

Randomized Trial of Laparoscopic Nissen Versus Anterior 180 Degree Partial Fundoplication – Late Clinical Outcomes at 15 to 20 years

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Objective: To determine very late clinical outcomes at up to 20 years follow-up from a randomized controlled trial of Nissen versus anterior 180-degree partial fundoplication.

Summary Background Data: Nissen fundoplication for gastroesophageal reflux can be followed by troublesome side effects. To address this, partial fundoplications have been proposed. Previously reports from a randomized controlled trial of Nissen versus anterior 180-degree partial fundoplication at up to 10 years follow-up showed good outcomes for both procedures.

Methods: One hundred seven participants were randomized to Nissen versus anterior 180-degree partial fundoplication. Fifteen to 20 year follow-up data was available for 79 (41 Nissen, 38 anterior). Outcome was assessed using a standardized questionnaire with 0 to 10 analog scores and yes/no questions to determine reflux symptoms, side-effects, and satisfaction with surgery.

Results: After anterior fundoplication heartburn (mean score 3.2 vs 1.4, $P=.001$) and proton pump inhibitor use (41.7% vs 17.1%, $P=.023$) were higher, offset by less dysphagia for solids (mean score 1.8 vs 3.3, $P=.015$), and better ability to belch (84.2% vs 65.9%, $P=.030$). Measures of overall outcome were similar for both groups (mean satisfaction score 8.4 vs 8.0, $P=.444$; 86.8% vs 90.2% satisfied with outcome). Six participants underwent revision after anterior fundoplication (Nissen conversion for reflux – 6), and 7 underwent revision after Nissen fundoplication (Nissen to partial fundoplication for dysphagia – 5; redo Nissen for reflux – 1; paraesophageal hernia – 1).

Conclusions: At 15 to 20 years follow-up Nissen and anterior 180-degree partial fundoplication achieved similar success, but with trade-offs between better reflux control versus more side-effects after Nissen fundoplication.

Keywords: fundoplication, gastro-esophageal reflux disease, laparoscopy, randomized controlled trial

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Nissen fundoplication is well-established for the treatment of gastro-esophageal reflux disease. However, it often produces an over-competent lower esophageal sphincter, and this can result in troublesome side-effects such as dysphagia and gas-bloat.^{1,2} These side-effects can negatively impact quality of life, despite good reflux control. To construct a more physiological antireflux barrier, and reduce side effects, we have previously proposed an anterior

180-degree partial fundoplication as an alternative approach for patients undergoing surgery for gastro-esophageal reflux.³

We have reported earlier clinical and objective outcomes from both a large case series and a randomized trial, demonstrating that the anterior 180-degree partial fundoplication can achieve a good outcome for most patients undergoing surgery for reflux, and with less side effects compared to Nissen fundoplication.^{4,5} In a case series of 548 patients who underwent an anterior 180-degree fundoplication, the procedure was effective and durable at up to 10 years follow-up.⁵ Consistent with this, outcomes from our randomized trial of anterior 180-degree versus Nissen fundoplication demonstrated good early and late objective outcomes measured by pH monitoring and esophageal manometry.^{4,6} It also demonstrated good clinical outcomes at 6 months, 5 years, and 10 years follow-up.^{4,7,8} Compared to Nissen fundoplication, effective control of reflux and less side effects were seen at follow-up to 5 years. Similar outcomes were seen at 10 years, but with trends towards a trade-off between reflux control versus side effects. Four other randomized trials have also been conducted and reported shorter-term follow-up with similar outcomes; either similar reflux control and less side effects, or some trade-offs between reflux control versus side effects.^{9–12}

However, questions have remained about the efficacy of anterior 180-degree partial fundoplication at very late follow-up, and no studies have reported outcomes beyond 10 to 12 years after surgery. As the original randomized trial of Nissen vs anterior 180-degree partial fundoplication completed enrolment in 1997, we sought to determine the outcome for patients enrolled in this trial at 20 years follow-up. The aim of the current study was to determine whether an anterior 180-degree partial fundoplication could provide sustained control of reflux symptoms, with less side effects compared to Nissen fundoplication, at very late follow-up of up to 20 years (minimum 15 years) from this randomized trial.

METHODS

Earlier results at follow-up of 6 months, 5 years, and 10 years from this trial have been reported previously, and the full protocol for the trial was described in a report of early outcomes.⁴ Patients with objective evidence of gastro-esophageal reflux and presenting for laparoscopic antireflux surgery at the Royal Adelaide Hospital and associated private hospitals in Adelaide, South Australia from December 1995 to April 1997 were considered for inclusion in a trial comparing anterior 180-degree partial fundoplication with Nissen fundoplication. Patients were excluded if the planned procedure was a revision operation, if they required an additional abdominal procedure, or were deemed unsuitable for a Nissen fundoplication due to esophageal dysmotility. Patients were also excluded if they were unable to complete questionnaires due to known intellectual or cognitive impairments, or poor English language comprehension. Data collection for late follow-up was coordinated through the Department

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of Surgery at Flinders University in Adelaide, South Australia after relocation of the senior author.

Participants were randomized 1:1 in the operating room after surgery commenced to undergo either Nissen or anterior 180-degree partial fundoplication. Patients were initially blinded, with the exact procedure performed concealed from participants for the first 12 months of follow-up, and then only revealed to participants who asked for this information. Follow-up data was obtained by a research assistant who remained blinded to the operation type for the full duration of follow-up. Data analysis for the current paper was performed independently by one of the authors (V.R-S.) who was also blinded to group allocation during the data analysis phase, with unblinding occurring only when results were ready to be interpreted.

The operative techniques for laparoscopic anterior 180-degree partial and Nissen fundoplication have been described in detail previously.^{1,3,13} Both procedures involved hiatal dissection, mobilization of the esophagus, and preservation of the hepatic branch of the vagus nerve. Posterior hiatal repair with sutures was performed in all patients. Short gastric vessel division was not undertaken for either procedure. For the Nissen fundoplication a 1 to 2 cm long 360-degree fundoplication was fashioned loosely, with a 52Fr intra-esophageal bougie in situ, and secured with 3 sutures. For anterior 180-degree partial fundoplication the anterior fundus of the stomach was placed in front of the esophagus and then sutured to the right postero-lateral wall of the esophagus and right hiatal pillar using 3 sutures. Additional apical sutures were used to close the space anterior to the esophagus.

After surgery, participants were followed prospectively using a standardized clinical questionnaire which was applied yearly to 20 years after surgery. Participants were initially sent the questionnaire and a reply paid envelope by mail. If not returned within one month, a second questionnaire was sent by mail. If no response was obtained from two mail-outs, a phone call was made and the questionnaire was then either returned by mail or administered over the phone by an investigator who remained unaware of participant's group allocation. If a participant indicated that they were no longer willing to participate then no further follow-up was attempted and these individuals were recorded as "lost-to-follow-up" from that time point. For participants who died during follow-up, an attempt was made to ascertain the cause of death. The current study evaluated outcomes at follow-up to 20 years. Any patients who had not completed an annual follow-up questionnaire at 20 years were still included if they had completed a prospective clinical follow-up questionnaire at 15 or more years after surgery, with the most recent follow-up time point analyzed for the current study.

The clinical follow-up questionnaire consisted of standardized questions and analog symptom scores which have been previously described and used in other reported studies.^{4,14} These questions assessed the status of each patient at yearly time points. Patients taking antisecretory medication such as proton pump inhibitors (PPIs) were not asked to stop medications before completing the questionnaires. Heartburn, dysphagia for solids, and dysphagia for liquids were assessed using 0 to 10 analog scales (0 = no symptoms, 10 = severe symptoms). A 0 to 45 dysphagia score, which integrated swallowing for 9 graded substances, was also applied.¹⁴ Symptoms of bloating, ability to relieve bloating, ability to belch normally, and ability to eat a normal diet were assessed using "yes" and "no" questions. Satisfaction with the overall surgical outcome was assessed using a 0 to 10 analog scale (0 = dissatisfied; 10 = highly satisfied). Satisfaction with surgery was also assessed using a yes/no question where patients were asked if they still considered their original decision to undergo surgery to be correct. Objective investigations (esophageal manometry, 24-hr pH monitoring, upper gastrointestinal endoscopy) were not repeated for the current report,

although late objective outcomes at 14 years follow-up have been reported previously.⁶

The trial assessed 2 primary outcomes; postoperative heartburn control and dysphagia. Before commencing the trial, it was determined that 84 patients (42 per group) would be needed to demonstrate a 20% difference for either outcome at $P < 0.05$ and power of 90%. One hundred seven patients were recruited, allowing for up to 20% of patients to be lost to follow-up. Data analysis was performed on an intention-to-treat basis using statistical software (Prism version 6.04 for Mac; Graphpad Software, La Jolla, California, USA). All patients remained in their original allocated group, irrespective of the type of fundoplication performed, or any subsequent revision surgery. Fisher exact test was used to determine the significance of 2×2 contingency tables. A 2-tailed Mann-Whitney U test was used to assess differences between nonparametric continuous data sets.

The original protocol and earlier follow-up was approved by the Royal Adelaide Hospital Human Research Ethics Committee. Late follow-up for the current study was approved by the Southern Adelaide Clinical Human Research Ethics Committee.

RESULTS

One hundred eighty-four patients were considered for this trial, and 107 patients were enrolled; 54 were allocated to an anterior 180-degree partial fundoplication and 53 to Nissen fundoplication. As reported previously both groups were well matched before surgery for demographics, duration and severity of reflux symptoms, other baseline symptoms, and objective outcomes measured by endoscopy and manometry, and pH monitoring.⁴

Follow-up is summarized in Figure 1. Of the original 107 patients, 79 provided clinical follow-up outcomes at 15 to 20 years, 38 in the anterior 180-degree partial fundoplication group and 41 in the Nissen group. Median follow-up was 19 and 18 years for the anterior and Nissen fundoplication groups, respectively. Of the 28 patients who did not contribute a clinical outcome to the current analysis, 15 (14.0%) had died before 15 years follow-up. None of these deaths were related to the original fundoplication. Two further patients could not complete a questionnaire due to dementia, one was unable to complete a questionnaire due to a terminal illness, and one was unable to complete questionnaires after trauma. Nine (8.4%) patients were either lost to follow-up ($n = 4$), or withdrew from the trial ($n = 5$).

Thirteen (12.1%) of the 107 patients in the trial underwent revision surgery during follow-up from 1 month to 20 years after surgery. Ten (9.3%) had undergone revision within the first 10 years, and 3 (2.8%) underwent revision between 10 and 20 years after surgery. Of the reoperations performed beyond 10 years follow-up, 1 entailed conversion of an anterior 180-degree partial fundoplication to Nissen fundoplication at 15 years for recurrent reflux. Two reoperations involved conversion of a Nissen fundoplication to an anterior 180-degree partial fundoplication at 11 and 14 years for persistent dysphagia. Both of these procedures also entailed re-dissection of the esophageal hiatus to ensure it was loose around the esophagus with a 52 Fr intraluminal bougie. Of the reoperations performed from 1 month to 20 years, a total of 6 (11.3%) participants in the anterior 180-degree fundoplication group underwent revision surgery entailing conversion to a Nissen fundoplication for recurrent reflux in all instances. In 4 of these reflux was well controlled at late follow-up with 1 reporting persistent mild dysphagia, whereas the other 2 developed recurrent reflux 7 and 10 years after revision and required PPIs to achieve symptom control – one of these patients also reported persistent mild dysphagia at late follow-up.

Seven (13.0%) participants in the Nissen fundoplication group underwent revision surgery beyond 1 month, including conversion to

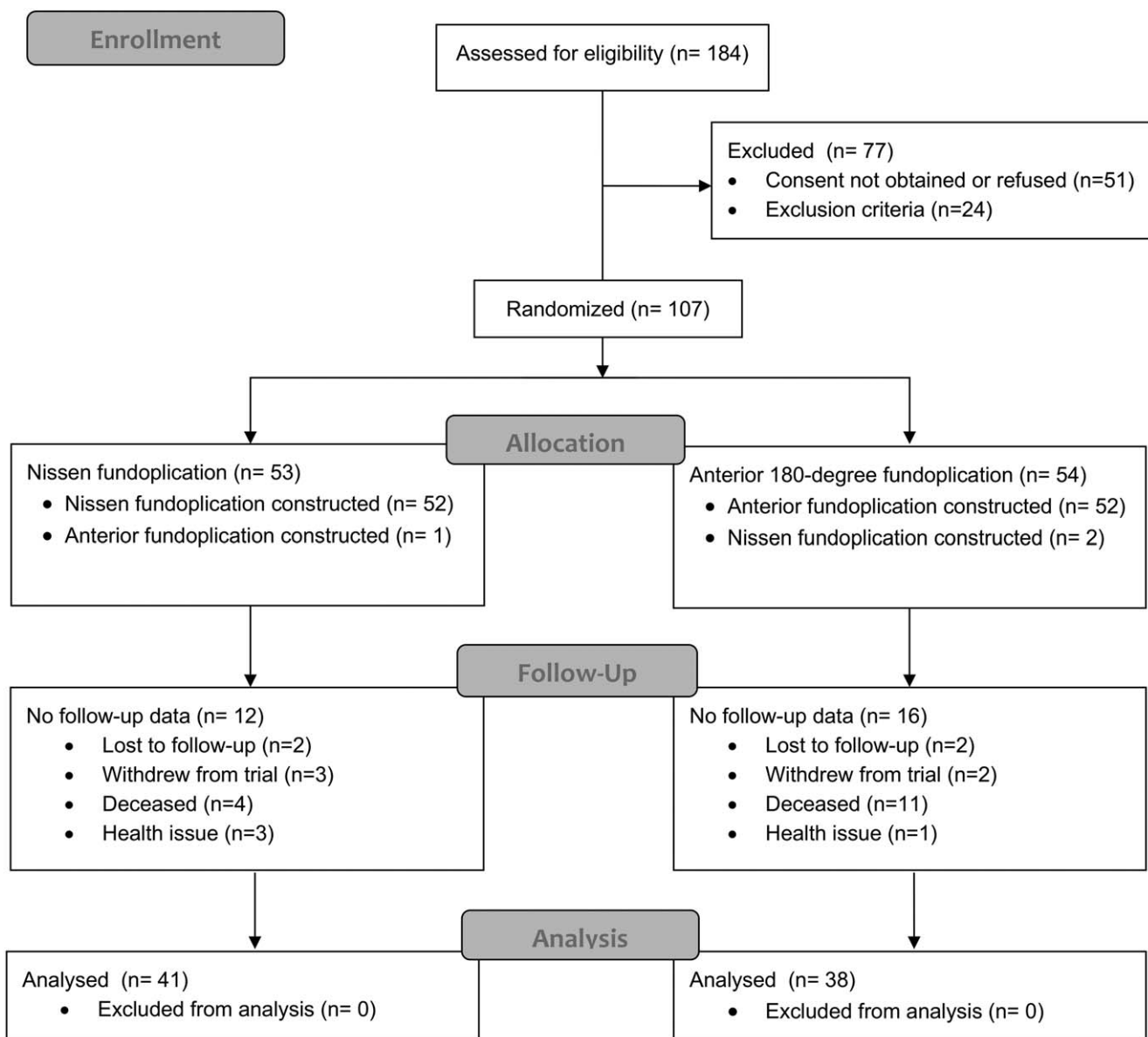


FIGURE 1. Consort diagram for randomised trial.

a partial fundoplication for dysphagia for 5 participants, a revision Nissen fundoplication for recurrent reflux for 1 participant, and repair of a paraesophageal hiatus hernia for 1 participant. Of the 5 undergoing revision to a partial fundoplication, three reported good late reflux symptom control, and 2 developed recurrent reflux symptoms at 3 and 11 years follow-up, with symptoms in both well-controlled by PPIs at late follow-up.

Clinical outcomes at 15 to 20 years follow-up are summarized in Tables 1 and 2. Heartburn scores were significantly higher at very late follow-up after anterior 180-degree partial fundoplication, whereas dysphagia scores for solid food were significantly lower. Belching was better preserved after anterior 180-degree partial fundoplication (84.2% vs 65.9%), bloating symptoms and dietary choices were similar for the 2 procedures, and PPI use was higher after anterior 180-degree partial fundoplication.

Most participants in both groups rated their overall satisfaction with their procedure highly, indicated that they were satisfied with their overall outcome at 15 to 20 years and considered their decision to undergo surgery to be correct (Table 3). Analog overall satisfaction scores were similar and high for both procedures. There were no statistically significant differences between the groups for these outcomes.

DISCUSSION

At 15 to 20 (median 18–19) years follow-up, the current study reports the longest follow-up for a randomized controlled trial of anterior partial versus Nissen fundoplication, and the longest follow-up for patients after an anterior partial fundoplication procedure. Participants in both groups rated their overall outcome after surgery highly, indicating that both Nissen and anterior 180-degree partial fundoplication can achieve good long-term outcomes.

TABLE 1. Zero to 10 Analog Scores for Heartburn, Dysphagia for Liquids, and Dysphagia for Solids

	Preoperative			15–20 yrs Postoperative		
	Nissen Fundoplication (n = 53)	Anterior 180-degree Partial Fundoplication (n = 54)	P-value	Nissen Fundoplication (n = 41)	Anterior 180-degree Partial Fundoplication (n = 38)	P-value
Heartburn score						
Mean Score	4.1 [3.1–5.0]	4.3 [3.4–5.1]	0.69	1.4 [0.7–2.1]	3.2 [2.3–4.2]	0.0010
Score = 0	5 (9.4%)	6 (11.1%)		22 (53.7%)	8 (21.1%)	
Score = 1–3	20 (37.7%)	17 (31.5%)		9 (22.0%)	13 (34.2%)	
Score = 4–6	9 (17.0%)	16 (29.6%)		7 (12.1%)	9 (23.7%)	
Score = 7–10	20 (37.7%)	15 (27.8%)		1 (2.4%)	6 (15.8%)	
Dysphagia score for liquids						
Mean Score	0.7 [0.2–1.1]	0.5 [0.1–0.9]	0.84	1.5 [0.8–2.2]	1.0 [0.3–1.7]	0.13
Score = 0	43 (81.1%)	47 (87.0%)		21 (51.2%)	25 (65.8%)	
Score = 1–3	4 (7.5%)	5 (9.3%)		13 (31.7%)	10 (26.3%)	
Score = 4–6	4 (7.5%)	2 (3.7%)		5 (12.2%)	0 (0%)	
Score = 7–10	2 (3.8%)	2 (3.7%)		2 (4.9%)	2 (5.3%)	
Dysphagia score for solids						
Mean Score	1.4 [0.7–2.1]	1.5 [0.8–2.5]	0.88	3.3 [2.3–4.2]	1.8 [1.0–2.7]	0.015
Score = 0	34 (64.2%)	37 (68.5%)		9 (22.0%)	16 (42.1%)	
Score = 1–3	8 (15.1%)	3 (5.6%)		15 (36.6%)	15 (39.5%)	
Score = 4–6	6 (11.3%)	12 (22.2%)		9 (22.0%)	2 (5.3%)	
Score = 7–10	5 (9.4%)	2 (3.7%)		5 (12.2%)	3 (7.9%)	

Mann–Whitney U test was used to determine statistical significance. Values in square brackets are 95% confidence intervals.

Earlier reports from this trial demonstrated similar reflux symptom control, but less side effects after anterior 180-degree partial fundoplication at 6 months⁴ and 5 years follow-up.⁷ High levels of satisfaction were reported by patients after both procedures at earlier follow-up. At 10 years follow-up, however, the earlier advantages of less side effects after anterior 180-degree partial fundoplication had largely disappeared, with patients reporting similar heartburn control, similar rates of side effects, and similar overall satisfaction after both types of fundoplication.⁸ These 10-year outcomes were similar to the late follow-up outcomes reported by Mardani et al from a trial of Nissen vs posterior partial fundoplication, which also reported that the advantage of less side effects at earlier follow-up after posterior partial fundoplication had largely disappeared as follow-up progressed to 20 years.¹⁵

Our current analysis assessed very late outcomes, and documents a shift in these outcomes, suggesting that the previously reported 10-year follow-up outcomes might have been an outlier.⁸ Anterior 180-degree partial fundoplication was associated with higher heartburn symptom scores and a higher rate of PPI consumption at 15 to 20 years follow-up, suggesting less effective overall

reflux control. However, this disadvantage seems to have been offset by significantly less dysphagia side effects, and better preservation of belching ability after anterior 180-degree partial fundoplication. Importantly, measures of overall outcome were similar for both procedures, confirming the trade-off between heartburn control versus side effects, with the balance of the trade-offs largely equal at follow-up to 20 years. Consistent with these symptom outcomes was the similar overall rates of surgical revision after each procedure, but with different reasons for requiring reoperation. Revision after Nissen fundoplication was predominantly for dysphagia, and revision of an anterior 180-degree partial fundoplication was for recurrent reflux.

Seven other randomized trials of anterior partial versus Nissen fundoplication have also been reported.^{9–12,16–18} Four of these specifically investigated an anterior 180-degree partial fundoplication.^{9–12} In general, those trials replicated outcomes we have previously reported. Cao et al reported 5-year follow-up for a trial enrolling 100 patients, and found good reflux control with less side effects at 5-years follow-up after an anterior 180-degree partial fundoplication.¹⁰ Roks et al reported 12-year follow-up for 90

TABLE 2. Outcome of Yes/No Questions at 15 to 20 Years Follow-up

	Preoperative			15–20 years postoperative		
	Nissen Fundoplication (n = 53)	Anterior 180-degree Partial Fundoplication (n = 54)	P-value	Nissen Fundoplication (n = 41)	Anterior 180-degree Partial Fundoplication (n = 38)	P-value
Able to eat a normal diet	36 (67.9%)	34 (63.0%)	0.67	39 (95.1%)	34 (89.5%)	0.42
Side effects						
Abdominal bloating	26 (49.1%)	28 (51.9%)	0.85	25 (61.0%)	18 (47.4%)	0.25
Unable to relieve bloating	10 (18.9%)	11 (20.4%)	>0.9999	14 (34.1%)	15 (39.5%)	>0.9999
Unable to belch normally	0 (0%)	0 (0%)	>0.9999	14 (34.1%)	6 (15.8%)	0.030
Medication use						
Using a proton pump inhibitor				7 (17.1)	15 (41.7)	0.023
Using other medication for “heartburn”				2 (4.9)	2 (5.3)	>0.9999

Fishers exact test was used to test for statistical significance.

TABLE 3. Overall Satisfaction With the Surgical Outcome at 15 to 20 Years Follow-up

	Nissen Fundoplication (n = 41)	Anterior 180-degree Partial Fundoplication (n = 38)	P-value
Analogue satisfaction score (Mean [95% confidence intervals])	8.0 [7.1–8.7]	8.4 [7.8–9.1]	0.4442*
Satisfied with outcome (yes/no question)	37 (90.2%)	33 (86.8%)	>0.9999†
Would choose surgery again (yes/no question)	35 (85.4%)	36 (94.7%)	0.2022†

*Mann–Whitney *U* test.

†Fishers exact test.

patients from a trial that originally enrolled 163 patients, and demonstrated similar outcomes for dysphagia, reflux symptom control and overall satisfaction after both fundoplication procedures, but with more patients consuming acid suppressing medication after partial fundoplication.¹⁹

More recently, the senior authors of the current paper reported 10-year outcomes from 2 trials of anterior 90-degree partial versus Nissen fundoplication.²⁰ In this study, the data sets were combined to yield a combined study of 191 patients. The outcomes were very similar to those seen in the current report, with similar overall satisfaction in the late outcome, and a balanced trade-off between reflux symptom control and side effects.

Randomized trials have also compared Nissen versus posterior partial fundoplication.^{15,21} Similar control of reflux symptoms has been demonstrated in most of these trials, although a reduction in side effects, in particular dysphagia, after posterior partial fundoplication was only demonstrated in a minority of the trials.^{15,22} Only the trial by Mardani et al has reported very long-term outcomes, with similar reflux control and side effects following both procedures after 2 decades of follow-up.¹⁵ When the evidence from all trials are considered together, it seems likely that antireflux procedures spread across a spectrum from anterior partial, to posterior partial and Nissen fundoplication, with shifting trade-offs between reflux control and side effects across this spectrum. Recently reported network meta-analyses confirm this view.^{23,24} Recognizing this spectrum and these trade-offs offer surgeons an opportunity to tailor the type of fundoplication constructed to a patient's esophageal physiology, expectations, and preferences from the perspective of minimizing side effects versus maximizing reflux symptom control.

The apparently high rates of PPI consumption at 15 to 20 years, with 41.7% and 17.1% of each group using these medications, do suggest a significant failure rate after surgery. The difference between these 2 rates also supports the contention that anterior 180-degree partial fundoplication delivered less effective reflux control than Nissen fundoplication. However, previous studies evaluating medication usage after fundoplication have shown that the majority of patients consuming PPIs after fundoplication do not actually have recurrent gastro-esophageal reflux.^{25,26} In an earlier study of 844 patients who were followed for mean 5.9 years after fundoplication, we identified medication usage in 37% of patients, but with only 31% of these patients (ie, 11.5% of the overall group) using medication for recurrent reflux symptoms, and only 26% (9.6% overall) of those investigated with pH monitoring demonstrating abnormal esophageal acid exposure.²⁵ In the current trial, however, the difference in PPI consumption between the 2 fundoplication types supports the contention of differences in reflux control.

However, the advantage of better reflux symptom control after Nissen fundoplication was offset by significantly more side effects, and the measures of overall outcome were similar for the 2 procedures, confirming trade-offs between these competing outcomes. We contend that a good outcome after fundoplication, and indeed any surgical procedure, should be success from the patient's

perspective. After antireflux surgery, several factors contribute to each patient's perspective of the outcome, and it is likely patients balance cure of the original symptoms versus side effects. Hence, it is possible that a patient who had poorly controlled reflux symptoms before surgery, an initially good surgical outcome, and then at late follow developed recurrent symptoms which could be fully controlled by PPIs, might still consider the original fundoplication to be a success. On the other hand, a patient with good reflux control after surgery, but also troublesome side effects, might consider that outcome to be unacceptable. These perspectives are best captured by global outcome measures, and are consistent with the data reported.

Strengths of our current study include the very long-term follow-up obtained, and the high rate of compliance with standardized clinical follow-up, with less than 10% of patients withdrawing or lost to follow-up at 15 to 20 years. A potential criticism of our study is that the Nissen fundoplication technique did not include division of the short gastric blood vessels and this might have contributed to dysphagia after Nissen fundoplication. However, this proposition is not supported by the randomized trials of Nissen fundoplication with versus without division of short gastric blood vessels which have all shown that dysphagia is not reduced by dividing these vessels.^{27,28} A further potential weakness is that the follow-up reported in this paper was clinical, and objective outcome measures were not sought at 15 to 20 years. We have previously tried to deal with this, but had difficulty achieving significant rates of compliance with what are perceived to be uncomfortable and invasive investigations in otherwise asymptomatic patients, and were only able to obtain consent for further esophageal manometry and pH monitoring at 14 years follow-up from 18 of the original 107 patients in our trial.⁶ Nonetheless, from the perspective of informing clinical practice and surgical decision making we consider it more likely that clinical symptom outcomes and overall satisfaction with surgical outcome measures from a large majority of the trial cohort is more informative than objective outcome measures from a significantly smaller subset of the original cohort.

In conclusion, the very late results from the current trial demonstrate good clinical outcomes after both Nissen and anterior 180-degree partial fundoplication, with approximately 90% of patients reporting a good overall outcome at follow-up of up to 20 years. A balance between reflux symptom control and side effects was seen, with less side effects after anterior 180-degree partial fundoplication, and better reflux symptom control after Nissen fundoplication. These outcomes can be used to inform patients considering surgery for gastro-esophageal reflux disease and guide decisions about what type of fundoplication to construct. Reassuringly, both types of fundoplication achieved high rates of success, confirming the long term efficacy of antireflux surgery.

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