

Single-Site Nissen Fundoplication Versus Laparoscopic Nissen Fundoplication

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ABSTRACT

Background: Advances in minimally invasive surgery have led to the emergence of single-incision laparoscopic surgery (SILS). The purpose of this study is to assess the feasibility of SILS Nissen fundoplication and compare its outcomes with traditional laparoscopic Nissen fundoplication.

Methods: This is a retrospective study of 33 patients who underwent Nissen fundoplication between January 2009 and September 2010.

Results: There were 15 SILS and 18 traditional laparoscopic Nissen fundoplication procedures performed. The mean operative time was 129 and 182 minutes in the traditional laparoscopic and single-incision groups, respectively ($P = .019$). There were no conversions in the traditional laparoscopic group, whereas 6 of the 15 patients in the SILS group required conversion by insertion of 2 to 4 additional ports ($P = .0004$). At short-term follow-up, recurrence rates were similar between both groups. To date, there have been no reoperations.

Conclusions: SILS Nissen fundoplication is both safe and feasible. Short-term outcomes are comparable with standard laparoscopic Nissen fundoplication. Challenges related to the single-incision Nissen fundoplication include overcoming the lengthy learning curve and decreasing the need for additional trocars.

Key Words: Gastroesophageal reflux, Fundoplication, Minimally invasive surgical procedures, Minimal access surgical procedures, Laparoscopic surgery.

INTRODUCTION

Nissen fundoplication is the gold standard for surgical treatment of gastroesophageal reflux disease.¹⁻³ In the past decade, laparoscopic Nissen fundoplication has been performed as the preference to open Nissen fundoplication because of its decreased morbidity and mortality rates, shorter length of hospitalization, less postoperative pain, and quicker patient return to activities of daily living.²⁻⁵ Additional benefits to the laparoscopic approach include reduced incidence of incisional hernias and disrupted fundoplications when compared with the open approach.⁶ Advances in minimally invasive surgery have led to the emergence of single-incision laparoscopic surgery (SILS), which also is known by several other acronyms, including single-port laparoscopy, one-port umbilical surgery, single-access surgery, single-site laparoscopy, natural orifice transumbilical surgery, or single-port access.⁷ Many procedures in the fields of urology, gynecology, bariatric surgery, and general surgery are now being performed through SILS.

The purpose of this study is to assess the feasibility of SILS Nissen fundoplication by comparing its outcomes with those of traditional laparoscopic Nissen fundoplication. Whereas others have described performing modified single-incision Nissen fundoplication with the aid of percutaneously placed transabdominal retraction devices, this review represents one of the largest series of Nissen fundoplication procedures using the true single-incision technique.¹

METHODS

All patients undergoing initial Nissen fundoplication for treatment of gastroesophageal reflux disease between January 2009 and September 2010 were reviewed. Patients were identified via billing records. There were no exclusions from the review, and all procedures were performed by one surgeon at the Scott & White Clinic in Round Rock, Texas. The decision to perform SILS was made according to surgeon preference, and there was no experience with SILS Nissen fundoplication before the study. Outcome measures included operative time, conversion rate, and postoperative results including recurrence of reflux, pro-

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ton pump inhibitor use, dysphagia, and anatomic failure. Patients were questioned regarding postoperative outcomes during standard follow-up appointments, which were routinely scheduled postoperatively at 1 and 2 weeks; 1, 2, and 6 months; and yearly thereafter.

The SILS Nissen fundoplication was performed with the patient lying supine on a beanbag chair in the low lithotomy position. The operating surgeon stood between the legs, with the first assistant on the patient's left. A 2-cm vertical umbilical incision was made within the umbilical folds and extended to the fascia. A 3-trocar SILS (Covidien, Mansfield, Massachusetts) port was inserted through the fascial defect using a Kelly clamp. Either a 5-mm bariatric 30°-angled scope or a 5-mm 360° flex-tip scope was placed through the SILS port, along with standard 5-mm nonarticulating instruments.

We used 2 methods of liver retraction in this case series. The first method, applied in the initial 3 single-incision Nissen fundoplications, involved the use of a series of Penrose drains to suspend the liver through a transabdominal approach, as described by Hamzaoglu et al.¹ The second method involved placement of a Snowden-Pencer 5-mm Diamond-Flex liver retractor (CareFusion, Waukegan, Illinois) down the side of the SILS port and through the fascial defect. The placement of the liver retractor in this fashion allowed for a true single-incision laparoscopic Nissen fundoplication to be performed in 12 of the 15 patients in the single-incision cohort. This liver retractor was held in place by an assistant, clamped to the drape, or fixated by a Universal Flex-Arm system (Mediflex, Long Island, New York) secured to the bed on the patient's right side. Harmonic ACE curved shears (Ethicon, Somerville, New Jersey) were used for most of the dissection. Dissection was started initially either along the greater curvature of the stomach or through the pars flaccida. The intra-abdominal esophagus was then completely mobilized, with care taken to identify and preserve the vagus nerves. Attachments in the mediastinum were released to gain appropriate intra-abdominal esophageal length as necessary. If present, a hiatal hernia was closed using nonabsorbable braided sutures. The use of mesh was optional but not routine. A loose, floppy Nissen-style fundoplication was then created with 3 interrupted nonabsorbable braided sutures positioned 180° opposite the short gastric arteries. One or two of the sutures incorporated the seromuscular layer of the esophagus. The SILS port was then removed. The fascial defect was closed using 2 figure-of-eight 0–0 absorbable braided sutures. Subcutaneous tissues were irrigated, and 3–0 deep dermal absorbable sutures were used to reapproximate the deep tissues.

Finally, a triple-antibiotic impregnated gauze dressing was placed over the incision, and excess air was suctioned to create a vacuum dressing.

The standard laparoscopic Nissen fundoplication was performed with identical patient and surgeon positioning as described above. The Universal Flex-Arm system was attached to the bed on the patient's right side and used to secure the liver retractor. The Hasson technique or 5-mm Optiview port was used to gain access to the peritoneal cavity, after which 4 additional 5-mm trocars were placed. The dissection, hiatal hernia repair, and fundoplication were then performed as described before. Trocars were removed, and the subcutaneous tissues were irrigated and closed using 4–0 absorbable sutures. Dermal adhesive was then applied.

Age, body mass index, DeMeester score, and operative time in the 2 groups were compared using an unequal variance *t* test. A Fisher exact test was used to examine the differences between the SILS and traditional laparoscopic cohorts with regard to gender percentages, American Society of Anesthesiology scores, previous abdominal surgeries, rates of conversion, and rates of recurrence both anatomic and symptomatic. To better understand the interplay of some of the relationships elucidated here, we built several regression models. To understand the odds ratio of recurrence in single-incision versus traditional laparoscopic patients, we built a logistic regression model with covariates of age, body mass index, previous abdominal surgery, and procedure (SILS vs traditional laparoscopic). Analogous models were built for conversion, estimated blood loss, anatomic recurrence, reflux recurrence, and dysphagia recurrence.

RESULTS

Of the 33 patients undergoing Nissen fundoplication between the dates of January 2009 and September 2010, 15 patients underwent SILS Nissen fundoplication and 18 underwent traditional laparoscopic Nissen fundoplication. There was no statistical difference between the two groups in terms of age (mean, 50.8 years), body mass index (mean, 29.1 kg/m²), American Society of Anesthesiologists score, previous abdominal surgeries, or gender (**Table 1**). The mean DeMeester score was 51.6 in the single-port cohort and 122.9 in the traditional laparoscopic cohort (*P* = .0032). There were 3 patients in each cohort who did not have documented DeMeester scores.

The mean operative time was 129 minutes (range, 101–184) and 182 minutes (range, 111–273) in the traditional

Table 1.
Demographics

	SILS	LAP	P Value
Male/female	5/10	5/13	1
Age (y)	52.13 (24–73)	49.67 (27–72)	.61
BMI (kg/m ²)	27.56 (21.9–31.9)	29.28 (25.1–34.4)	.13
ASA class 1	1	0	.78
ASA class 2	12	16	
ASA class 3	2	2	
Previous Abd Sx	10/15	12/18	1
DeMeester score	51.59 (24.2–90.0)	122.86 (36.7–264.0)	.0032

SILS = single-incision laparoscopic Nissen fundoplication; LAP = standard 5-port laparoscopic Nissen fundoplication; BMI = body mass index; ASA = American Society of Anesthesiologists score; Abd Sx = abdominal surgery.

Ranges are displayed in parentheses.

laparoscopic and SILS groups, respectively ($P = .0004$). Of note, 3 patients in the single-incision group underwent simultaneous secondary procedures, including 2 SILS cholecystectomies and 1 open incisional hernia repair. In the standard laparoscopic group, 1 patient underwent a simultaneous laparoscopic cholecystectomy. There was no need for additional trocars in the traditional laparoscopic group, but 6 of the 15 SILS Nissen patients required conversion ($P = .005$), which involved the insertion of 2 to 4 additional ports (**Table 2**). Typically, additional ports were required in the right and left lateral flanks for retraction assistance. No patient in either group required conversion to an open procedure. There was no perioperative morbidity or mortality in either cohort. All patients in both cohorts were discharged on postoperative day 1, except for one SILS patient who was discharged home on postoperative day 2.

Short-term follow-up revealed symptomatic relief of gastroesophageal reflux in 100% of patients in the SILS group and 94% in the traditional laparoscopic group. Postoperative use of proton pump inhibitors was also similar (0% SILS, 5.6% traditional laparoscopy). Dysphagia rates were similar in each arm (6.7% SILS vs 5.6% traditional laparoscopy). Anatomic recurrence rates were also similar in each arm (0 SILS, 5.6% traditional laparoscopy). There was no statistical difference between the SILS and traditional laparoscopic groups in any of these outcome measures (**Table 3**). Logistic regression models revealed that the surgical approach was not a significant indicator for recurrence, con-

Table 2.
Operative Outcomes

	SILS	LAP	P Value
Operative time (min)	182.13 (111–273)	129.06 (101–184)	.0004
Conversions	6/15	0/18	.0045
Number of ports used			
1	9	0	<.001
2	0	0	
3	1	0	
4	3	0	
5	2	18	

SILS = single-incision laparoscopic Nissen fundoplication; LAP = standard 5-port laparoscopic Nissen fundoplication.

Ranges are displayed in parentheses.

Table 3.
Recurrence

	SILS	LAP	P Value
Anatomic	0/15	1/18	1
PPI	0/15	1/18	1
Reflux	0/15	1/18	1
Dysphagia	1/15	1/18	1

SILS = single-incision laparoscopic Nissen fundoplication; LAP = standard 5-port laparoscopic Nissen fundoplication; PPI = proton pump inhibitor.

version, or greater than minimal blood loss. To date, there have been no reoperations. The average length of follow-up was 26 weeks and 28 weeks in the SILS and standard laparoscopic cohorts, respectively.

DISCUSSION

Although traditional laparoscopic Nissen fundoplication involves the use of 5 separate ports—1 for the camera and 4 working ports for dissection—this comparative study of our initial experience indicates that performing a Nissen fundoplication through a single laparoscopic incision is both safe and feasible in the hands of an experienced laparoscopic surgeon. Although the average operative time was longer than for the traditional approach, this may be attributed to the learning curve associated with adopting a new procedure or technique. The literature indicates that the learning curve for traditional laparoscopic fundoplication in terms of operative time and conversion rate

reaches a plateau between 20 and 50 cases.^{8,9} Although our operative times may be partially artificially lengthened by the inclusion of secondary procedures, further experience with this procedure is clearly needed to overcome the learning curve and gain efficiency.

Although the SILS Nissen fundoplication group had a 40% conversion rate, 86% remained in reduced-port laparoscopy (<5 points of entry). Despite this conversion rate, we believe the benefits of reduced-port laparoscopy should not be discounted because the use of laparoscopic trocars has been directly associated with reports of morbidity and mortality.^{10,11} The actual benefits of single-incision procedures over traditional laparoscopic procedures are heavily debated, but there is an undeniable interest in single-incision surgery, both on the part of physicians and patients. To date, the evidence available indicates that SILS is a safe and feasible alternative to traditional laparoscopy with regard to more common laparoscopic procedures, with no apparent added risk to the patient when compared with traditional laparoscopy.^{12–17} Some studies investigating its advantages have documented decreased postoperative pain and recovery time but continue to show equivalent rather than improved wound infection and hernia rates.^{4,12,13,18–21} There are also several publications indicating improved patient satisfaction with cosmesis.^{12,13,22} The clinical significance of such evidence has not yet been firmly established, but several large randomized trials focusing on patient-centered outcomes are underway, which will provide a more definitive understanding of the advantages and disadvantages of the reduction in ports.^{12,18,22,23} The anticipation of these benefits prompted the exploration of the single-incision laparoscopic Nissen fundoplication as an alternative to traditional laparoscopy in our facility.

SILS is not, however, without controversy, and the operative times in this comparative series raise concerns regarding the ease of its adoption in more advanced laparoscopic procedures. Arguments against SILS often focus on the potential for increased cost and increased operative difficulty as a result of crowding, decreased triangulation, and reduction in the number of working ports. Longer operative times are documented in early studies concerning single-incision cholecystectomy, but this learning curve can be overcome with increased experience, standardized training, and meticulous application of techniques.^{19,22} These issues have been partially addressed by the wider array of devices available in the operating room, but they continue to be a valid concern. This particular comparative series suggests that the learning curve for a SILS Nissen fundoplication is greater than our 15 cases and

may require extensive experience with the specialized procedure before the minimally invasive approach is attempted. Furthermore, it is possible that the use of SILS in an operation of this complexity may not offer significant benefit for the patient other than cosmesis.

There are several limitations to this study, including its retrospective design and lack of long-term follow-up. Our analysis indicates that the short-term outcomes for SILS Nissen fundoplication were comparable with standard laparoscopic Nissen fundoplication, but long-term outcomes are not yet available. In addition, inquiry into both short- and long-term symptomatic recurrence would benefit from standardization by the use of a validated questionnaire to assess the control of symptoms, the use of proton pump inhibitors, and the development of dysphagia. The relatively small sample size in this comparative series makes it difficult to see both the positive and negative statistically significant differences between the 2 cohorts. In addition, the series contains our initial experience with SILS Nissen fundoplication and does not appear to extend beyond the previously discussed learning curve inherent to this technically demanding approach, as evidenced by persistently longer operative times in the SILS cohort.

In conclusion, a true single-incision laparoscopic Nissen fundoplication procedure is safe and feasible, but surgeons may need to perform a large number of them to overcome the learning curve and improve operative times. Short-term results are comparable with standard laparoscopic Nissen fundoplication, but further follow-up is required to assess the long-term outcomes of SILS Nissen fundoplication. Proving the benefits of this procedure beyond cosmesis will likely be difficult. At our institution, single-incision laparoscopic Nissen fundoplication continues to be offered and performed primarily when requested by patients for whom cosmesis is an important consideration. We continue to believe that SILS is an important skill for surgeons to learn for a variety of procedures, primarily because of the increased patient satisfaction and outstanding cosmesis. As health care institutions begin placing larger emphasis on patient satisfaction for reimbursement, these benefits should not be ignored. Large randomized trials are needed to draw definitive conclusions regarding the clinically significant advantages of SILS over traditional multiport laparoscopy, especially for more specialized procedures like the Nissen fundoplication.

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