



20 years later: laparoscopic fundoplication durability

Ben Robinson · Christy M. Dunst · Maria A. Cassera ·
Kevin M. Reavis · Ahmed Sharata ·
Lee L. Swanstrom

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Abstract

Background Laparoscopic surgery for gastrointestinal reflux disease was introduced in 1991. Early safety, efficacy, and 5–10-year durability have been amply documented, but long-term patient outcomes have been criticized. This study presents 20-year outcomes after laparoscopic fundoplication (LF) in a consecutive patient cohort.

Methods Patients who underwent primary LF procedures for gastroesophageal reflux disease (GERD) were identified from a prospectively collected IRB-approved database (1991–1995). A phone symptom questionnaire was administered using a 5-point validated GERD scoring system (heartburn, regurgitation, and dysphagia). Symptomatic success was defined by a lack of surgical re-intervention and a low symptom score.

Results One-hundred and ninety-three patients were identified during the time period. Fifty-one patients completed the survey (100 lost to follow-up, 40 deceased, 2 declined to answer). Respondents had a median follow-up of 19.7 years. Overall, 38/51 (74.5 %) of patients reported complete control of heartburn and regurgitation. Ten patients reported only occasional heartburn. Eight of fifty-one (16 %) reported daily dysphagia, and 22/51 (43 %) of respondents were using proton pump inhibitors at the time of telephone interview. Nine of fifty-one (18 %) underwent revision of the original surgery which did not negatively impact the satisfaction rating, with 8/9 (89 %) of these patients reporting the highest satisfaction rating. Overall, 46/51 (90 %) were satisfied with their choice of surgery.

Conclusion Long-term results from the early experience with LF are excellent with 94 % of patients reporting only occasional or fewer reflux symptoms at 20-year follow-up. However, 18 % required surgical revision surgery to maintain their results. There is a relatively high rate of daily dysphagia but 90 % of patients are happy to have had LF.

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B. Robinson (✉) · C. M. Dunst · K. M. Reavis · A. Sharata ·
L. L. Swanstrom
Foundation for Surgical Innovation and Education, Portland, OR,
USA
e-mail: benny@spu.edu

L. L. Swanstrom
e-mail: lswanstrom@gmail.com

C. M. Dunst · K. M. Reavis · L. L. Swanstrom
Division for Gastrointestinal Minimally Invasive Surgery, The
Oregon Clinic, 4805 NE Glisan St, Suite 6N60, Portland,
OR 97213, USA

C. M. Dunst · M. A. Cassera · L. L. Swanstrom
Providence Cancer Center, Portland, OR, USA

L. L. Swanstrom
Institut Hospitalo Universitaire, Strasbourg, France

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Laparoscopic fundoplication (LF) popularity rapidly increased following its introduction in the early 1990s [1]. Since then, favor has begun to shift away from the procedure due to increased availability of potent anti-reflux medications, to reports of variable outcomes, and a perception that fundoplications have limited durability. Nonetheless, LF has been demonstrated to be a safe, effective and cost-effective treatment for gastroesophageal reflux disease (GERD) in multiple studies. Although a few long-term studies have confirmed the durability of LF for

up to 10 years, there is very little data describing results beyond this time frame. The objective of this study was to review the current status of patients from our early experience with LF 20 years ago.

Materials and methods

Operative and clinical data were collected prospectively on all patients since the first LF was performed by the senior author (LLS). All initial LF's were performed under an IRB-approved study protocol until 1995, and all outcomes data were collected on a prospective IRB-approved database. This foregut surgery database was queried for all patients who underwent primary LF procedures for GERD between 1991 and 1995 by a single surgeon. Patient records were used to obtain follow-up contact information. Internet-based personal directory search engines were used to locate and contact subjects that could not be reached using information on file.

Patients were contacted by telephone and interviewed by a single investigator (BR). Each patient was administered questions using a standardized script devised by the co-authors. They were then given a validated symptom questionnaire that ranked the frequency of GERD symptoms (Table 1). Specific symptoms and side effects included heartburn, regurgitation, dysphagia, abdominal pain post meal, nausea, diarrhea, hyper-flatulence, trouble belching, and early satiety. Inquiries of surgery revisions, current medications, and the number of food impactions were also made. Patients were asked to grade their subjective satisfaction with their decision to have surgery on a scale of 0–4 (0 = unsatisfied, 4 = completely satisfied). Patients reporting proton pump inhibitors (PPI) use were contacted a second time and questioned about their reason for such treatment, about their expected symptom occurrence should they stop taking their medication, and a general review of the original standardized script.

Results

One-hundred and ninety-three patients were identified as having LF during 1991–1995. Of these, 100 patients could

not be reached and were listed as lost to follow-up. Another 40 patients were deceased, and 2 declined to answer, leaving 51 patients who completed the survey (Fig. 1). Respondents had a median post-surgical follow-up of 19.7 years (range 18.2–21.8 years). There were 29 males and 22 females. The average age at surgery was 47 years. Patient demographics are listed in Table 2.

Overall, 38/51 (74.5 %) of patients reported complete control of heartburn and regurgitation at 20-year follow-up. An additional 10/51 (19.6 %) patients reported only occasional heartburn (<1 episode per week). Only 3/51 (5.9 %) reported both heartburn and regurgitation. No patients reported having isolated regurgitation (Fig. 2). Twenty-four of fifty-one (47 %) described any symptom of dysphagia with 8/51 (16 %) reporting dysphagia on a daily basis. Additional comorbid gastrointestinal conditions were identified in 78 % of the cohort. Complete symptom profiles are shown in Fig. 3. Twenty-two percent of patients had a completely negative symptom questionnaire.

Five patients reported at least one food impaction at any time post-fundoplication, but only one experienced an impaction on two occasions. Twenty-two of fifty-one (43 %) respondents were using PPIs at the time of the telephone interview. Fifty-nine percent of patients taking PPI were symptom free on medication. For the second follow-up with PPI patients, 19/22 (86.4 %) were successfully contacted. Off of medication, 4/19 (21.1 %) of these patients reported no heartburn or regurgitation, 5/19 (26.3 %) had only heartburn, 1/19 (5.3 %) had only regurgitation, 7/19 (36.8 %) reported both heartburn and regurgitation, and 2/19 (10.5 %) were unsure of symptoms off of the PPI (Fig. 4).

Table 1 Symptom scale

Score	Frequency
0	Never
1	Rare
2	Occasional
3	Daily
4	Continuous

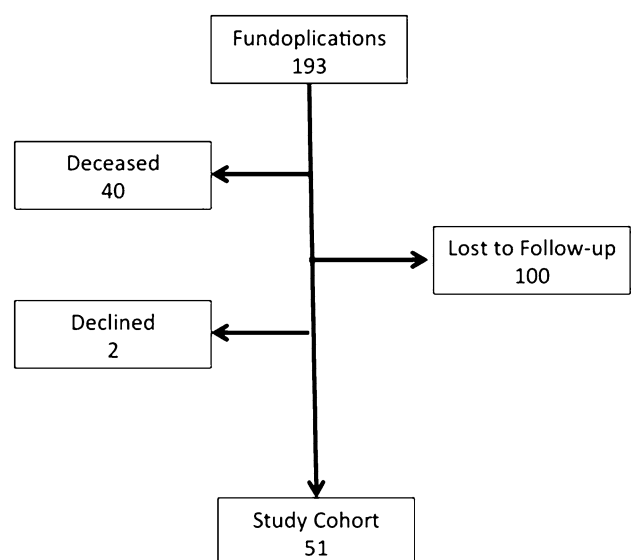


Fig. 1 Study design. The breakdown of identified patients into deceased, unable to contact, and declined to answer groups

Table 2 Demographics of 51 respondents

Demographics	Number
Mean age at surgery, years (range)	47 (27–70)
Male:female	29:22

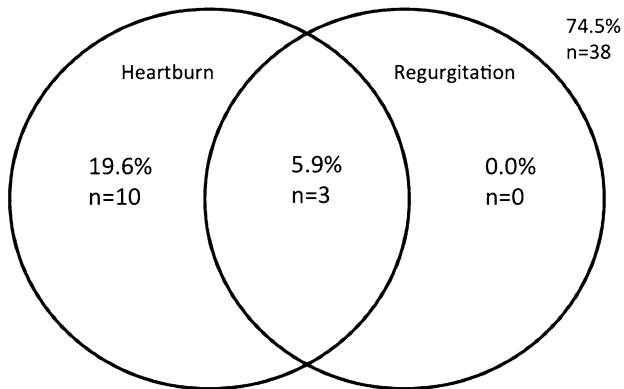


Fig. 2 Heartburn and regurgitation 20 years after fundoplication. The majority of patients were free of heartburn and regurgitation at long-term follow-up. Isolated heartburn was the most frequent symptom while isolate regurgitation was not reported

Forty-six of fifty-one (90 %) patients were satisfied with their choice of surgery, with 39/51 (75 %) answering with the maximal approval rating (Table 3). The satisfaction

scores were higher in patients not taking any antacids (96 %) compared to those who were on PPIs (81 %). Of the five unsatisfied respondents, three had persistent daily dysphagia and two of these also had reflux. The fourth patient was not happy to have to take PPI’s again, and the final patient was dissatisfied because of transient post-op dysphagia. Interval revision surgery had occurred in 9/51 (17.6 %) with complete resolution of symptoms in 7/9 (77.8 %). Only one patient underwent multiple revisions. The average duration between the original procedure and the revision was 11 years. The revision surgeries occurred 2, 4, 6, 7, 12, 13, 14, 16, and 20 years after their respective original surgeries (Fig. 5). Revision surgery did not negatively impact the satisfaction rating with 8/9 (88.9 %) responding with the highest satisfaction rating.

Discussion

LF has been demonstrated to provide excellent relief of gastroesophageal reflux symptoms and to be safe and well tolerated in numerous short-term studies. Throughout the 1990s, this contributed to rapid adoption of the procedure as an alternative to chronic medical treatment. Unfortunately, while the population incidence of GERD continues to rise, LF procedure numbers have peaked and even declined in most parts of the world. Reasons for this are

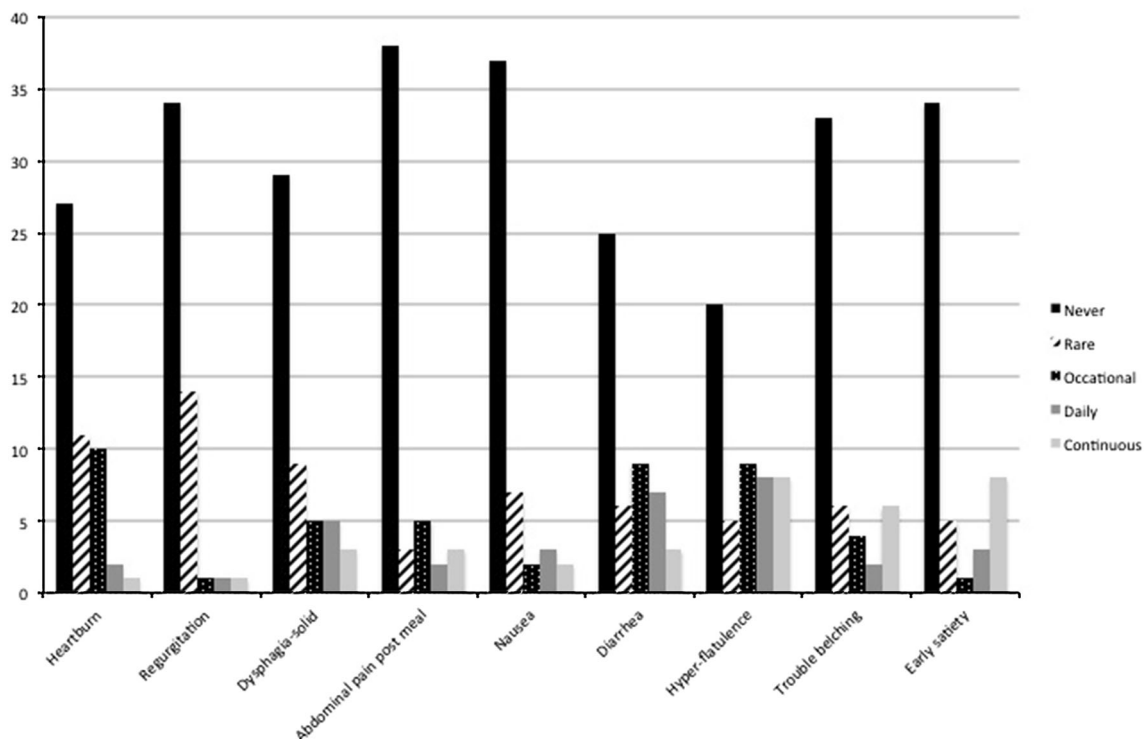


Fig. 3 Clinical symptoms 20 years after fundoplication. Detailed symptom questionnaire results from the entire cohort

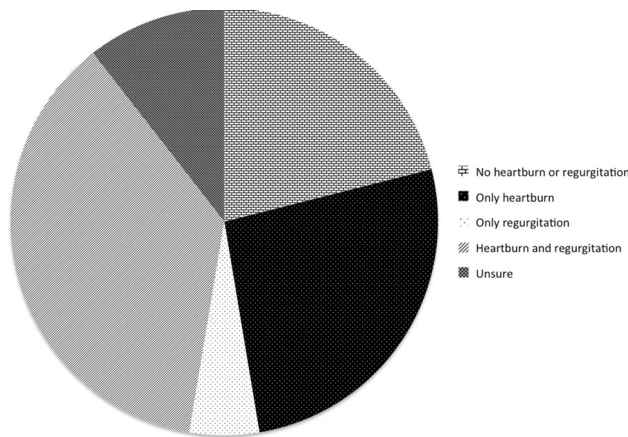


Fig. 4 GERD symptoms of medically treated patients off of PPI. Heartburn and regurgitation results of patients currently treated with PPI if they were to discontinue medical treatment

Table 3 Satisfaction grading

Unsatisfied	
0	6 % (3)
1	4 % (2)
2	0 % (0)
3	14 % (7)
4	75 % (39)
Totally satisfied	

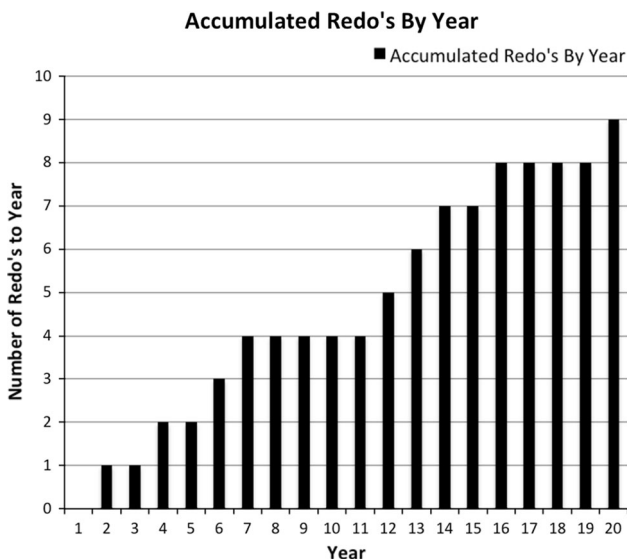


Fig. 5 Revision surgery accumulation. Graph showing the relationship between years after surgery and number of revisions performed to date

multifactorial and include over the counter access to PPI medications, disparity in operative results between high-volume “experts” and lower volume providers [2], and widely held perceptions in the GI community that

funduplications are a temporary “fix” for GERD and are rife with troublesome side effects [3, 4]. Foregut specialty surgeons typically disagree with this perception and feel that laparoscopic anti-reflux surgery in fact presents a good alternative to lifetime medication use and in fact can provide lifetime control of most symptoms of GERD for most patients if it is performed skillfully and in carefully evaluated and selected patients. We therefore drew on our 23-year experience with laparoscopic anti-reflux surgery to document that good results persist in the majority of patients up to 20 years. This study, drawn from prospectively collected data, in fact demonstrates that 20 years after their surgery, 75 % of patients are enjoying complete relief of their reflux symptoms, and an additional 19 % have only rare or occasional symptoms. An overwhelming majority of patients (90 %) are happy with the original decision to have surgery regardless of whether or not they are taking medications, have side effects, or required revisionary surgery.

Our absolute GERD control rate of 75 % is on the low end of the range reported in long-term outcomes for open funduplications (75–91 % success rate) [5, 6]. This may be due to the fact that the cases in this study included the surgeon’s learning curve for LF. As is the case with all new operations, LF has been progressively modified to reduce complications and improve outcomes, and one would expect that the subsequent patient cohort from this surgeon’s experience would have even better 20-year results. A relatively high number of respondents reported at least occasional dysphagia. Historically, dysphagia has been reported in 12–22 % of patients at 10/11-year follow-up [7, 8]. While we show a rate on the higher end of this range (25 %), it may again be because of learning curve issues. One example of this is that the patient cohort in this study included patients who did not have division of the short gastric vessels and who were subsequently shown to have a higher dysphagia rate in a study published in 1996. This study led to a subsequent change in our technique with the adoption of routine vessel division [9]. The author’s technique in fact, continued to evolve based on a series of outcomes studies until 2000, where it has remained mostly the same for the last 3,000 cases.

Nine respondents (18 %) underwent a remedial surgery prior to the 20-year follow-up. Shorter follow-up studies have reported a similar 11–17 % revision rate for LFs when the learning curve period is included [10]. Of the patients who underwent revision, 7/9 (78 %) also had no or rare heartburn and regurgitation. This rate is identical to short-term data for LF revision that we have previously published [11]. In addition, all revision patients were satisfied with their original choice for surgery.

As is typical in any GERD population, a relatively high number of respondents were taking PPIs at 20-year follow-

up. However, when questioned, over 21 % of patients taking a PPI had no GERD symptoms when off of their medication, and another 11 % were unsure if they had GERD symptoms when not taking their PPI. This relatively high number of respondents taking PPIs might be the result of the United States provision of highly advertised, easy to acquire, and indiscriminately prescribed PPIs. It has been previously shown that following fundoplication, PPI use does not define failure of the fundoplication because PPI usage is not correlated with symptomatic outcomes or objective findings of reflux [12].

One weakness of our study is that we rely on subjective responses to our GERD survey tool. Symptomatic evaluation of the GERD patient has been shown to possibly overestimate wrap failure rate [12]. Ideally, this study should be followed by a 20-year study that includes objective testing—though this is of course logistically difficult particularly as 90 % of the patients were perfectly happy and therefore less likely to want invasive testing. Furthermore, laparoscopic anti-reflux surgery has evolved as new technologies have been introduced and every surgeon's technique evolves based on their experiences and outcomes [13]. Examples of this include the introduction of ultrasonic tissue sealing that contributed to making division of the short gastric vessels routine, studies showing the importance of secure hiatal closure, the use of esophageal dilators, etc. [14]. It would be expected that results from a 20-year follow-up patient cohort that excluded this period of procedure development would show even higher success rates than reported here.

Conclusions

At 20-year follow-up, 90 % of patients are happy with having had a LF. Seventy-five percent are heartburn and reflux free and an additional 19 % have only occasional GERD symptoms. As GERD is a chronic disease and frequently associated with other digestive problems, it is not surprising that 78 % of patients had some, mostly mild, GI complaints and that 43 % of patients were taking a PPI—frequently for non-GERD-related reasons. We hope that this data, showing the long-term patient benefits of LF, will

help dispel the myth that it is a transient fix or subject to devastating side effects.

Disclosures Ben Robinson, Christy M. Dunst, Maria A. Cassera, Kevin M. Reavis, Ahmed Sharata, and Lee L. Swanstrom have no conflicts of interest or financial relationships to disclose.

References

1. Finks JF, Wei Y, Birkmeyer JD (2006) The rise and fall of antireflux surgery in the United States. *Surg Endosc* 20:1698–1701
2. Carlson MA, Frantzides CT (2001) Complications and results of primary minimally invasive antireflux procedures: a review of 10,735 reported cases. *J Am Coll Surg* 193:428–439
3. Richter JE, Dempsey DT (2008) Laparoscopic antireflux surgery: key to success in the community setting. *Am J Gastroenterol* 103:289–291
4. Richter JE (2003) Let the patient beware: the evolving truth about laparoscopic antireflux surgery. *Am J Med* 114:71–73
5. DeMeester TR, Bonavina L, Albertucci M (1986) Nissen fundoplication for gastroesophageal reflux disease: evaluation of primary repair in 100 consecutive patients. *Ann Surg* 204:9–20
6. Luostarinen M (1993) Nissen fundoplication for reflux esophagitis: long-term clinical and endoscopic results in 109 of 127 consecutive patients. *Ann Surg* 217:329–337
7. DelleMagne B, Weerts J, Markiewicz S, Dewandre JM, Wahlen C, Monami B, Jehaes C (2006) Clinical results of laparoscopic fundoplication at ten years after surgery. *Surg Endosc* 20:159–165
8. Morgenthal CB, Shane MD, Stival A, Gletsu N, Milam G, Swafford V, Hunter JG, Smith CD (2007) The durability of laparoscopic Nissen fundoplication: 11-year outcomes. *J Gastrointest Surg*. doi:10.1007/s11605-007-0161-8
9. Hunter J, Swanstrom L, Waring JP (1996) Dysphagia after laparoscopic antireflux surgery. *Ann Surg* 224:51–57
10. Kelly JJ, Watson DI, Chin KF, Devitt PG, Game PA, Jamieson GG (2007) Laparoscopic Nissen fundoplication: clinical outcomes at 10 years. *J Am Coll Surg* 205:570–575
11. Khajanchee YS, O'Rourke R, Cassera MA, Gatta P, Hansen PD, Swanstrom LL (2007) Laparoscopic reintervention for failed antireflux surgery. *Arch Surg* 142:785–792
12. Khajanchee YS, O'Rourke RW, Lockhart BA, Patterson EJ, Hansen PD, Swanstrom LL (2002) Postoperative symptoms and failure following antireflux surgery. *Arch Surg* 137:1008–1014
13. Dallemagne B, Weerts JM, Jehaes C, Markiewicz S, Lombard R (1991) Laparoscopic Nissen fundoplication: preliminary report. *Surg Laparosc Endosc* 1:138–143
14. Patterson EJ, Herron DM, Hansen PD, Ramzi N, Standage BA, Swanstrom LL (2000) Effect of an esophageal bougie on the incidence of dysphagia following Nissen fundoplication: a prospective blinded randomized trial. *Arch Surg* 135:1055–1062