but one patient (Fig. 9). When all patients with presurgical dysphagia were considered together, dysphagia improved after surgery.

### Healing of Esophagitis

Forty-six patients had erosive esophagitis before surgery, 38 grade II and 8 grade III. Of these, 30 returned for follow-up endoscopy, and esophagitis was completely resolved in 28 (93%). Two patients had persistent esophagitis; the one who returned for postsurgical pH studies had a persistent increased esophageal acid exposure.

#### Physiologic Assessment

All patients were asked before surgery to return for postsurgical manometric studies. Twenty-eight agreed to undergo studies both before and after surgery. LES characteristics were significantly improved from presurgical values (p < 0.001). Figure 10 shows that the Nissen fundoplication restored LES pressure, overall length, and abdominal length to normal. Esophageal acid exposure returned to normal in 26 of 28 patients (Fig. 11). The two in whom it did not return to normal had markedly reduced acid exposure. Mean composite acid scores decreased from 50 to <5 (normal < 14.8, p < 0.05), and the mean percentage of time the esophagus was exposed to pH < 4 was also reduced to less than the normal range of <4.3% (p < 0.05).

### Quality of Life Analysis

Quality of life before and after surgery was assessed using the SF-36 standardized instrument. This evaluation began approximately halfway through the accrual of patients for this report. Consequently, the final 46 consecutive patients were evaluated before surgery, and 43 of the 46 were evaluated again after surgery. The scores were compared with each other and with an age- and gender-matched U.S. population. After surgery, the scores for bodily pain improved significantly (p < 0.01; Table 5). When the patients were asked to compare their current general health to

#### Table 1. PHYSICIANS ASSESSMENT

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Definition</th>
<th>Number of Patients (n = 95) (%)</th>
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</thead>
<tbody>
<tr>
<td>Excellent</td>
<td>Asymptomatic</td>
<td>67 (71)</td>
</tr>
<tr>
<td>Good</td>
<td>Relief of primary symptom, but minor GI symptoms, no therapy</td>
<td>23 (24)</td>
</tr>
<tr>
<td>Fair</td>
<td>Improved, persistent GERD symptoms, therapy required</td>
<td>3 (3)</td>
</tr>
<tr>
<td>Failure</td>
<td>Not improved and/or long term dysphagia as a consequence of surgical therapy</td>
<td>2 (2)</td>
</tr>
</tbody>
</table>

GERD = Gastroesophageal reflux disease.

#### Table 2. PATIENTS ASSESSMENT OF OUTCOME

<table>
<thead>
<tr>
<th>Status</th>
<th>Number of Patients (n = 95) (%)</th>
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</thead>
<tbody>
<tr>
<td>Cured</td>
<td>83 (87)</td>
</tr>
<tr>
<td>Improved</td>
<td>11 (12)</td>
</tr>
<tr>
<td>Worsened</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Satisfied with surgery</td>
<td>83 (87)</td>
</tr>
<tr>
<td>Would have surgery again</td>
<td>89 (94)</td>
</tr>
</tbody>
</table>

#### Table 3. ANTIREFLUX MEDICATION BEFORE AND AFTER SURGERY

<table>
<thead>
<tr>
<th>Type</th>
<th>Preoperative (n = 100)</th>
<th>Postoperative (n = 95)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proton pump inhibitor</td>
<td>47 (1)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>H2-blocker</td>
<td>29 (1)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Prokinetic</td>
<td>8 (1)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>Antacids</td>
<td>6 (1)</td>
<td>1 (1)</td>
</tr>
<tr>
<td>None</td>
<td>10 (10)</td>
<td>91 (95)</td>
</tr>
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</table>

#### Table 4. SIDE EFFECTS OF THE OPERATION

<table>
<thead>
<tr>
<th>Side Effect</th>
<th>Number of Patients (n = 95) (%)</th>
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</thead>
<tbody>
<tr>
<td>Temporary swallowing discomfort</td>
<td>47 (50)</td>
</tr>
<tr>
<td>Dysphagia &gt; 3 months</td>
<td>7 (7)</td>
</tr>
<tr>
<td>Increased flatus</td>
<td>45 (47)</td>
</tr>
<tr>
<td>Complaints of bloating</td>
<td>42 (44)</td>
</tr>
<tr>
<td>Inability to belch</td>
<td>19 (20)</td>
</tr>
<tr>
<td>Inability to vomit</td>
<td>24 (25)</td>
</tr>
</tbody>
</table>
that 1 year before the surgical procedure (5 = much better, 4 = somewhat better, 3 = same, 2 = somewhat worse, 1 = much worse), they reported a significant improvement (4.51 ± 0.87 after vs. 2.65 ± 0.5 before, p < 0.01). We did not find differences in the scores for the mental health, emotional state, social functioning, vitality, physical state, and physical functioning categories.

**DISCUSSION**

Laparoscopic fundoplication was introduced into clinical practice in 1991.\textsuperscript{15} Even though no prospective randomized trials have been conducted comparing its efficacy to that of proton pump inhibitor therapy, evidence is rapidly accumulating to indicate that the procedure is highly effective in controlling symptomatic gastroesophageal reflux.\textsuperscript{9-11,16-18} This study has shown that laparoscopic fundoplication relieved the "typical" symptoms of heartburn, regurgitation, and dysphagia in 95% of patients for up to 4 years. Erosive esophagitis was healed in 90% of patients returning for follow-up endoscopy, and 24-hour ambulatory esophageal pH profiles returned to normal in 92% of patients tested >1 year after surgery. Hunter et al.\textsuperscript{10} Hinder et al.\textsuperscript{11} have also reported >90% improvement in symptoms and a similar reduction in esophageal acid exposure measured by 24-hour pH monitoring.

These results can be achieved by a single therapeutic intervention with minimal discomfort and minor disruption of the patient's life.\textsuperscript{19,20} Although the invasive nature of surgery is associated with risk, complications are uncommon after laparoscopic fundoplication and those that do occur tend to be minor. Gastric and esophageal perforations are among the most serious complications reported. They are probably a consequence of inadequate experience with the laparoscopic technique and unfamiliarity with the hiatal anatomy.\textsuperscript{21} No foregut perforations occurred in our patients.

The goal of surgical treatment for GERD is to relieve the symptoms of reflux by reestablishing the gastroesophageal barrier. The challenge is to accomplish this without inducing dysphagia or other untoward side effects. Dysphagia present before surgery usually improves after laparoscopic fundoplication.\textsuperscript{22-24} Temporary dysphagia is common after surgery (perhaps even desirable) and generally resolves within 3 months. Dysphagia persisting >3 months has been reported in up to 10% of patients. Dysphagia (i.e., occasional difficulty swallowing solids) was present in 7% of our patients at 3 months, 5% at 6 months, 2% at 12 months, and in a single patient at 24 months after surgery. Others have observed a similar improvement in postsurgical dysphagia with time.\textsuperscript{24} Induced dysphagia is usually mild, does not require dilatation, and is temporary. It can be induced by technical misjudgments, but this explanation does not hold in all instances. In experienced hands, its prevalence should be <3% at 1 year.\textsuperscript{8}

It is our firm belief that widespread application of laparoscopic Nissen fundoplication in patients without objective documentation of increased esophageal acid exposure by 24-hour esophageal pH monitoring and the identification of deficits in esophageal length or function will lead to poor results in a significant number of patients. Physiologic assessment before antireflux surgery is particularly important.
because of the lessened threshold for surgical referral brought about by the rising popularity and enthusiasm for a minimally invasive surgical approach. Patients with gastroesophageal reflux who have a relatively early form of the disease and can be managed with intermittent acid suppression therapy do not need antireflux surgery. When chronic daily acid suppression therapy is necessary, particularly if proton pump inhibitors or dose escalation is required to control symptoms, antireflux surgery should be discussed as an option.

Traditionally, the presence of esophagitis has been the primary criteria to identify patients with severe disease who are candidates for surgical therapy. This remained true in the early years of laparoscopic fundoplication, but the excellent outcome achieved with the procedure has encouraged reevaluation of this guideline. Many now consider antireflux surgery in patients who do not have esophagitis but are dependent on proton pump inhibitors to remain symptom-free. This is particularly true in patients younger than 50 years and those at risk for severe disease. Studies of the natural history of GERD have suggested that approximately 25% of patients fall into this category. High-risk features include supine reflux, a structurally defective LES, reflux of a mixture of gastric and duodenal juice, and the presence of severe esophagitis, stricture, or Barrett’s esophagus at the initial endoscopy. In these patients, the need for long-term medical therapy is likely and may be problematic. We believe these patients should be identified early and given the option of laparoscopic fundoplication if their physiology and anatomy permit.

The advent of the laparoscopic approach provides an ideal opportunity to standardize the technique of Nissen fundoplication because it markedly limits the technical variability that can occur with the open procedure. When the technical aspects of the procedure are agreed on, the referring physician can have greater confidence in a predictable outcome, once the properly trained surgeon has experience with 30 to 50 procedures. For the present, considerable discussion continues regarding the importance of technical aspects such as the orientation of the fundoplication and the need for fundic mobilization and crural closure. It has become clear that failure to close the diaphragmatic hiatus by approximating the crura during fundoplication has resulted in a high prevalence of migration of the fundoplication into the chest. Routine crural closure prevents this problem. It is also clear that dysphagia may result from undue lateral tension on the fundoplication from undivided short gastric vessels and the resultant incomplete mobilization of the fundus.

Recent studies have suggested that the learning curve for laparoscopic procedures, including cholecystectomy and fundoplication, is in the range of 35 to 50 procedures. At the present rate of surgical referral, most surgeons encounter only a handful of patients with gastroesophageal reflux each year. This makes it difficult to develop technical expertise. Although the advent of laparoscopic fundoplication has increased both patient and physician acceptance of antireflux surgery, most of these procedures are concentrated in centers with demonstrated interest in the surgical treatment of gastroesophageal reflux. The training of a gastroenterologist with a GI surgeon allows both to increase their experience of using surgery to treat this disease. In so doing, they bring a balanced approach that becomes an important community resource.

Quality of life analyses have become an important part of surgical outcome analysis. Both generic and disease-specific questionnaires have been used in an attempt to quantitate quality of life before and after medical intervention. In general, these measures attempt to relate the effect of disease management to the overall well-being of the patient. We elected to use the SF-36 instrument because it is rapidly administered and well validated. This questionnaire measures 12 health-related quality of life parameters, encompassing mental and physical well-being. Our data indicate significant improvement in scores for the area of bodily pain and in a portion of the general health index. Most other measures were improved but failed to achieve statistical significance. Laycock et al. also analyzed SF-36 scores before and after laparoscopic antireflux surgery. In contrast to our data, scores in all fields were significantly better after surgery; however, their presurgical scores were dramatically lower than ours. Thus, the difference is probably secondary to the relatively high scores of our patients before surgery (perhaps indicating good disease control on

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<th>Table 5. SF-36 HEALTH ASSESSMENT SCORES</th>
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<tr>
<td></td>
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<tr>
<td>Preoperative n = 46</td>
</tr>
<tr>
<td>Postoperative n = 43</td>
</tr>
<tr>
<td>p Value</td>
</tr>
<tr>
<td>General Population</td>
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<td>Population by Age &amp; Gender</td>
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<tr>
<td>Bodily pain (BP)*</td>
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<tr>
<td>Mental health (MH)</td>
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<td>Role emotional (RE)</td>
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<tr>
<td>Social functioning (SF)</td>
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<td>Vitality (VT)</td>
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<td>General health (GH)</td>
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<td>Role physical (RP)</td>
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<td>Physical functioning (PF)</td>
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medical therapy) and to our small sample size. We continue to accrue such data for further analysis.

Other investigators have also reported improvement in quality of life after antireflux surgery. Glise et al. used two standardized and validated questionnaires, the Psychological General Well-Being Index and the Gastrointestinal Symptom Rating Scale, to evaluate quality of life in 40 patients after laparoscopic antireflux surgery. Scores with both instruments were improved after antireflux surgery and were better than in untreated patients. The scores were as good as or better than those of patients receiving optimal medical therapy. Velonovich et al. using a 10-item health-related quality of life questionnaire specific for GERD, also showed an improvement in quality of life after antireflux surgery.

We conclude that laparoscopic fundoplication will abolish gastroesophageal reflux and relieve the typical symptoms of the disease in >90% of patients. Symptomatic relief has persisted for up to 4 years after surgery, and there is every reason to expect that the effect will persist for the life expectancy of the patients.

References


