

Twenty years of experience with laparoscopic antireflux surgery

C. Engström^{2,3}, W. Cai², T. Irvine², P. G. Devitt¹, S. K. Thompson¹, P. A. Game¹, J. R. Bessell², G. G. Jamieson¹ and D. I. Watson²

¹University of Adelaide Discipline of Surgery, Royal Adelaide Hospital, Adelaide, and Flinders University Department of Surgery², Flinders Medical Centre, Bedford Park, South Australia, Australia, and ³Department of Surgery, Sahlgrenska University Hospital, Göteborg, Sweden

Correspondence to: Professor D. I. Watson, Flinders University Department of Surgery, Room 3D211, Flinders Medical Centre, Bedford Park, South Australia 5042, Australia (e-mail: david.watson@flinders.edu.au)

Background: There are few reports of large patient cohorts with long-term follow-up after laparoscopic antireflux surgery. This study was undertaken to evaluate changes in surgical practice and outcomes for laparoscopic antireflux surgery over a 20-year period.

Methods: A standardized questionnaire, prospectively applied annually, was used to determine outcome for all patients undergoing laparoscopic fundoplication in two centres since commencing this procedure in 1991. Visual analogue scales ranging from 0 to 10 were used to assess symptoms of heartburn, dysphagia and satisfaction with overall outcome. Data were analysed to determine outcome across 20 years.

Results: From 1991 to 2010, 2261 consecutive patients underwent laparoscopic fundoplication at the authors' institutions. Follow-up ranged from 1 to 19 (mean 7.6) years. Conversion to open surgery occurred in 73 operations (3.2 per cent). Revisional surgery was performed in 216 patients (9.6 per cent), within 12 months of the original operation in 116. There was a shift from Nissen to partial fundoplication across 20 years, and a recent decline in operations for reflux, offset by an increase in surgery for large hiatus hernia. Dysphagia and satisfaction scores were stable, and heartburn scores rose slightly across 15 years of follow-up. Heartburn scores were slightly higher and reoperation for reflux was more common after anterior partial fundoplication ($P = 0.005$), whereas dysphagia scores were lower and reoperation for dysphagia was less common ($P < 0.001$). At 10 years, satisfaction with outcome was similar for all fundoplication types.

Conclusion: Laparoscopic Nissen and partial fundoplications proved to be durable and achieved good long-term outcomes. At earlier follow-up, dysphagia was less common but reflux more common after anterior partial fundoplication, although differences had largely disappeared by 10 years.

Paper accepted 1 June 2012

Published online in Wiley Online Library (www.bjs.co.uk). DOI: 10.1002/bjs.8870

Introduction

Laparoscopic antireflux surgery was first described in 1991^{1,2}. Good outcomes were reported initially, although early critics of this approach highlighted the lack of long-term outcomes. The weight of evidence now confirms that laparoscopic Nissen fundoplication is an effective treatment for gastro-oesophageal reflux disease^{3,4}. However, postfundoplication side-effects have encouraged various modifications to Nissen's procedure and the development of partial fundoplications⁵⁻⁷.

The first laparoscopic antireflux procedure undertaken in the authors' units was performed in 1991. This entailed

a modified Nissen fundoplication technique. Initially the hiatus was not repaired routinely or the short gastric blood vessels divided routinely. Outcome data were collected in a standardized manner and audit analysis of postoperative outcomes led to incremental changes to the operative technique. Some of these modifications were then evaluated in prospective randomized trials⁸⁻¹¹. The results of these trials suggested that division of the short gastric blood vessels during laparoscopic Nissen fundoplication is generally not necessary, and that laparoscopic anterior 180° partial fundoplication achieves equivalent control of reflux but with fewer side-effects at early and late follow-up.

Similar outcomes have been reported from trials conducted elsewhere¹².

However, these randomized trials have looked only at specific aspects of surgical technique, rather than the bigger picture, which can be evaluated only by measuring outcomes in all patients undergoing antireflux surgery. Hence, this study evaluated the overall experience with laparoscopic antireflux surgery in the authors' units since commencing the procedure in 1991. The aim of the study was prospectively to measure and document outcomes in a large cohort of patients undergoing antireflux surgery, and to identify changes in antireflux surgery practice and their impact on outcome over two decades.

Methods

All patients who underwent an attempted laparoscopic fundoplication for gastro-oesophageal reflux and/or a large hiatus hernia at the Royal Adelaide Hospital, Flinders Medical Centre and associated private hospitals in Adelaide, South Australia, from October 1991 (when the first laparoscopic fundoplication was attempted) until December 2010 were included in this study. Procedures were performed by either a consultant upper gastrointestinal surgeon or an upper gastrointestinal surgery fellow working under direct supervision. Preoperative, operative and postoperative outcome data were collected prospectively for all patients, and data were managed on a computerized database.

During the study period all primary antireflux procedures were commenced using the laparoscopic approach, and from 1992 onwards no patient underwent a primary open antireflux procedure. Operative techniques included total 360° (Nissen), posterior 270°, anterior 180° and anterior 90° partial fundoplications. These techniques have all been described in detail elsewhere^{5,6,13}. Following an initially high rate of postoperative hiatus hernia, posterior hiatal repair was used routinely for all fundoplications from 1994 onwards¹⁴. Nissen fundoplication entailed the construction of a loose 360° total fundoplication after selective division of the short gastric vessels. A 50–52-Fr bougie was used to calibrate the fundoplication and ensure it was not too tight. Anterior 180° partial fundoplication involved suturing the anterior fundus across the front of the oesophagus, and anchoring it to the wall of the oesophagus and the hiatal rim, including the right hiatal pillar. Anterior 90° partial fundoplication entailed suturing the anterior fundus to the left side of the oesophagus and left hiatal pillar, and then halfway across the front of the oesophagus, with anchorage to the wall of the oesophagus and the apex of the hiatal rim. Both types of partial fundoplication aimed

to stabilize the distal oesophagus in the abdomen, and to anchor the fundus to the oesophagus and the hiatal rim.

After surgery, patients were followed using a standardized set of questions that were applied at fixed time points. Follow-up was managed by a team of research nurses. A questionnaire was mailed to all patients at 3 and 12 months, and annually thereafter. If this questionnaire was not returned and the location of the patient was known, the questionnaire was administered by a research nurse by telephone. Patients were asked questions about symptoms of heartburn, postoperative dysphagia for liquids and solids, and overall satisfaction with the outcome following surgery. These outcomes were assessed using a visual analogue scale (VAS) ranging from 0 to 10^{8–10}. For the assessment of heartburn, dysphagia for liquids and dysphagia for solids, 0 indicated no symptoms and 10 indicated severe symptoms. For the assessment of overall satisfaction the scale was reversed, so that 0 indicated dissatisfied and 10 highly satisfied. In general, symptom scores of 0–3 indicated either no symptoms or minor symptoms that did not interfere with quality of life, whereas 4–6 indicated moderate and 7–10 severe symptoms. A satisfaction score of 7–10 indicated a high level of satisfaction with the overall outcome, 4–6 a moderate level of satisfaction, and 0–3 a low level of satisfaction.

Patients were also asked to answer yes or no to the question whether or not they thought they had made the correct decision to undergo their original surgery, and also whether or not they were consuming antisecretory medication, irrespective of the indication.

Data on symptom scores were analysed at each year of follow-up. The decision question and use of proton pump inhibitor (PPI) medication were analysed at 5 and 10 years' follow-up for each fundoplication type.

Statistical analysis

Continuous data, expressed as mean(s.d.), were compared using the Mann–Whitney *U* test, and categorical variables by means of the χ^2 test. InStat[®] version 3.1a (GraphPad Software, La Jolla, California, USA) was used for analysis of symptom scores.

Results

A total of 2261 patients underwent an attempted laparoscopic fundoplication and were included in this study; 1108 (49.0 per cent) were male and 1153 (51.0 per cent) female. Mean age was 52.4(15.5) (range 15–95) years. Mean weight was 82.7(17.2) (range 40–160) kg and mean body mass index was 28.9(5.7) (range 15.6–60.2) kg/m². The mean duration of symptoms before surgery was 8.5(9.4) years.

Perioperative outcomes

The mean duration of operation was 81(5) (range 20–260) min. Some 2188 operations (96.8 per cent) were completed laparoscopically and 73 (3.2 per cent) were converted to an open surgical procedure. A total of 1209 patients (53.5 per cent) underwent a Nissen fundoplication, 977 (43.2 per cent) an anterior partial fundoplication (612 anterior 180°, 365 anterior 90°) and 63 (2.8 per cent) a posterior partial fundoplication. Nine patients (0.4 per cent) underwent repair of a large hiatus hernia without a fundoplication. Because of intraoperative complications, three procedures (0.1 per cent) were converted to a resection procedure (2 oesophagectomy, 1 partial gastrectomy).

The short gastric blood vessels were divided in 265 patients (11.7 per cent), all of whom had a Nissen fundoplication. They were never divided during a partial fundoplication. Before mid-1994 the hiatus was not repaired routinely except in patients with a significant hiatus hernia. However, from mid-1994, hiatal repair was routine. A 52-Fr intraoesophageal bougie was used to calibrate the fundoplication in 1528 patients (67.6 per cent). It was used routinely for Nissen fundoplication, but omitted in many partial fundoplication procedures.

The mean postoperative hospital stay was 3(3) days. Three patients died during the hospital admission (in-hospital mortality rate 0.1 per cent), two following repair of a very large hiatus hernia (complications of oesophageal perforation 1, myocardial infarction 1) and one after a procedure for reflux (ischaemic gut due to mesenteric artery thrombosis). Mean follow-up was 7.6(4.7) (range 1–19) years.

Revisional surgery

A total of 216 patients (9.6 per cent) underwent revisional surgery at some stage. One hundred and sixteen of the revisions were undertaken within 12 months of the original operation. In this group, the commonest indications were dysphagia (62, 53.4 per cent) and hiatus hernia (26, 22.4 per cent). Other reasons for early reoperation in 28 patients included: recurrent reflux (11), oesophageal perforation or leakage (6), sepsis (4), abdominal pain (3), bleeding (2), wound dehiscence (1) and mesenteric artery thrombosis (1).

Revision 12 months or more after the original surgery was undertaken in 100 patients. The commonest reasons for later revision were: dysphagia (25, 25.0 per cent), hiatus hernia (24, 24.0 per cent) and recurrent reflux (47, 47.0 per cent). Other reasons in four patients included bloating (3) and abdominal pain (1). Revisional surgery was undertaken beyond 10 years in ten (1.4 per cent) of 703

patients followed for more than 10 years. Four of these very late reoperations were for symptoms of recurrent reflux.

Overall, reoperation was undertaken in 11.8 per cent of patients (143 of 1209) after Nissen fundoplication, in 6.0 per cent (37 of 612) after anterior 180° partial fundoplication, in 8.2 per cent (30 of 365) after anterior 90° partial fundoplication, and in 6 per cent of patients (4 of 63) after posterior partial fundoplication. The reoperation rate was significantly higher in patients who underwent a Nissen fundoplication ($P = 0.005$).

Reasons for reoperation in relation to the original fundoplication type are summarized in *Table 1*. Compared with Nissen fundoplication, reoperation for recurrent reflux was significantly more common after both types of anterior partial fundoplication (3.1 and 4.9 per cent for 180° and 90° respectively *versus* 1.7 per cent; $P = 0.005$), but much less frequently undertaken for dysphagia (1.0 and 0.8 per cent *versus* 6.3 per cent; $P < 0.001$).

Changing workload

Fig. 1 shows the number of laparoscopic fundoplications performed each year according to the indication for surgery. Initially, from 1992 to 1998, there was a rapid increase in the number of laparoscopic fundoplications undertaken for gastro-oesophageal reflux, but subsequently there was a slow decline in the number of operations each year for this indication. This decline was offset by an increase in the number of operations performed for repair of a very large hiatus hernia; the proportion of patients undergoing surgery for a very large hiatus hernia reached 50 per cent of the total caseload in 2010. The conversion rate to open surgery declined with experience from 14 per cent in 1992 to approximately 2 per cent in the late 1990s, and to zero for the last 5 years.

Fig. 2 shows the different types of fundoplication. From the late 1990s there was a reduction in the number of Nissen fundoplications, offset by an increase

Table 1 Reasons for reoperation in relation to type of fundoplication at the original surgery

	Nissen (<i>n</i> = 1209)	Anterior 180° (<i>n</i> = 612)	Anterior 90° (<i>n</i> = 365)	Posterior partial (<i>n</i> = 63)	<i>P</i> *
Recurrent reflux	20 (1.7)	19 (3.1)	18 (4.9)	1 (2.0)	0.005
Dysphagia	76 (6.3)	6 (1.0)	3 (0.8)	2 (3.0)	< 0.001
Hiatus hernia	38 (3.1)	8 (1.3)	7 (1.9)	1 (2.0)	0.089
Other reason	9 (0.7)	4 (0.7)	2 (0.5)	0 (0)	
Total (all reasons)	143 (11.8)	37 (6.0)	30 (8.2)	4 (6.0)	0.005

Values in parentheses are percentages. *Nissen *versus* anterior 180° *versus* anterior 90° *versus* posterior fundoplication (χ^2 test).

in the number of anterior partial funduplications. Anterior partial fundoplication is now the commonest procedure performed, entailing more than 80 per cent of the current workload.

Long-term clinical outcomes

Fig. 3 shows the mean VAS scores for heartburn, dysphagia and satisfaction at each year of follow-up for all

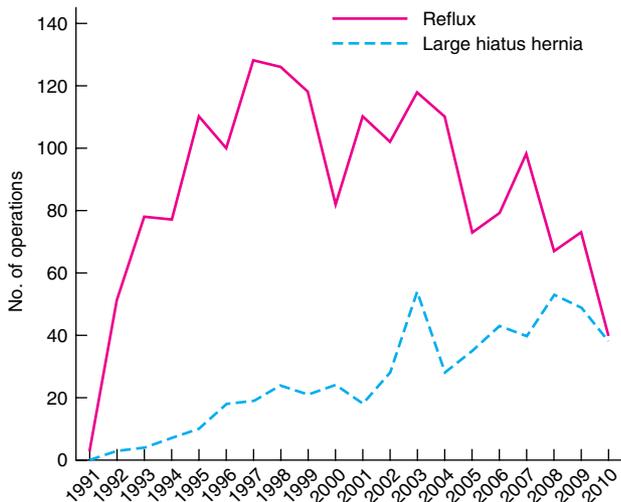


Fig. 1 Number of laparoscopic operations performed for gastro-oesophageal reflux and large hiatus hernia from 1991 to 2010

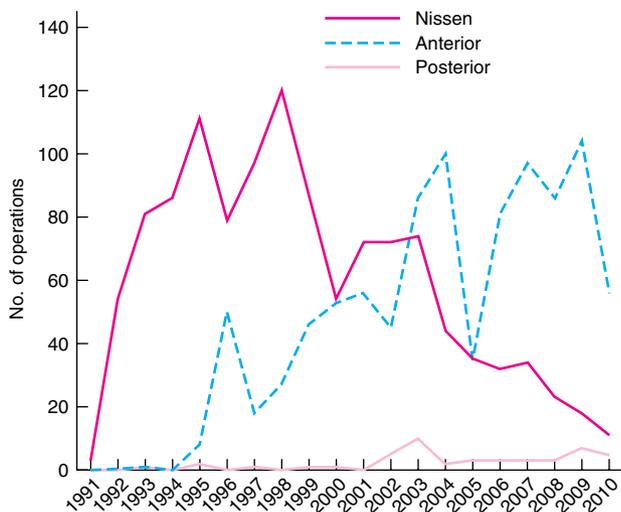


Fig. 2 Number of laparoscopic funduplications performed each year from 1991 to 2010 by fundoplication subtype: Nissen fundoplication, anterior (90° and 180°) partial fundoplication and posterior partial fundoplication

fundoplication types, across the first 15 years after surgery. All scores were reasonably stable up to 15 years' follow-up. There was a slight rise in heartburn scores as follow-up lengthened, although the extent of the increase was unlikely to be clinically significant. Dysphagia scores were stable and did not improve at late follow-up. Overall satisfaction remained stable and high across the first 15 years.

Fig. 4 shows mean heartburn scores at each year of follow-up for each of the three commonest fundoplication

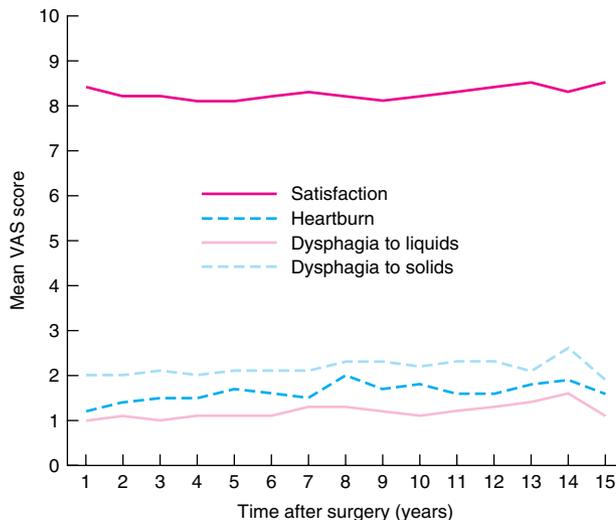


Fig. 3 Mean scores on a visual analogue scale (VAS) from 0 to 10 for heartburn, dysphagia and satisfaction at each year of follow-up for the first 15 years

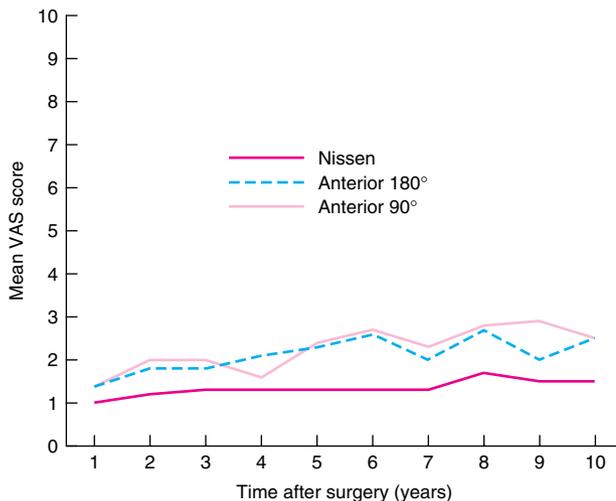


Fig. 4 Mean visual analogue scale (VAS) scores for heartburn after different fundoplication types at each year of follow-up for the first 10 years

types. This analysis was limited to the first 10 years of follow-up because anterior 90° funduplications were started later in the series, and an insufficient number were followed beyond 10 years. The heartburn scores remained fairly stable across the first 10 years, although there tended to be a gradual increase as follow-up lengthened for all funduplications types. However, the scores remained low at 10 years' follow-up compared with preoperative symptom scores, suggesting that effective reflux control was achieved in most patients by all funduplications variants. PPIs were used at 5 years' follow-up by 8.8 per cent after Nissen fundoplication, 23.4 per cent after anterior 180° partial and 26.2 per cent after anterior 90° partial fundoplication ($P < 0.001$). Respective values at 10 years were 19.7, 29.7 and 30.1 per cent ($P = 0.027$).

Fig. 5 summarizes dysphagia scores for solids for each funduplications type over the first 10 years of follow-up. The dysphagia score for solids after Nissen fundoplication remained stable across the 10 years. Although the scores for anterior 180° and 90° partial fundoplication were initially lower, they increased gradually with time. At 10 years' follow-up scores were identical to those reported following Nissen fundoplication.

The dysphagia scores for liquids followed a similar pattern. They were stable following Nissen fundoplication across the first 10 years of follow-up. Scores were similarly lower after anterior partial fundoplication during the first 5 years of follow-up, but rose to the same level as those following Nissen fundoplication by 10 years.

Satisfaction scores were generally stable for all funduplications types across the first 10 years of follow-up, with similar scores for Nissen and anterior 180° partial fundoplication at each year of follow-up. Satisfaction scores following anterior 90° partial fundoplication were lower

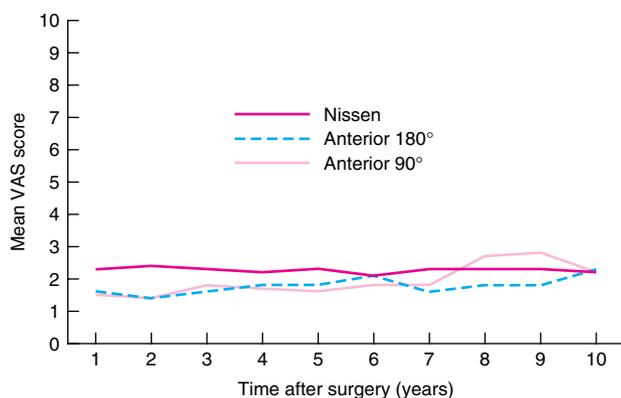


Fig. 5 Mean visual analogue scale (VAS) scores for dysphagia for solid food after different funduplications types at each year of follow-up for the first 10 years

than those for the other funduplications types at 5–8 years' follow-up, but by 10 years were similar to satisfaction scores for the other funduplications types.

The overall success rate at 5-year follow-up, determined as the proportion of patients who answered 'yes' to the question addressing the correctness of the original decision to undergo antireflux surgery, was 87.0 per cent after Nissen fundoplication, 89.7 per cent after anterior 180° partial and 88.1 per cent after anterior 90° partial fundoplication ($P = 0.527$). At 10 years' follow-up the success rates were 90.8, 94.1 and 91.8 per cent respectively ($P = 0.573$).

Discussion

Since the introduction of laparoscopic techniques for Nissen fundoplication in 1991^{1,2,13}, many centres have accumulated large experiences. This, in combination with prospective audit of outcome data, has provided a better understanding of how best to undertake antireflux surgery, facilitating modifications to surgical procedures used for the treatment of gastro-oesophageal reflux. The authors of the present study have evaluated modifications to the original laparoscopic Nissen fundoplication technique in a series of prospective randomized trials^{8–11}, and have also performed more than 1700 laparoscopic antireflux procedures outside these trials. Evaluation of prospective outcomes from the overall experience has led to changes in practice, and allowed outcomes to be determined across two decades.

Following the introduction of laparoscopic fundoplication, a progressive increase in surgical workload occurred in the authors' institution from 1991 to 1995. From 1992 onwards, all primary antireflux procedures were attempted laparoscopically. The increase in workload after this time appeared to be due to a larger number of referrals, generated by a combination of increased patient demand and redistribution of workload from general surgeons to specialist upper gastrointestinal surgeons. For much of the next 12 years the rate of surgery remained stable, although it peaked in 2003 and declined slightly thereafter.

It is possible that a reduction in the rate of referral for antireflux surgery is now being seen, a pattern that has been reported in Europe and the USA^{15,16}. It is also possible that in Australia laparoscopic fundoplication is now transitioning from a subspecialty operation to a more routine procedure, being undertaken by a larger number of surgeons, and that this has led to fewer operations being captured within the authors' database. This view is supported by a recent analysis of Australian population

data, which suggested that the rate of surgery for gastro-oesophageal reflux is still increasing slowly¹⁷. However, any decline in surgery for reflux in the authors' units has been offset by a steady increase in the number of patients undergoing surgery for large hiatus hernia. These patients now represent 50 per cent of the laparoscopic fundoplication workload. This trend probably reflects the perception that laparoscopic repair can now be achieved safely and reliably, as well as the ageing of the Australian population. The decline since 2005 to a very low rate of conversion to open surgery supports the view that these procedures can be reliably performed laparoscopically.

The surgical technique of fundoplication has evolved over time. Changes were made as data emerged from outcome audits and clinical trials. For instance, when laparoscopic fundoplication was commenced, hiatal repair was undertaken only in patients who had what the operating surgeon considered at that time to be a major hiatus hernia. However, in mid-1994, following a study that demonstrated a fivefold increased risk of further surgery for postoperative hiatus hernia in patients in whom the hiatus had not been repaired, routine hiatal repair was instituted¹⁴. From 1996 a series of prospective randomized trials evaluated various techniques for laparoscopic anterior partial fundoplication *versus* Nissen fundoplication^{9–11}. As the outcomes from these trials emerged and confidence was developed in the long-term efficacy¹⁸, the partial fundoplication technique was used for an increasing proportion of patients undergoing surgery for reflux. Hence, the proportion of Nissen fundoplications declined from nearly 100 per cent to fewer than 20 per cent of all fundoplications over recent years in the present series.

Revisory operations were undertaken in 9.6 per cent of patients in this series. More than half were done in the first 12 months after surgery, and very few more than 5 years after the original fundoplication. Some of the reinterventions, especially those undertaken within the first 12 months, could have been related to early learning curve issues, as well as technical problems such as failure to undertake routine hiatal repair during the first 200 procedures, or the opposite problem of overtightening the oesophageal hiatus during posterior hiatal repair¹⁹. However, reintervention for either recurrent reflux or persistent dysphagia is probably still inevitable in a proportion of patients, and it is likely that similar reintervention rates will occur elsewhere. The data from this study suggest that reintervention is infrequently required beyond 5 years' follow-up.

The patient-reported clinical scores for heartburn and dysphagia were stable over 15 years' follow-up, and satisfaction remained high at late follow-up. Any

deterioration in reflux control over time was fairly minimal, and the data support the proposal that laparoscopic antireflux surgery achieves effective reflux control in most patients at late follow-up. This is supported by the stable satisfaction scores across extended follow-up. Interestingly, the dysphagia scores did not improve over time. The scores after Nissen fundoplication remained stable, and those after anterior partial fundoplication actually increased slightly to equivalence with Nissen fundoplication by 10 years' follow-up. These data do not support the idea that postfundoplication dysphagia improves beyond 12 months. Rather, it suggests that troublesome dysphagia at 12 months might require active reintervention to achieve resolution.

Other outcomes, including heartburn and satisfaction scores, and the overall success rate, were also similar for all fundoplication subtypes at 10 years' follow-up. Both the anterior 90° and 180° partial fundoplication procedures were associated with slightly higher heartburn scores compared with Nissen fundoplication, and there was a slow increase in these scores over time. However, the magnitude of the differences was small, and probably none was clinically important. It should also be noted that the heartburn scores and PPI use do not provide objective evidence of recurrent gastro-oesophageal reflux. Rather the score is a patient-reported score for the symptom of 'heartburn', which relies on how each individual interprets this symptom. Other studies have shown that only 30–35 per cent of PPI use after antireflux surgery is actually for recurrent gastro-oesophageal reflux²⁰. Nevertheless, previous studies have demonstrated that the heartburn score does correlate with reflux^{8–11}, and it provides one way of comparing different procedure types and measuring changes in outcome over time. Furthermore, these data are supported by the higher surgical revision rate for recurrent reflux, and the higher rate of PPI use after anterior partial fundoplication. Although it would be desirable to validate these outcomes with pH monitoring, good compliance with repeated objective outcome measures, such as 24-h pH monitoring, is not feasible for the purpose of this study, and the present clinical results are more indicative of longer-term outcomes.

Overall, the outcomes in the present study are consistent with those reported in previous randomized trials^{9–12}. Overall satisfaction following surgery was similar for Nissen and anterior partial fundoplication, and 5 years after surgery there was some trade-off between heartburn control and postoperative dysphagia, with the advantages and disadvantages for these procedures balancing to achieve similar rates of satisfaction. These differences seemed

to disappear by 10 years, and satisfaction rates were approximately 90 per cent for all fundoplication types at late follow-up. These outcomes are consistent with the higher surgical revision rate for dysphagia, and the lower revision rate for recurrent reflux following Nissen fundoplication. Based on these data, anterior 180° partial fundoplication is now offered to patients thought to be at high risk of side-effects following Nissen fundoplication, a choice of anterior 180° or Nissen fundoplication for those deemed to be at a lower risk of side-effects, and an anterior 90° partial fundoplication to more elderly patients undergoing surgery primarily for a very large hiatus hernia.

Acknowledgements

The authors thank Ms Lorelle Smith, Ms Carolyn Lally, Ms Janet Sullivan and Ms Nicky Carney for their assistance with follow-up of patients after laparoscopic fundoplication. Some of the follow-up in this study was supported by Research Project Grants from the National Health and Medical Research Council of Australia (grant numbers 157986 and 375111).

Disclosure: The authors declare no conflict of interest.

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Commentary

Twenty years of experience with laparoscopic antireflux surgery (*Br J Surg* 2012; 99: 1415–1421)

Laparoscopic antireflux surgery is an effective treatment for patients with well established chronic gastro-oesophageal reflux disease (GORD)¹. Criticisms of antireflux surgery are the perceived high failure rates, the need for revisional surgery and the frequent use of antireflux medication among surgical patients. The authors of the present paper have demonstrated that the indications, techniques and outcomes of laparoscopic antireflux surgery for GORD and hiatal hernia have evolved substantially over 20 years.

Most patients are highly satisfied with the procedure and report low heartburn scores. Importantly, this good outcome is sustained well beyond 15 years of follow-up. An obvious limitation of the study is that no objective follow-up is reported. However, the systematic repetition of tests aimed at studying reflux cannot be planned on such a cohort over a period of 20 years. Proton pump inhibitors were being used by 20–30 per cent at 10 years' follow-up. Most patients who use acid suppression medication after antireflux surgery do not have abnormal oesophageal acid exposure, and the use of these medications is thus often inappropriate². However, reinterventions for dysphagia, recurrent reflux or herniation are probably inevitable and still needed in approximately 10 per cent of patients. As to what type of fundoplication is preferred, a recent meta-analysis supports the use of a partial fundoplication given the lower rate of dysphagia and other side-effects³. The present study is in line with this.

Can the findings of this study be extrapolated to the broader surgical community? One should realize that the patients were operated on by a very experienced surgical team, pioneering antireflux surgery since 1991. Selecting the right patients for surgery, exploring their expectations and the surgeon's experience are crucial factors that contribute to the high success rates reported in the present study.

B. P. L. Wijnhoven

*Department of Surgery, Erasmus MC, University Medical Centre Rotterdam, PO Box 2040, 3000 CA Rotterdam, The Netherlands
(e-mail: b.wijnhoven@erasmusmc.nl)*

DOI: 10.1002/bjs.8894

Disclosure

The author declares no conflict of interest.

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