

# Impact of Surgeon Experience on 5-Year Outcome of Laparoscopic Nissen Fundoplication

Joris A. J. L. Broeders, MD; Werner A. Draaisma, MD, PhD; Hilda G. Rijnhart-de Jong, MSc; André J. P. M. Smout, MD, PhD; Jan J. B. van Lanschot, MD, PhD; Ivo A. M. J. Broeders, MD, PhD; Hein G. Gooszen, MD, PhD

**Objective:** To investigate the 5-year effect of surgeon experience with laparoscopic Nissen fundoplication (LNF). In 2000, a randomized controlled trial (RCT) was prematurely terminated because LNF for gastroesophageal reflux disease was associated with a higher risk to develop dysphagia than conventional Nissen fundoplication (CNF). Criticism focused on alleged bias caused by the relative lack of experience with the laparoscopic approach of the participating surgeons.

**Design:** Multicenter RCT and prospective cohort study.

**Setting:** University medical centers and tertiary teaching hospitals.

**Patients:** In the RCT, 74 patients underwent CNF and 93 patients underwent LNF (LNFI). The complete setup of the cohort study (LNFII) (n=121) mirrored the RCT, except that surgeon experience increased from more than 5 to more than 30 LNFs per surgeon.

**Interventions:** Conventional Nissen fundoplication, LNFI, and LNFII.

**Main Outcome Measures:** Intraoperative and in-hospital characteristics, objective reflux control, and clinical outcome.

**Results:** In LNFII, operating time (110 vs 165 minutes;  $P < .001$ ), dysphagia (2.5% vs 12.3%;  $P = .008$ ), dilatations for dysphagia (0.8% vs 7.0%;  $P = .02$ ), and conversions (3.5% vs 7.7%;  $P = .19$ ) were reduced compared with LNFI. Moreover, in LNFII, hospitalization (4.2 vs 5.6 days;  $P = .07$  and 4.2 vs 7.6 days;  $P < .001$ ) and in-hospital complications (5.1% vs 13.5%;  $P = .046$  and 5.1% vs 19.3%;  $P = .005$ ) were reduced compared with LNFI and CNF, respectively. In LNFII, the 6-month reintervention rate was reduced compared with LNFI (0.8% vs 10.1%;  $P = .002$ ). Esophagitis and esophageal acid exposure at 3 months and reflux symptoms, proton-pump inhibitor use, and quality of life at 5 years improved similarly.

**Conclusions:** Operating time, complications, hospitalization, early dysphagia, dilatations for dysphagia, and reintervention rate after LNF improve significantly when surgeon experience increases from more than 5 to more than 30 LNFs. In contrast, short-term objective reflux control and 5-year clinical outcome do not improve with experience. In experienced hands, LNF reduces in-hospital complications and hospitalization compared with CNF, with similar 5-year effectiveness and reoperation rate.

*Arch Surg.* 2011;146(3):340-346

## Author Affiliations:

Department of Surgery, Gastrointestinal Research Unit, University Medical Center Utrecht, Utrecht (Drs J. A. J. L. Broeders, Draaisma, and Gooszen and Ms Rijnhart-de Jong), Department of Gastroenterology and Hepatology, Academic Medical Centre, Amsterdam (Dr Smout), Department of Surgery, Erasmus Medical Center, Rotterdam (Dr van Lanschot), and Department of Surgery, Meander Medical Center, Amersfoort (Dr I. A. M. J. Broeders), the Netherlands.

**L**APAROSCOPIC NISSEN FUNDOPPLICATION (LNF) rapidly replaced conventional Nissen fundoplication (CNF) as surgical therapy for gastroesophageal reflux disease (GERD) after its first report in 1991.<sup>1</sup> As with the introduction of laparoscopic cholecystectomy, evidence from randomized studies that proved

## See Invited Critique at end of article

equivalence of the new approach was lacking at that time. Therefore, in 1997, a multicenter randomized clinical trial (RCT) was initiated in the Netherlands to compare the effectiveness of LNF (LNFI) with CNF. Interim analysis demonstrated that LNF carries a substantially higher risk to develop dysphagia needing dilatation or reopera-

tion (LNFI, 7 vs CNF, 0;  $P = .02$ ) than its open counterpart, and consequently, the trial was prematurely terminated.<sup>2</sup> The harsh criticism in response to the publication of these results<sup>3-8</sup> focused on alleged bias caused by the relative lack of experience with the laparoscopic approach of the participating surgeons.

We responded by initiating a second cohort study on LNF only (LNFII) to investigate the effect of experience on long-term outcome. In the cohort study, the complete setup was the same as in the RCT, except that surgeon experience had grown from a minimum of 5 LNFs<sup>9</sup> to more than 30 LNFs per surgeon in accordance with new insights.<sup>10-13</sup> Participating surgeons, indications for surgery, techniques, and patient management were identical to those in the RCT. As a result, the effect of surgical skill was the only new variable in this

second study. The Achilles' heel of studies that have so far evaluated the effect of surgeon experience on the outcome of LNF is that surgical techniques have been changed during the course of the study.<sup>9,14-17</sup> These studies are biased because improvement of surgical technique, as well as increased experience, accounts for the better outcome in the latter patients. The purpose of this prospective study was thus to determine the isolated effect of surgeon experience on intraoperative and in-hospital characteristics, short-term objective reflux control, and 5-year outcome of LNF. These results were compared with the outcome after the initial LNF experience and CNF.

## METHODS

### STUDY DESIGN AND PARTICIPANTS

From 1997 to 1999, 177 patients were included in a multicenter RCT to undergo Nissen fundoplication for refractory GERD. Surgical treatment was proposed to patients with heartburn and regurgitation insufficiently responding to at least 40 mg of omeprazole daily. If 40 mg of omeprazole was insufficient to suppress symptoms, the dosage was raised to 40 mg 2 or 3 times daily. If symptoms recurred after return to 40 mg daily, patients were classified as having proton pump inhibitor-refractory GERD. At the time of the interim analysis, 46 patients underwent CNF and 57 patients, LNF. Four patients were never operated on; 6 patients withdrew; and, in the period needed for conducting and discussing the interim analysis, another 64 patients were randomized. Consequently, 74 patients underwent CNF and 93 patients underwent laparoscopic 360° fundoplication (LNF I). All participating surgeons had completed the learning curve of more than 5 LNFs for experienced laparoscopic surgeons and more than 20 for less experienced laparoscopic surgeons, defined by Watson et al.<sup>9</sup> The short-<sup>2</sup> and long-term<sup>18</sup> results of the RCT have been published previously. The operations of the second cohort study were performed by surgeons who participated in the initial RCT, after extension of the learning curve to a minimum of 30 LNFs in accordance with new insights.<sup>10-13</sup> The surgical techniques in the RCT included standardized mobilization of the esophagus over 5 to 7 cm in length, division of the short gastric vessels, posterior crural repair, and creation of a floppy 360° fundoplication of 3 to 3.5 cm and were identical for the cohort study. The cranial fundoplication suture was also stitched to the diaphragm and the caudal suture was fixed to the esophagus at the level of the lower esophageal sphincter ("3-point fixation"). A total of 121 patients were included in the cohort study (LNF II).

Surgical techniques, operating time, blood loss, conversions, splenectomy rate, in-hospital complications, and hospitalization were registered on case record forms. All patients were asked to fill out a questionnaire on quality of life, GERD symptoms, and use of acid-suppressing drugs before surgery and at 3 months and 5 years after surgery. In addition, all patients were asked to rate the change in their reflux symptoms (Visick score) and general health status compared with the preoperative state. At 5 years, patients were asked whether they would choose surgery again in retrospect. Surgical reinterventions, indications for reintervention, and surgical procedures performed were recorded up to 5 years after initial surgery. For objective evaluation, all patients were asked to undergo upper endoscopy and 24-hour pH monitoring both before and at 3 months after surgery. These data and subjective outcome data were collected prospectively in consecutive patients.

## CLINICAL OUTCOME

The Visick score, the only "overall score" available and validated, correlates well with the most prominent symptom of GERD (heartburn)<sup>19</sup> and with a validated questionnaire<sup>20</sup> for reflux symptoms<sup>21</sup> and was used in this study to score the effect of surgery on symptoms in 4 grades: complete resolution (grade I), improvement (grade II), no effect of surgery (grade III), or deterioration (grade IV), always in comparison with their preoperative state. In addition, the frequency of heartburn, regurgitation, and dysphagia were scored from 0 to 5. The severity of these symptoms was scored from 0 to 3. For the final assessment of these symptoms, a combined frequency and severity grading system was used resulting in a grade from 0 (symptom absent) to 3 (symptom frequent and severe).<sup>22</sup> The impact on quality of life was measured using a visual analog scale validated for quality of life assessment after esophageal surgery.<sup>23</sup> The scale of this instrument ranged from worst possible health to perfect health (0-100).<sup>24</sup>

### UPPER GASTROINTESTINAL TRACT ENDOSCOPY

Experienced gastroenterologists evaluated the presence of esophagitis and hiatal hernia size during endoscopy. Initially, the Savary-Miller classification<sup>25</sup> was used to grade esophagitis, and later, the Los Angeles classification<sup>26</sup> for esophagitis was applied.

### 24-HOUR ESOPHAGEAL pH MONITORING

Ambulatory 24-hour pH monitoring was performed according to previously described methods,<sup>27</sup> after suspending medication that could affect the results at least 7 days beforehand.

### STATISTICAL ANALYSIS

For parameters that were scored before and after surgery, only those patients were included for whom both the preoperative data and the results at 3 months or 5 years after surgery were available. The number of patients for whom data were available was determined for each parameter. Continuous variables were expressed as mean and standard error of the mean and were analyzed for differences between the 3 groups using a 1-way analysis of variance and Bonferroni post hoc test. To determine significant effects of surgery on quantitative data, the paired-samples *t* test was used. The  $\chi^2$  test was used to compare nominal variables between groups, and effects of surgery on these variables were analyzed using the McNemar-Bowker test. Differences were considered statistically significant at a *P* value less than .05. Statistical analysis was performed using SPSS version 15.0 (SPSS, Chicago, Illinois).

## RESULTS

### PATIENT POPULATION

The study population comprised 288 patients (74 CNF, 93 LNF I, and 121 LNF II). Patient characteristics and mean hiatal hernia size were similar at baseline (**Table 1**).

### PROCEDURAL CHARACTERISTICS

All but 3 surgical procedures included mobilization of the fundus with division of the short gastric vessels. Mean length of the fundoplication and the percentage of patients with crural repair and 3-point fixation of the fun-

**Table 1. Patient Characteristics**

|                      | Mean (SEM)   |              |              |
|----------------------|--------------|--------------|--------------|
|                      | CNF          | LNFI         | LNFI         |
| No. of patients      | 74           | 93           | 121          |
| Age, y, mean (range) | 42.6 (20-77) | 42.5 (17-85) | 41.0 (16-64) |
| Male/female          | 49/25        | 42/51        | 78/43        |
| BMI                  | 26.7 (0.4)   | 26.1 (0.5)   | 26.1 (0.5)   |
| Hiatal hernia, cm    | 2.8 (0.3)    | 3.4 (0.4)    | 3.0 (0.3)    |

Abbreviations: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared); CNF, conventional Nissen fundoplication; LNFI, laparoscopic Nissen fundoplication in the 2000 randomized controlled trial; LNFI, laparoscopic Nissen fundoplication in the cohort study.

**Table 2. Surgical Techniques of CNF, LNFI, and LNFI**

|  | No./Total No. (%)  |                    |                     |
|--|--------------------|--------------------|---------------------|
|  | CNF                | LNFI               | LNFI                |
| Mobilization of the fundus and division of the short gastric vessels | 67/68 (98.5)       | 89/91 (97.8)       | 113/113 (100)       |
| Crural repair  | 51/64 (79.7)       | 67/89 (75.3)       | 111/111 (100)       |
| 3-Point fixation fundoplication                                      | 60/66 (90.9)       | 72/90 (80.0)       | 112/112 (100)       |
| Fundoplication length, cm, mean (SEM)                                | 3.4 (0.1) (n = 52) | 3.4 (0.1) (n = 52) | 3.1 (0.1) (n = 105) |

Abbreviations: CNF, conventional Nissen fundoplication; LNFI, laparoscopic Nissen fundoplication in the 2000 randomized controlled trial; LNFI, laparoscopic Nissen fundoplication in the cohort study.

doplication were similar in CNF, LNFI, and CNFII (**Table 2**). In the second LNF cohort, skin-to-skin time was reduced compared with the first LNF group (mean [SEM], 110 [3.7] vs 165 [5.3] minutes;  $P < .001$ ) and approached the operating time of the open procedure (mean [SEM], 98 [4.3] minutes;  $P = .22$ ). Blood loss was reduced in the LNFI and LNFI groups compared with the CNF group (mean [SEM], 92 [19] vs 207 [41] mL;  $P = .04$  and 107 [29] vs 207 [41] mL;  $P = .07$ ). There were no differences in splenectomy rate between LNFI and LNFI (0.8% vs 1.8%;  $P = .58$ ). In LNFI, the conversion rate was substantially reduced compared with LNFI, but this difference did not reach statistical significance (3.5% vs 7.7%;  $P = .19$ ). There was a nonsignificant trend toward a lower splenectomy rate in the LNF II cohort compared with the CNF cohort as well (0.8% vs 4.3%;  $P = .13$ ) (**Table 3**).

#### HOSPITAL STAY AND IN-HOSPITAL COMPLICATIONS

Mean (SEM) hospital stay was reduced from 7.6 (0.7) days after CNF to 5.6 (0.4) days after LNFI ( $P = .009$ ). Hospitalization decreased even more after LNFI to mean (SEM) 4.2 (0.4) days, both compared with CNF ( $P < .001$ ) and LNFI ( $P = .07$ ). In-hospital complications were significantly lower after LNFI, compared with CNF (5.1% vs 19.3%;  $P = .005$ ) and LNFI (5.1% vs 13.5%;  $P = .046$ ) (**Table 4**).

#### CLINICAL OUTCOME 3 MONTHS AFTER SURGERY

The prevalence of dysphagia was higher after LNFI, compared with both CNF (12.3% vs 0%;  $P = .01$ ) and LNFI (12.3% vs 2.5%;  $P = .008$ ). Compared with CNF and

LNFI, the percentage of patients who underwent dilatation for dysphagia was higher after LNFI as well (0% vs 7.0%;  $P = .07$  and 0.8% vs 7.0%;  $P = .02$ ) (Table 4). Quality of life and the percentage of patients using acid-suppressing drugs improved significantly at 3 months compared with preoperatively, with no differences between the groups (**Figure 1** and **Figure 2**).

#### OBJECTIVE OUTCOME 3 MONTHS AFTER SURGERY

The effectiveness of surgery in terms of controlling esophagitis and the esophageal acid exposure was high (all  $P < .001$  vs preoperatively), without divergences in any of the 3 groups before or after surgery (**Figure 3** and **Figure 4**).

#### CLINICAL OUTCOME 5 YEARS AFTER SURGERY

The self-rated effect of surgery on reflux symptoms was similar in the 3 groups. At 5 years, the 3 groups had similar heartburn, regurgitation, and dysphagia grades. The self-rated change in general health and the percentage of patients who would choose surgery again in retrospect was similar as well (**Table 5**). Quality of life and the percentage of patients using acid-suppressing drugs remained significantly improved at 5 years compared with the preoperative values, without significant differences between the 3 groups (Figure 1 and Figure 2). However, the use of acid-suppressing drugs increased with time in the 3 groups.

#### SURGICAL REINTERVENTION

After LNFI, the high early reoperation rate that was observed in LNFI was no longer shown (**Figure 5**). At

**Table 3. Procedural Characteristics**

|                                 | No./Total No. (%) |                                 |                                  |
|---------------------------------|-------------------|---------------------------------|----------------------------------|
|                                 | CNF               | LNFI                            | LNFI                             |
| Operating time, min, mean (SEM) | 98 (4.3) (n = 62) | 165 (5.3) <sup>a</sup> (n = 81) | 110 (3.7) <sup>b</sup> (n = 109) |
| Blood loss, mL, mean (SEM)      | 207 (41) (n = 62) | 92 (19) <sup>a</sup> (n = 81)   | 107 (29) <sup>c</sup> (n = 101)  |
| Conversion rate                 |                   | 7/91 (7.7)                      | 4/113 (3.5)                      |
| Splenectomy                     | 2/46 (4.3)        | 1/57 (1.8)                      | 1/121 (0.8)                      |

Abbreviations: CNF, conventional Nissen fundoplication; LNFI, laparoscopic Nissen fundoplication in the 2000 randomized controlled trial; LNFI, laparoscopic Nissen fundoplication in the cohort study.

<sup>a</sup>  $P < .05$  vs CNF.

<sup>b</sup>  $P < .05$  vs LNFI.

<sup>c</sup>  $P = .06$  vs CNF.

**Table 4. Hospital Stay, In-Hospital Complications, and (Dilatations for) Dysphagia 3 Months After CNF, LNFI, and LNFI**

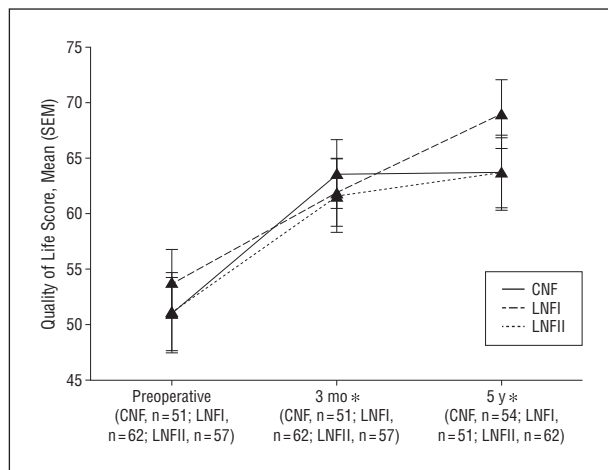
|                              | No./Total No. (%)  |                                 |                                    |
|------------------------------|--------------------|---------------------------------|------------------------------------|
|                              | CNF                | LNFI                            | LNFI                               |
| Hospital stay, d, mean (SEM) | 7.6 (0.7) (n = 59) | 5.6 (0.4) <sup>a</sup> (n = 89) | 4.2 (0.4) <sup>a,b</sup> (n = 102) |
| In-hospital complications    | 11/57 (19.3)       | 12/89 (13.5)                    | 5/98 (5.1) <sup>a,d,c</sup>        |
| Ileus                        | 2                  |                                 |                                    |
| Pneumothorax                 | 1                  | 3                               |                                    |
| Wound infection              | 2                  | 1                               | 1                                  |
| Wound abscess                | 2                  | 1                               |                                    |
| Subphrenic abscess           | 1                  | 1                               | 1                                  |
| Intrathoracic herniation     | 1                  | 1                               |                                    |
| Pleural effusion             |                    | 2                               |                                    |
| Other complications          | 2                  | 3                               | 3                                  |
| Dysphagia                    | 0/46 (0)           | 7/57 (12.3) <sup>a</sup>        | 3/121 (2.5) <sup>b</sup>           |
| Dilatations for dysphagia    | 0/46 (0)           | 4/57 (7.0)                      | 1/121 (0.8) <sup>b</sup>           |

Abbreviations: CNF, conventional Nissen fundoplication; LNFI, laparoscopic Nissen fundoplication in the 2000 randomized controlled trial; LNFI, laparoscopic Nissen fundoplication in the cohort study.

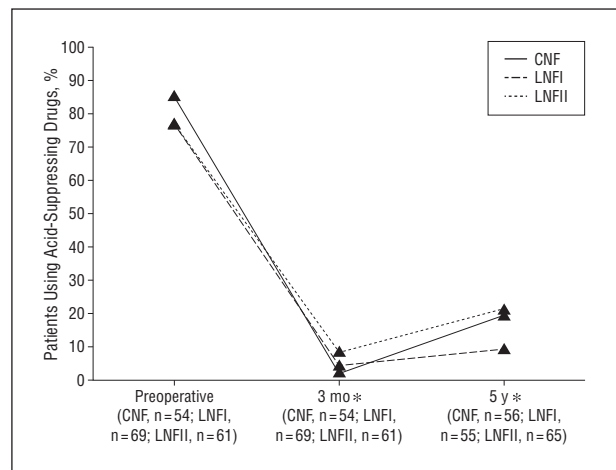
<sup>a</sup>  $P < .05$  vs CNF.

<sup>b</sup>  $P = .07$  vs LNFI.

<sup>c</sup>  $P < .05$  vs LNFI.



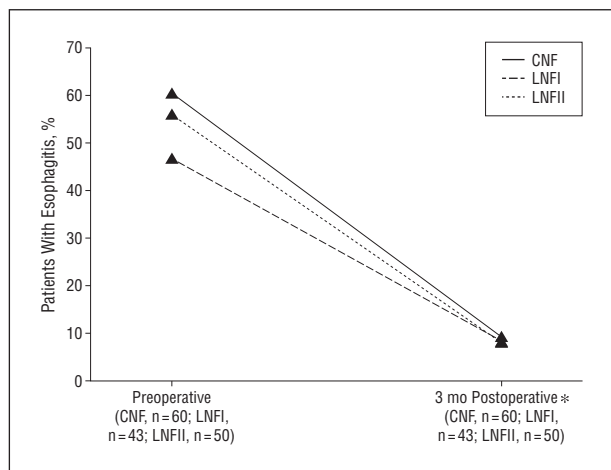
**Figure 1.** Quality of life (visual analog scale) before surgery and 3 months and 5 years after conventional Nissen fundoplication (CNF) and laparoscopic Nissen fundoplication in the 2000 randomized controlled trial (LNFI) and the cohort study (LNFI). \* $P < .05$  vs preoperative results for the 3 groups.



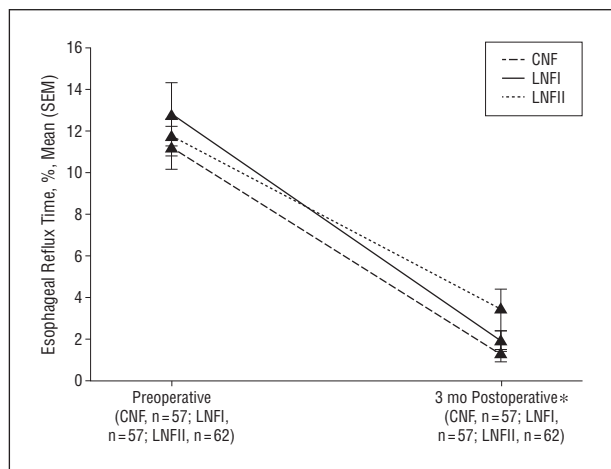
**Figure 2.** Percentage of patients using acid-suppressing drugs before surgery and 5 years after conventional Nissen fundoplication (CNF) and laparoscopic Nissen fundoplication in the 2000 randomized controlled trial (LNFI) and the cohort study (LNFI). \* $P < .001$  vs preoperative results for the 3 groups.

6 months, the reintervention rate was significantly higher after LNFI (10.1%), compared with CNF (1.4%;  $P = .03$ ) and LNFI (0.8%;  $P = .002$ ). In the LNFI group, most patients underwent reoperation for persistent dysphagia.

The percentage of patients free from reintervention stabilized after 12 months in the LNFI group, while in the CNF and LNFI groups, this took 2.5 years. As a result, the difference in reintervention rate after LNFI (15.2%)



**Figure 3.** Percentage of patients with esophagitis before surgery and 3 months after conventional Nissen fundoplication (CNF) and laparoscopic Nissen fundoplication in the 2000 randomized controlled trial (LNFI) and the cohort study (LNFI). \* $P < .05$  vs preoperative results for the 3 groups.



**Figure 4.** Total esophageal acid exposure time before surgery and 3 months after conventional Nissen fundoplication (CNF) and laparoscopic Nissen fundoplication in the 2000 randomized controlled trial (LNFI) and the cohort study (LNFI). \* $P < .001$  vs preoperative results for the 3 groups.

was reduced and lost significance at 5 years compared with CNF (11.6%;  $P = .52$ ) and LNFI (11.6%;  $P = .46$ ). The shift of the reintervention curve from LNFI to LNFI illustrates the effect of surgeon experience on outcome (Figure 5). The indications for surgical reintervention are presented in **Table 6**.

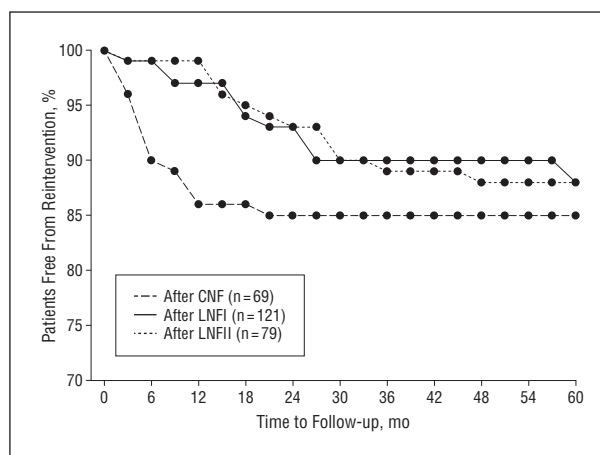
### COMMENT

In 2000, an RCT was prematurely terminated at interim analysis because LNF for GERD was associated with a higher risk to develop dysphagia than CNF.<sup>2</sup> The indication for surgery, construction of the fundoplication, and potential bias caused by relative lack of laparoscopic experience were criticized after the publication of the trial.<sup>3-8</sup> The current study was designed to evaluate whether the unfavorable outcome after LNF was the result of relative inexperience with the laparoscopic approach. A long-term cohort study was initiated, mirroring the methods

**Table 5. Clinical Outcome 5 Years After CNF, LNFI, and LNFI**

|  | No. (%)   |           |           |
|--|-----------|-----------|-----------|
|  | CNF       | LNFI      | LNFI      |
| Self-rated change in reflux symptoms (vs preoperative state) | n = 64    | n = 72    | n = 98    |
| Visick I: resolved   | 30 (46.9) | 37 (51.4) | 49 (50.0) |
| Visick II: improved  | 26 (40.6) | 31 (43.1) | 39 (39.8) |
| Visick III: unchanged  | 3 (4.7)   | 2 (2.8)   | 4 (4.1)   |
| Visick IV: worsened  | 5 (7.8)   | 2 (2.8)   | 6 (6.1)   |
| Heartburn  | n = 66    | n = 74    | n = 96    |
| Grade 0  | 38 (57.6) | 46 (62.2) | 59 (61.5) |
| Grade 1  | 18 (27.3) | 26 (35.1) | 28 (29.2) |
| Grade 2  | 9 (13.6)  | 2 (2.7)   | 6 (6.3)   |
| Grade 3  | 1 (1.5)   |           | 3 (3.1)   |
| Regurgitation  | n = 63    | n = 71    | n = 95    |
| Grade 0  | 41 (65.1) | 54 (76.1) | 70 (73.7) |
| Grade 1  | 13 (20.6) | 15 (21.1) | 19 (20.0) |
| Grade 2  | 8 (12.7)  | 2 (2.8)   | 4 (4.2)   |
| Grade 3  | 1 (1.6)   |           | 2 (2.1)   |
| Dysphagia  | n = 63    | n = 71    | n = 96    |
| Grade 0  | 29 (46.0) | 38 (53.5) | 49 (51.0) |
| Grade 1  | 25 (39.7) | 28 (39.4) | 35 (36.5) |
| Grade 2  | 6 (9.5)   | 5 (7.0)   | 6 (6.3)   |
| Grade 3  | 3 (4.8)   |           | 6 (6.3)   |
| Self-rated change in general health (vs preoperative state)  | n = 65    | n = 74    | n = 98    |
| Improved   | 49 (75.4) | 56 (75.7) | 72 (73.5) |
| Unchanged  | 10 (15.4) | 12 (16.2) | 13 (13.3) |
| Worsened   | 6 (9.2)   | 6 (8.1)   | 13 (13.3) |
| Opt for surgery again in retrospect                          | n = 65    | n = 72    | n = 96    |
| Yes  | 43 (66.2) | 55 (76.4) | 77 (80.2) |
| No   | 11 (16.9) | 8 (11.1)  | 10 (10.4) |
| No opinion   | 11 (16.9) | 9 (12.5)  | 9 (9.4)   |

Abbreviations: CNF, conventional Nissen fundoplication; LNFI, laparoscopic Nissen fundoplication in the 2000 randomized controlled trial; LNFI, laparoscopic Nissen fundoplication in the cohort study.



**Figure 5.** Time curve of percentage of patients free from reintervention after conventional Nissen fundoplication (CNF) and laparoscopic Nissen fundoplication in the 2000 randomized controlled trial (LNFI) and the cohort study (LNFI).

of the RCT, except for the laparoscopic experience that had grown to more than 30 LNFI per surgeon. Previous studies that evaluate the impact of surgeon experience on outcome are biased because surgical techniques



changed during the study. In contrast, the present study further expands on the data currently available in the literature by showing the isolated effect of surgeon experience on long-term outcome of LNF. Operating time, conversion rate, and complications are the most commonly used parameters to define the effect of experience on outcome of antireflux surgery.<sup>9,14-16</sup> However, objective reflux control and long-term subjective outcome would be more relevant in clinical practice. To our knowledge, the current study is the first to objectively document the effect of surgeon experience on 5-year outcome of LNF.

Studies that evaluate the impact of individual surgeon experience are scarce, but several studies have investigated the effect of institutional experience on outcome of LNF. In line with the results of the present study, these reports have demonstrated that experience reduces operating time,<sup>9,11-13,15,28-32</sup> conversions,<sup>9-13,28,29,32</sup> intraoperative complications,<sup>12,30</sup> in-hospital complications,<sup>11,30,32</sup> hospital stay,<sup>13,31</sup> early dysphagia,<sup>10,11,15</sup> and reinterventions.<sup>9</sup> In agreement with the present study, the only study that evaluated the effect on acid exposure during postoperative 24-hour pH monitoring did not identify differences between the first 40 and subsequent institutional cases.<sup>29</sup> The current study did not focus on the effect of institutional expert experience, but on individual surgeon experience in a pragmatic trial with "all-day practice" applicability. It demonstrates significant improvement of highly comparable parameters.

The results of the current study should be compared with those of 6 earlier studies that report on the impact of individual surgeon experience.<sup>9,14-17,33</sup> The results of the studies that have previously addressed this issue are biased because changes in surgical techniques were introduced in the course of the study.<sup>9,14-17</sup> As a result, the effect of the increase in experience cannot be separated from the impact of changes in surgical technique. In the present study, surgical technique was deliberately left unchanged during the course of the study. The only previous study free of modifications of surgical technique violated the intention-to-treat principle because patients with major complications were excluded from follow-up and this percentage was twice as high in the learning group.<sup>33</sup> Despite these sources of bias, the results of the previous studies are in line with the present report and demonstrate that individual surgeon experience reduces operating time,<sup>9,14,15,17</sup> conversions,<sup>9,14,17</sup> in-hospital complications,<sup>15,17</sup> hospital stay,<sup>14</sup> early dysphagia,<sup>15,17</sup> dilatations for dysphagia,<sup>14,16,17</sup> and surgical reinterventions<sup>9,14</sup> of LNF. In contrast, the current study and earlier reports show that objective reflux control<sup>33</sup> and long-term clinical outcome<sup>17</sup> are not correlated with experience. Once a good result is obtained, the effect lasts at least 5 years after surgery, as shown by postoperative reflux symptoms, proton pump inhibitor use, and quality of life.

The current analysis confirms the criticism expressed in 2000 by showing that early outcome of LNF improves with experience increasing from 5 to a minimum of 30 procedures. Moreover, it shows a reduction of blood loss, splenectomy rate, in-hospital complications, and duration of hospitalization, with similar long-term effectiveness and reoperation rate compared with CNF. Two recent meta-

**Table 6. Surgical Reinterventions and Reoperation Indications 5 Years After CNF, LNFI, and LNFI**

|                                | No. (%)         |                  |                      |
|--------------------------------|-----------------|------------------|----------------------|
|                                | CNF<br>(n = 69) | LNFI<br>(n = 79) | LNFI<br>(n = 121)    |
| Surgical reintervention        | 8 (11.6)        | 12 (15.2)        | 14 (11.6)            |
| Reoperation indication         |                 |                  |                      |
| Persistent dysphagia, >3 mo    | 2 (2.9)         | 6 (7.6)          | 6 (5.0)              |
| Recurrent reflux               | 3 (4.3)         | 2 (2.5)          | 5 (4.1)              |
| Dysphagia and recurrent reflux | 2 (2.9)         | 2 (2.5)          |                      |
| Intrathoracic migration        | 1 (1.4)         | 1 (1.3)          | 3 (2.5) <sup>a</sup> |
| Cicatrical hernia              |                 | 1 (1.3)          |                      |

Abbreviations: CNF, conventional Nissen fundoplication; LNFI, laparoscopic Nissen fundoplication in the 2000 randomized controlled trial; LNFI, laparoscopic Nissen fundoplication in the cohort study.

<sup>a</sup>Including 1 patient who needed reoperation for a paraesophageal hernia due to a car crash.

analyses comparing LNF and CNF confirm that the most important benefits of LNF are reduction of in-hospital complications and hospital stay, with similar efficacy compared with CNF.<sup>34,35</sup> The 10-year results of 2 RCTs comparing LNF and CNF have demonstrated that laparoscopic fundoplication reduces the incidence of incisional hernias<sup>36</sup> and incisional hernia corrections.<sup>37</sup> In contrast, the current study reports only 1 incisional hernia correction in the first laparoscopic cohort and none in the open group and the second laparoscopic cohort at 5 years. Our group has previously demonstrated that the higher rate of incisional hernias after open surgery is not present at 5 years<sup>18</sup> and becomes clinically relevant between 5 and 10 years of follow-up.<sup>36,37</sup>

In conclusion, this analysis clearly illustrates the effect of experience on the early outcome of laparoscopic antireflux surgery and represents a plea for centralization or concentration of expertise, even more so because the outcome after reoperation is inferior to that of the primary operation.<sup>38,39</sup>

**Accepted for Publication:** March 10, 2010.

**Correspondence:** Hein G. Gooszen, MD, PhD, Department of Surgery, HP G04.228, University Medical Center Utrecht, PO Box 85500, 3508 GA Utrecht, the Netherlands (h.gooszen@ok.umcn.nl).

**Author Contributions:** Dr J. A. J. L. Broeders had full access to all of the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis. All authors have seen and approved the final version of the manuscript. *Study concept and design:* van Lanschot and Gooszen. *Acquisition of data:* Draaisma and Rijnhart-de Jong. *Analysis and interpretation of data:* J. A. J. L. Broeders, Smout, and I. A. M. J. Broeders. *Drafting of the manuscript:* J. A. J. L. Broeders and Draaisma. *Critical revision of the manuscript for important intellectual content:* Rijnhart-de Jong, Smout, van Lanschot, I. A. M. J. Broeders, and Gooszen. *Statistical analysis:* J. A. J. L. Broeders. *Administrative, technical, and material support:* Rijnhart-de Jong. *Study supervision:* Gooszen.

**Financial Disclosure:** None reported.

**Funding/Support:** Dr J. A. J. L. Broeders is supported by a University Medical Center Utrecht Alexandre Suerman MD/PhD grant.

**Previous Presentation:** Oral presentation at the annual meeting of the European Association for Endoscopic Surgery; June 13, 2008; Stockholm, Sweden.

## REFERENCES

1. Dallemagne B, Weerts JM, Jehaes C, Markiewicz S, Lombard R. Laparoscopic Nissen fundoplication: preliminary report. *Surg Laparosc Endosc.* 1991;1(3):138-143.
2. Bais JE, Bartelsman JF, Bonjer HJ, et al; The Netherlands Antireflux Surgery Study Group. Laparoscopic or conventional Nissen fundoplication for gastro-oesophageal reflux disease: randomised clinical trial. *Lancet.* 2000;355(9199):170-174.
3. Bloechle C, Mann O, Gawad KA, Izbickei JR. Gastro-oesophageal reflux disease. *Lancet.* 2000;356(9223):69-73.
4. Gorecki PJ, Hinder RA. Gastro-oesophageal reflux disease. *Lancet.* 2000;356(9223):70-73.
5. Booth M, Dehn TC. Gastro-oesophageal reflux disease. *Lancet.* 2000;356(9223):70-71.
6. Pellegrini CA. Gastro-oesophageal reflux disease. *Lancet.* 2000;356(9223):71-73.
7. de Beaux AC, Watson DI, Jamieson GG. Gastro-oesophageal reflux disease. *Lancet.* 2000;356(9223):71-72.
8. de Brauw LM, Beets GL. Gastro-oesophageal reflux disease. *Lancet.* 2000;356(9223):69-70.
9. Watson DI, Baigrie RJ, Jamieson GG. A learning curve for laparoscopic fundoplication: definable, avoidable, or a waste of time? *Ann Surg.* 1996;224(2):198-203.
10. Voitk A, Joffe J, Alvarez C, Rosenthal G. Factors contributing to laparoscopic failure during the learning curve for laparoscopic Nissen fundoplication in a community hospital. *J Laparoendosc Adv Surg Tech A.* 1999;9(3):243-248.
11. Champault GG, Barrat C, Rozon RC, Rizk N, Catheline JM. The effect of the learning curve on the outcome of laparoscopic treatment for gastroesophageal reflux. *Surg Laparosc Percutan Tech.* 1999;9(6):375-381.
12. Soot SJ, Eshraghi N, Farahmand M, Sheppard BC, Deveney CW. Transition from open to laparoscopic fundoplication: the learning curve. *Arch Surg.* 1999;134(3):278-281.
13. Deschamps C, Allen MS, Trastek VF, Johnson JO, Pairler PC. Early experience and learning curve associated with laparoscopic Nissen fundoplication. *J Thorac Cardiovasc Surg.* 1998;115(2):281-284.
14. Gill J, Booth MI, Stratford J, Dehn TC. The extended learning curve for laparoscopic fundoplication: a cohort analysis of 400 consecutive cases. *J Gastrointest Surg.* 2007;11(4):487-492.
15. Hwang H, Turner LJ, Blair NP. Examining the learning curve of laparoscopic fundoplications at an urban community hospital. *Am J Surg.* 2005;189(5):522-526.
16. Munro W, Brancatisano R, Adams IP, Falk GL. Complications of laparoscopic fundoplication: the first 100 patients. *Surg Laparosc Endosc.* 1996;6(6):421-423.
17. Salminen P, Hiekkanen H, Laine S, Ovaska J. Surgeons' experience with laparoscopic fundoplication after the early personal experience: does it have an impact on the outcome? *Surg Endosc.* 2007;21(8):1377-1382.
18. Draaisma WA, Rijnhart-de Jong HG, Broeders IA, Smout AJ, Furnee EJ, Gooszen HG. Five-year subjective and objective results of laparoscopic and conventional Nissen fundoplication: a randomized trial. *Ann Surg.* 2006;244(1):34-41.
19. Rijnhart-De Jong HG, Draaisma WA, Smout AJ, Broeders IA, Gooszen HG. The Visick score: a good measure for the overall effect of antireflux surgery? *Scand J Gastroenterol.* 2008;43(7):787-793.
20. Velanovich V, Karmy-Jones R. Measuring gastroesophageal reflux disease: relationship between the Health-Related Quality of Life score and physiologic parameters. *Am Surg.* 1998;64(7):649-653.
21. Zéman Z, Rózsa S, Tihanyi T, Tarkó E. Psychometric documentation of a quality-of-life questionnaire for patients undergoing antireflux surgery (QOLARS). *Surg Endosc.* 2005;19(2):257-261.
22. Horbach JM, Masclee AA, Lamers CB, Gooszen HG. Prospective evaluation of 24 hour ambulatory pH metry in Belsey Mark IV antireflux surgery. *Gut.* 1994;35(11):1529-1535.
23. de Boer AG, van Lanschot JJ, Stalmeier PF, et al. Is a single-item visual analogue scale as valid, reliable and responsive as multi-item scales in measuring quality of life? *Qual Life Res.* 2004;13(2):311-320.
24. Nord E. The validity of a visual analogue scale in determining social utility weights for health states. *Int J Health Plann Manage.* 1991;6(3):234-242.
25. Savary M, Miller G. *The Esophagus Handbook and Atlas of Endoscopy.* Solothurn, Switzerland: Verlag Gossman; 1978.
26. Lundell LR, Dent J, Bennett JR, et al. Endoscopic assessment of oesophagitis: clinical and functional correlates and further validation of the Los Angeles classification. *Gut.* 1999;45(2):172-180.
27. Draaisma WA, Ruurda JP, Scheffer RC, et al. Randomized clinical trial of standard laparoscopic versus robot-assisted laparoscopic Nissen fundoplication for gastro-oesophageal reflux disease. *Br J Surg.* 2006;93(11):1351-1359.
28. Paluzzi MW. Laparoscopic Nissen fundoplication at a teaching center: prospective analysis of 103 consecutive patients. *Surg Laparosc Endosc.* 1997;7(5):363-368.
29. Remzi M, Lenglinger J, Erne B, et al. Effect of the learning phase on safety and efficiency of laparoscopic fundoplication [in German]. *Chirurg.* 2001;72(3):261-265.
30. Endzinas Z, Maleckas A, Mickevicius A, Kiudelis M. Follow-up results and learning curve in laparoscopic gastrofundoplications [in German]. *Zentralbl Chir.* 2002;127(11):939-943.
31. Gotley DC, Smithers BM, Rhodes M, Menzies B, Branicki FJ, Nathanson L. Laparoscopic Nissen fundoplication: 200 consecutive cases. *Gut.* 1996;38(4):487-491.
32. Zacharoulis D, O'Boyle CJ, Sedman PC, Brough WA, Royston CM. Laparoscopic fundoplication: a 10-year learning curve. *Surg Endosc.* 2006;20(11):1662-1670.
33. Contini S, Scarpignato C. Does the learning phase influence the late outcome of patients with gastroesophageal reflux disease after laparoscopic fundoplication? *Surg Endosc.* 2004;18(2):266-271.
34. Catarci M, Gentileschi P, Papi C, et al. Evidence-based appraisal of antireflux fundoplication. *Ann Surg.* 2004;239(3):325-337.
35. Peters MJ, Mukhtar A, Yunus RM, et al. Meta-analysis of randomized clinical trials comparing open and laparoscopic anti-reflux surgery. *Am J Gastroenterol.* 2009;104(6):1548-1561.
36. Salminen PT, Hiekkanen HI, Rantala AP, Ovaska JT. Comparison of long-term outcome of laparoscopic and conventional Nissen fundoplication: a prospective randomized study with an 11-year follow-up. *Ann Surg.* 2007;246(2):201-206.
37. Broeders JA, Rijnhart-de Jong HG, Draaisma WA, Bredenoord AJ, Smout AJ, Gooszen HG. Ten-year outcome of laparoscopic and conventional Nissen fundoplication: randomized clinical trial. *Ann Surg.* 2009;250(5):698-706.
38. Furnée EJ, Draaisma WA, Broeders IA, Smout AJ, Gooszen HG. Surgical re-intervention after antireflux surgery for gastroesophageal reflux disease: a prospective cohort study in 130 patients. *Arch Surg.* 2008;143(3):267-274.
39. Furnée EJ, Draaisma WA, Broeders IA, Gooszen HG. Surgical re-intervention after failed antireflux surgery: a systematic review of the literature. *J Gastrointest Surg.* 2009;13(8):1539-1549.