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Senhance-Assisted vs Laparoscopic Pediatric Nissen Fundoplication: A Single-Center Multidisciplinary Comparative Cohort Study from a German Tertiary Center

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Abstract

Background

Evidence on Senhance®-assisted robotic surgery in pediatric fundoplication is limited, particularly regarding perioperative workflow and anesthesia-related outcomes during early program implementation. This study compared Senhance®-assisted robotic Nissen fundoplication (RNF) with conventional laparoscopic Nissen fundoplication (LNF) in children, focusing on surgical safety, efficiency, and anesthetic impact.

Methods

This single-center prospective comparative cohort study was conducted at a tertiary pediatric surgery center. Consecutive children with gastroesophageal reflux disease undergoing RNF using the Senhance® Surgical System (November 2022 through August 2025; n = 18) were compared with a contemporaneous LNF cohort (2021 through 2025; n = 18). Primary outcomes were intraoperative safety, primarily assessed by complication and conversion rates, and perioperative efficiency. Secondary outcomes included postoperative morbidity, length of stay, readmissions, and structured anesthesia-related parameters. Distribution-appropriate statistical tests were applied.

Results

RNF patients were older and heavier, with comparable sex distribution. No intraoperative complications occurred and no case required open conversion; conversion from RNF to laparoscopy occurred in 3/18 cases (16.7%) due to workflow-related factors. Operative time was comparable (172.7 ± 51.5 vs. 168.8 ± 45.5 min; p = 0.809), whereas preparation time was longer in RNF (104.7 ± 54.2 vs. 68.8 ± 19.4 min; p = 0.015) with a trend towards lower times over consecutive cases (first vs. second half: 121.7 ± 61.3 vs. 87.8 ± 42.9 min; p = 0.195), demonstrating a learning effect. Length of stay, 30-day complications, readmissions, and reoperations were similar. Anesthesia duration, blood loss, recovery-room time, pain scores, delirium screening, and opioid consumption did not differ significantly between groups.

Conclusions

Senhance®-assisted pediatric Nissen fundoplication is feasible and safe, with surgical and anesthesia-related outcomes comparable to laparoscopy. Robotic assistance did not increase anesthetic risk. Early workflow-related limitations reflect the learning phase and underscore the importance of structured multidisciplinary training. These findings support RNF as a complementary alternative technique in pediatric minimally invasive surgery and warrant multicenter and long-term evaluation.

Introduction

Gastroesophageal reflux disease (GERD) represents a frequent and clinically relevant condition in the pediatric population, with particularly high prevalence and morbidity among neurologically impaired children [1, 2]. When medical management fails, surgical intervention becomes necessary to prevent complications such as failure to thrive, recurrent aspiration, or esophagitis. Over the past decades, laparoscopic Nissen fundoplication has evolved into the standard surgical approach in most pediatric surgical centers, demonstrating favorable outcomes with reduced postoperative pain, faster recovery, improved cosmetic results, and shorter hospital stay compared with open techniques [3–5].

In parallel with advances in minimally invasive surgery, robotic-assisted surgery has gained increasing attention as a potential next step in surgical innovation. Robotic platforms aim to overcome inherent limitations of conventional laparoscopy by enhancing dexterity, precision, ergonomics, and visualization, thereby optimizing human–machine interaction and surgical workflow [6, 7]. In pediatric surgery, the da Vinci® robotic system has been the most extensively studied platform, with reports demonstrating feasibility and safety for various procedures, including fundoplication [8, 9]. However, it is not licensed for use in children and the 8mm instruments are quite large for the application in pediatric patients, where most laparoscopic fundoplications are performed using 5mm or even 3mm instruments.

The Senhance® Surgical System (Asensus® Surgical, Research Triangle Park, NC, USA) represents a newer generation of robotic technology and incorporates several features that may be particularly advantageous in pediatric surgery. These include haptic feedback, eye-tracking camera control, an open-console architecture, the use of reusable instruments, and compatibility with small-diameter trocars down to 3 mm, potentially reducing abdominal wall trauma and improving system adaptability to pediatric anatomy [10]. Moreover, the system's design and cost structure may offer economic advantages over established robotic platforms, an aspect of particular relevance in publicly funded healthcare systems [11].

Despite these theoretical benefits, published data on the application of the Senhance® system in pediatric surgery remain limited, and experience with Senhance®-assisted fundoplication in children is scarce [11–13]. The introduction of a novel robotic platform into pediatric surgical practice poses specific challenges, including restricted intra-abdominal working space, instrument articulation, and the need for a structured multidisciplinary learning curve involving surgeons, anesthesiologists, and operating room personnel [9, 14].

Our institution adopted the Senhance® robotic system in 2022 and is among the first pediatric surgical centers worldwide to implement this platform on a routine basis. Nissen fundoplication was selected as one of the initial standardized procedures due to its high procedural volume and well-established laparoscopic technique, allowing meaningful comparison between robotic-assisted and conventional approaches.

The aim of this study is to evaluate the feasibility, safety, and perioperative outcomes of Senhance®-assisted pediatric Nissen fundoplication compared with conventional laparoscopic fundoplication in a single-center cohort. We hypothesized that Senhance®-assisted fundoplication is not inferior to the laparoscopic approach regarding perioperative outcomes while offering potential ergonomic, technical, and economic advantages. In contrast to the limited and predominantly surgeon-centered data currently available, our analysis follows a multidisciplinary approach, incorporating surgical, anesthesiological, and perioperative workflow-related parameters. By doing so, this study addresses aspects that have not been systematically evaluated in previous pediatric Senhance reports and aims to provide clinically relevant evidence to inform future implementation strategies.

This cohort study has been reported in line with the *STROCSS 2025 guidelines* [15].

Material and Methods

Study Design and Setting

This single-center comparative cohort study was conducted at a large academic department of pediatric surgery which serves as a publicly funded tertiary referral center, in collaboration with the department of pediatric anesthesiology.

The robotic surgery program was initiated in November 2022. Between November 2022 and through August 2025, all consecutive pediatric patients undergoing robotic-assisted Nissen fundoplication (RNF) were prospectively included. The laparoscopic control cohort (LNF) consisted of patients treated between January 2021 and August 2025 and was analyzed retrospectively using identical eligibility criteria.

No changes to the study protocol occurred during the study period.

The study was approved by the Ethics Committee of the local faculty of medicine (project number 24–0349). Written informed consent was obtained from all patients and their legal guardians.

Patient Selection and Indications

Diagnosis of gastroesophageal reflux disease and indication for surgical antireflux treatment were established according to ESPGHAN guidelines [16].

Inclusion criteria were patient age 1 through 16 years, primary Nissen fundoplication, surgery performed by the same lead surgeon, and admission exclusively related to GERD and fundoplication. We excluded patients who required intra- or postoperative treatment for conditions unrelated to GERD or fundoplication.

Patient age, sex and weight were recorded as baseline characteristics.

The exposure of interest was the surgical approach (robotic-assisted versus conventional laparoscopic Nissen fundoplication).

Since the introduction of robotic surgery, all patients meeting the CE requirements and study inclusion criteria were offered a robotic approach. However, the final treatment decision was made by the caregivers, and 6 of 24 eligible patients (25%) ultimately underwent conventional laparoscopy and were included in the laparoscopic cohort. Patients were included consecutively. No monetary or non-monetary incentives were provided. Due to the exploratory character of this early implementation study, no formal sample size calculation or power analysis was performed. The sample size reflects all eligible cases treated during the predefined period.

Robotic System and Surgical Team

Robotic procedures were performed using the Senhance® Surgical System (Asensus® Surgical, Research Triangle Park, NC, USA), consisting of three independent robotic arms and an open-console platform with haptic feedback and eye-tracking camera control. According to its CE marking, the system is indicated for abdominal and urological procedures in pediatric patients aged ≥ 1 year and weighing ≥ 10 kg. Thoracic applications are not included within this indication.

Instrument size selection was adapted to patient size, with 3-mm instruments preferentially used in smaller children and 5-mm instruments in older pediatric patients.

To ensure comparability with laparoscopy, three-dimensional visualization was not utilized for this study.

All procedures were performed by a single pediatric surgeon with extensive laparoscopic experience and formal robotic certification. Prior to clinical implementation, standardized dry- and wet-lab training was completed. Institutional support included structured team training and intraoperative technical assistance by a manufacturer-employed specialist.

Consistent team composition and standardized operative protocols were used to minimize inter-operator variability.

Surgical Technique

All procedures were performed under general anesthesia in anti-Trendelenburg position.

A standardized five-port setup was used, consisting of three robotic trocars and two conventional laparoscopic trocars. The 5-mm robotic camera port was placed at the umbilicus (No. 1 in Fig. 1). Two robotic instrument ports (3 mm or 5 mm, depending on patient size) were positioned in the right and left lower quadrants, approximately 3–5 cm lateral and inferior to the umbilicus. A 5-mm assistant port was placed in the left upper quadrant, and a subxiphoid port was used for liver retraction.

Robotic-assisted Nissen fundoplication followed the conventional laparoscopic steps: mobilization of the distal esophagus and gastric fundus, division of short gastric vessels, creation of a retrogastric window, posterior hiatal closure using a single non-absorbable 2 – 0 or 3 – 0 silk suture (adapted to patient size), and construction of a 360° floppy fundoplication using two or three non-absorbable 2 – 0 or 3 – 0 silk sutures.

Predefined criteria for conversion included insufficient visualization, limited instrument mobility, technical malfunction, or intraoperative complications.

Postoperatively, patients followed a standardized feeding protocol with gradual oral intake as tolerated. Discharge criteria included adequate pain control with oral analgesics, sufficient enteral feeding, and absence of complications.

Follow-up was performed during inpatient stay and at routine outpatient review approximately 4 to 6 weeks postoperatively.

Outcome Measures

The primary outcomes were perioperative feasibility and safety. Feasibility was defined as the successful and stable integration of the new technology into the operative workflow, without system failure or unexpected technical or mechanical issues. Feasibility measures included operative time (incision to closure), preparation time (start of OR setup to incision), and conversion rate. Safety was evaluated by comparing the incidence and type of intra- and postoperative complications between robotic-assisted and conventional laparoscopic Nissen fundoplication.

Secondary outcomes included anesthesiologic parameters (anesthesia duration, blood loss, recovery time), postoperative pain via visual analogue scale (VAS), postoperative delirium screened with the Nursing Delirium Screening Scale (NuDESC) [17], peri- and postoperative analgesic consumption, length of hospital stay and instrument size.

At 30 days postoperatively, cases were evaluated for surgical complications using the Clavien–Dindo classification [18]. In addition, readmission and reoperation rates within this period were recorded.

Data collection

Data were systematically collected from electronic medical records, specifically including operative reports, nursing and anesthesia logs, inpatient charts, discharge summaries, and outpatient follow-up reports. The collected data were stored pseudonymized and fully anonymized upon completion of the study.

Statistical Analysis

Descriptive statistics were used to summarize demographic, operative, and clinical variables. Normality of continuous data was assessed using the Shapiro–Wilk test in conjunction with visual inspection of histograms and Q–Q plots. Depending on data distribution, Welch's t-test or the Mann–Whitney U test was applied for comparisons of continuous variables. Categorical variables were analyzed using the Chi-square test or Fisher's exact test when more than 20% of expected cell counts were below five.

Temporal changes in operative and preparation times within the robotic cohort were evaluated using Welch's t-test and visualized using boxplots and trend graphs. Effect sizes were reported as mean or median differences with corresponding 95% confidence intervals, or as odds ratios where appropriate. Statistical significance was defined as a p-value < 0.05. All analyses were performed using IBM SPSS Statistics, version 31.0 (IBM Corp., Armonk, NY, USA).

Results

Participant Flow and Demographics

A total of 36 pediatric patients were included, with 18 undergoing robotic-assisted Nissen fundoplication (RNF) and 18 treated with conventional laparoscopic fundoplication (LNF). Sex distribution was similar between groups (robotic: 61.1% male vs. laparoscopic: 72.2% male; p = 0.480).

Patients in the robotic cohort were significantly older, with a median age of 10.0 years (IQR 4.0–11.4; range 1.2–16.2) compared with 3.0 years (IQR 1.8–6.1; range 0.5–13.5) in the laparoscopic cohort (median difference 3.2 years; 95% CI 0.7–7.9; p = 0.019). Correspondingly, median body weight was higher in the robotic group (19.2 kg, IQR 11.8–38.0) than in the laparoscopic group (11.3 kg, IQR 8.5–16.3; median difference 6.5 kg; 95% CI 1.4–21.0; p = 0.011) (see Table 1).

Table 1

Overview of demographic, intraoperative, postoperative, and anesthesia-related variables in the robotic and laparoscopic groups. Continuous data are presented as mean ± standard deviation (SD) or median with interquartile range (IQR), depending on distribution. Categorical variables are presented as counts and percentages. Mean or median differences with corresponding 95% confidence intervals are provided where applicable, and odds ratios are shown for categorical comparisons.

	RNF (n = 18)	**LNF (n = 18)**	**Mean / Median Difference (95% CI)**	**Odds-Ratio (95% CI)**	**p Value [a]**
Demographics					
Age at surgery (years)	10.0 (4.0–11.4)	3.0 (1.8–6.1)	3.2 (0.7–7.9)		**0.019**
Sex Male Female	11 (61.1%) 7 (38.9%)	13 (72.2) 5 (27.8)			0.480
Weight (kg)	19.2 (11.8–38.0)	11.3 (8.5–16.3)	6.5 (1.4–21.0)		**0.011**
Intraoperative					
Conversion to conventional laparoscopy	3 (16.7%)				
Conversion to open	0 (0.0%)	0 (0.0%)			1.000
Intraoperative complications	0 (0.0%)	0 (0.0%)			1.000
Operative time (min) total First half Latter half	172.7 (± 51.5) 188.3 (± 63.5) 157.1 (± 32.6)	168.8 (± 45.5)	3.9 (-29.0–36.9) 31.2 (-20.6–83.1)		0.809 0.214

[a] Continuous variables were analyzed using Welch's t-test for normally distributed data or the Mann–Whitney U test for non-normally distributed data (asymptotic, two-sided p-values). Categorical variables were compared using the Chi-Square test. If more than 20% of expected cell counts were < 5, Fisher's Exact Test was used instead. A p-value < 0.05 was considered statistically significant. [b] Calculated with n = 16 due to two missing data points. [c] Calculated with n = 14 due to four missing data points. [d] Postoperative analgesic variables in the laparoscopic group were calculated with n = 17 because one data point was missing.

	RNF (n = 18)	LNF (n = 18)	Mean / Median Difference (95% CI)	Odds-Ratio (95% CI)	p Value [a]
Demographics					
Preparation time (min) total	104.7 (± 54.2)	68.8 (± 19.4)	35.9 (7.7–64.2)		**0.015**
First half	121.7 (± 61.3)		33.9 (-19.5–87.3)		0.195
Latter half	87.8 (± 42.9)				
3mm Instruments used	3 (16.7)	13 (72.2)			**< 0.001**
Postoperative					
Postoperative length of stay (days)	4 (3–5)	3 (2–6)	0 (-1–1)		0.457
Postoperative complications	3 (16.7%)	2 (11.1%)		1.6 (0.23–10.95)	1.000
Readmission	2 (11.1%)	1 (5.6%)		2.1 (0.18–25.78)	1.000
Reoperation	0 (0.0%)	0 (0.0%)			1.000
Anesthesia					
Anesthesia duration (min)	251.5 (231.0–272.3)	241.5 (223.5–284.0)	-1.0 (-33.0–30 – 0)		0.912
Absolute blood loss (ml)	15.0 (5.0–50.0)	10.0 (1.5–42.5)	3.0 (-10.0–20.0)		0.523
Relative blood loss (ml/kg body weight)	0.8 (0.2–2.0)	0.9 (0.1–3.4)	0.0 (-1.5–0.6)		0.874
Any postoperative VAS > 2	0 (0.0%) [b]	0 (0.0%) [b]			1.000

[a] Continuous variables were analyzed using Welch's t-test for normally distributed data or the Mann–Whitney U test for non-normally distributed data (asymptotic, two-sided p-values). Categorical variables were compared using the Chi-Square test. If more than 20% of expected cell counts were < 5, Fisher's Exact Test was used instead. A p-value < 0.05 was considered statistically significant. [b] Calculated with n = 16 due to two missing data points. [c] Calculated with n = 14 due to four missing data points. [d] Postoperative analgesic variables in the laparoscopic group were calculated with n = 17 because one data point was missing.

	RNF (n = 18)	LNF (n = 18)	Mean / Median Difference (95% CI)	Odds-Ratio (95% CI)	p Value [a]
Demographics					
Any positive NuDESC	0 (0.0%) [c]	0 (0.0%) [b]			1.000
Time in recovery room (min)	53.0 (31.5–63.3)	51.5 (26.8–67.0)	0.5 (-18.0–21.0)		0.975
AWR piritramide given	8 (44.4%)	7 (38.9%)		1.3 (0.33–4.74)	0.735
AWR piritramide dose (µg/kg body weight)	0.0 (0.0–47.9)	0.0 (0.0–96.0)	0.0 (-10.6–0.0)		0.860
Piritramide administered	12 (66.7%)	12 (70.6%) [d]		0.8 (0.20–3.49)	0.803
Total postoperative opioid days	1 (0–2)	1 (0–2) [d]	0.0 (-1.0–0.0)		0.701
Opioid-free days 0–48h	50 (0–100)	50 (0–100) [d]	0 (0–50)		0.833
Piritramide dose (µg/kg per 24h, 0–48h)	28.1 (0.0–88.7)	43.2 (0.0–94.7) [d]	0.0 (-43.5–25.0)		0.789
Piritramide intensity (µg/kg per 24h, on days with administration)	56.3 (0.0–109.3)	56.8 (0.0–168.8) [d]	0.0 – (-59.7–45.5)		0.776
Total postoperative analgesic days	4 (3–4)	3 (2–4) [d]	0 (0–1)		0.331
Paracetamol dose (mg/kg per 24h, 0–48h)	13.6 (3.6–29.8)	9.9 (5.5–20.1) [d]	2.2 (-5.6–15.0)		0.530
Ibuprofen dose (mg/kg per 24h, 0–48h)	0.0 (0.0–10.1)	0.0 (0.0–12.6) [d]	0.0 (-6.8–0.0)		0.666

[a] Continuous variables were analyzed using Welch's t-test for normally distributed data or the Mann–Whitney U test for non-normally distributed data (asymptotic, two-sided p-values). Categorical variables were compared using the Chi-Square test. If more than 20% of expected cell counts were < 5, Fisher's Exact Test was used instead. A p-value < 0.05 was considered statistically significant. [b] Calculated with n = 16 due to two missing data points. [c] Calculated with n = 14 due to four missing data points. [d] Postoperative analgesic variables in the laparoscopic group were calculated with n = 17 because one data point was missing.

	RNF (n = 18)	LNF (n = 18)	Mean / Median Difference (95% CI)	Odds-Ratio (95% CI)	p Value [a]
Demographics					
Metamizole dose (mg/kg per 24h, 0–48h)	40.7 (± 9.3)	31.4 (± 14.8) [d]	9.3 (0.7–18.0)		**0.036**

[a] Continuous variables were analyzed using Welch's t-test for normally distributed data or the Mann–Whitney U test for non-normally distributed data (asymptotic, two-sided p-values). Categorical variables were compared using the Chi-Square test. If more than 20% of expected cell counts were < 5, Fisher's Exact Test was used instead. A p-value < 0.05 was considered statistically significant. [b] Calculated with n = 16 due to two missing data points. [c] Calculated with n = 14 due to four missing data points. [d] Postoperative analgesic variables in the laparoscopic group were calculated with n = 17 because one data point was missing.

Intraoperative Outcomes

No intraoperative complications occurred in either cohort, and no procedure required conversion to an open approach. Conversion from RNF to conventional laparoscopy was necessary in three robotic cases (16.7%) due to procedure-specific limitations: restricted robotic arm mobility after docking (n = 1), interference of force feedback during initial dissection of the gastrohepatic ligament (n = 1), and limited instrument mobility during myotomy (n = 1).

Total operative time did not differ significantly between groups (robotic: 172.7 ± 51.5 min vs. laparoscopic: 168.8 ± 45.5 min; p = 0.809). In contrast, preparation time was significantly longer in the robotic cohort (104.7 ± 54.2 min vs. 68.8 ± 19.4 min; p = 0.015).

To explore potential learning effects, procedural times of the first nine robotic cases were compared with the last nine. Both operative time (188.3 ± 63.5 min vs. 157.1 ± 32.6 min) and preparation time (121.7 ± 61.3 min vs. 87.8 ± 42.9 min) decreased numerically over time, though these differences were not statistically significant (p = 0.214 and p = 0.195, respectively) (see Figs. 2 and 3).

Use of 3-mm instruments differed significantly between groups, being employed in 16.7% of robotic cases compared with 72.2% of laparoscopic procedures (p < 0.001).

Boxplots summarize the distribution of operative and preparation times in the early (Period 1) and later (Period 2) phases of the robotic program. Although both parameters showed lower median values in Period 2, the differences did not reach statistical significance (p = 0.214 and p = 0.195). Numeric labels next to outliers indicate the chronological case number of the respective robotic fundoplication. None of the upward outliers represent cases that required conversion

Postoperative Outcomes

Postoperative length of hospital stay was similar between groups, with a median of 4 days (IQR 3–5) following RNF and 3 days (IQR 2–6) after LNF (median difference 0 days; 95% CI − 1 to 1; p = 0.457).

Postoperative complications within 30 days were infrequent and did not differ significantly (robotic: 16.7% vs. laparoscopic: 11.1%; OR 1.6, 95% CI 0.23–10.95; p = 1.000). In the robotic cohort, one Grade II complication (postoperative fever requiring intravenous antibiotics) and two Grade IIIb complications (recurrent dysphagia requiring readmission and diagnostic endoscopy) were observed. All endoscopic evaluations confirmed intact fundoplication without evidence of stenosis, and symptoms resolved without further intervention. One patient later showed features suggestive of a functional or psychosomatic etiology. In the laparoscopic group, one Grade II complication occurred (localized trocar-site inflammation requiring antibiotics), and one patient was readmitted for suspected recurrent esophageal stenosis; endoscopy confirmed an intact fundoplication without intervention. In the laparoscopic group, two postoperative complications were recorded, including one Grade II complication (localized trocar-site inflammation requiring antibiotics) and one Grade IIIb complication (suspected recurrent esophageal stenosis requiring readmission and diagnostic endoscopy), with endoscopy confirming an intact fundoplication without further intervention required. Readmission rates were low and comparable between groups (robotic: 11.1% vs. laparoscopic: 5.6%; p = 1.000). No reoperations were required in either cohort (see Table 1).

Anesthesia-Related Outcomes

Anesthesia-related parameters were comparable between groups. Median anesthesia duration was 251.5 min (IQR 231.0–272.3) in the robotic cohort and 241.5 min (IQR 223.5–284.0) in the laparoscopic cohort (p = 0.912). Intraoperative blood loss was minimal and similar between approaches, both in absolute terms (15.0 mL vs. 10.0 mL; p = 0.523) and relative to body weight (0.8 vs. 0.9 mL/kg; p = 0.874).

Early postoperative recovery was favorable in both groups. During the postoperative time in the recovery room, no patient reported a VAS pain score > 2 or demonstrated a positive NuDESC screening. Time spent in the recovery room was comparable (53.0 min vs. 51.5 min; p = 0.975), as were rates of piritramide administration in the recovery room (44.4% vs. 38.9%; p = 0.735). Opioid dosing was zero-inflated due to the high number of patients not requiring opioids, with no significant differences between groups.

Postoperative analgesic requirements during the first 48 hours showed considerable variability within each cohort but were broadly comparable between the two approaches. Opioid use occurred with similar frequency, duration, and intensity. Non-opioid analgesic use was also comparable, except for metamizole, which was administered at higher doses in the robotic cohort (40.7 ± 9.3 mg/kg vs. 31.4 ± 14.8 mg/kg; p = 0.036) (see Table 1).

Discussion

This single-center, prospective cohort study provides a comprehensive, multidisciplinary evaluation of Senhance-assisted versus conventional laparoscopic Nissen fundoplication in a nonselected pediatric population, assessing intraoperative safety, operative workflow, anesthesia-related parameters and early postoperative recovery. Importantly, anesthesia outcomes were systematically and concomitantly assessed, a unique aspect not previously reported in pediatric robotic fundoplication studies [25–27]. Our findings demonstrate that robotic-assisted fundoplication using the Senhance® Surgical System (SSS®) is feasible and safe according to the predefined criteria, and functionally comparable to conventional laparoscopy, without increased postoperative morbidity, length of hospital stay, or anesthesia-related complications.

Patients in the robotic cohort were older and heavier, reflecting CE approval constraints (> 10 kg and > 1 year) and the chronological introduction of robotic surgery at our institution in 2022, rather than selective allocation based on disease severity. All eligible patients were offered robotic surgery, and the final decision was made by caregivers, thereby reducing surgeon-driven selection bias. While these differences may have influenced technical complexity and operative times, no adverse impact on intraoperative safety, postoperative outcomes, or recovery was observed, although residual confounding cannot be excluded. Comparable sex distribution and uniform surgical indications according to ESPGHAN guidelines further support valid inter-group comparisons. Similar cohort imbalances have been reported in other pediatric robotic series, for example by Killaars et al., who observed older and heavier robotic patients despite statistical matching [11, 19].

No intraoperative complications occurred in either cohort, and no conversion to open surgery was required. Early conversions from robotic to conventional laparoscopy occurred in three cases (16.7%) during the implementation phase, due to system- or workflow-related factors rather than patient anatomy, and decreased with experience, reflecting a learning curve. This aligns with Killaars et al., who reported lower conversion rates in later series [12], highlighting that early conversion serves as a safety measure rather than a failure of robotic technique [9, 14]. Operative times were comparable between RNF and LNF (172.7 ± 51.5 min vs. 168.8 ± 45.5 min; $p = 0.809$), while preparation was longer for robotic cases (104.7 ± 54.2 min vs. 68.8 ± 19.4 min; $p = 0.015$), reflecting additional setup and team coordination. Within the robotic cohort, both preparation (− 33.9 min) and operative times (− 31.2 min) decreased between the first and last nine cases, indicating a clinically relevant learning effect, consistent with prior pediatric and adult reports [11, 12, 20–23]. Lack of statistical significance likely reflects the limited sample size, a common limitation in early pediatric robotic series [8, 12].

Technical evaluation revealed significantly lower use of 3-mm instruments in robotic cases (16.7% vs. 72.2%; $p < 0.001$). Although supported by the Senhance® system, limited availability and ergonomic constraints were evident, particularly during complex foregut maneuvers in smaller children, indicating that robotic systems do not yet fully replace advanced laparoscopic techniques across all pediatric age groups. Nevertheless, Senhance-specific features features – including haptic feedback, digital fulcrum control, and flexible port placement – enabled precise dissection and construction of the fundoplication,

demonstrating that the system can address pediatric-specific surgical challenges despite instrument limitations [10, 11, 24].

Postoperative outcomes were favorable and comparable, with similar length of stay, complication rates, readmissions, and reoperations. In the robotic cohort, Clavien-Dindo grade IIIb events were diagnostic, resolved without intervention, and unrelated to technical failure. Endoscopic evaluation confirmed intact fundoplications, supporting functional safety even during early implementation [3–5, 11–13, 20].

A key strength of this study is the systematic evaluation of anesthesia-related outcomes, rarely addressed in prior work. Median anesthesia duration, intraoperative blood loss, recovery-room time, and perioperative analgesic use were similar between cohorts despite longer robotic preparation. Postoperative recovery was equally favorable, with low pain scores (VAS), minimal opioid use, and no positive delirium screenings (NuDESC), indicating good tolerability without additional physiological burden. Non-opioid analgesic use was generally low, though metamizole doses were slightly higher in robotic cases, while opioid consumption was not significantly different and numerically higher in the laparoscopic group, suggesting a possible shift toward non-opioid analgesia. Overall, robotic assistance in our setting did not increase perioperative anesthetic risk, extending prior observations [25–27].

The study's prospective design with consecutive patient inclusion minimized selection bias, and all procedures were performed by a single experienced pediatric surgeon, reducing inter-operator variability. By integrating intraoperative, postoperative, and anesthesia-related outcomes with functional and robotic workflow parameters, it provides a comprehensive evaluation of Senhance-assisted pediatric fundoplication. Analysis of preparation and operative times confirms a learning curve, supporting safe early adoption, while standardized surgical technique and systematic documentation of robotic-specific considerations enhance reproducibility and practical applicability.

Limitations include the single-center setting, small cohort size, and non-randomized design, which may restrict generalizability. Differences in age and weight were incidental, reflecting regulatory and chronological factors, and minor residual confounding cannot be excluded. The limited sample size also precluded formal matching, reducing the power to detect subtle differences or rare complications, including nuanced anesthesia-related effects.

Despite these limitations, this study provides robust early evidence that Senhance®-assisted pediatric fundoplication is safe, effective, and reproducible, demonstrating both technical feasibility and functional safety. By integrating multidimensional perioperative outcomes with objective learning-curve analysis, it addresses gaps in the literature where previous reports focused primarily on surgical endpoints without structured evaluation of anesthesia or workflow [8, 10–13, 25–27]. Clinically, the findings support robotic assistance as a feasible alternative to conventional minimally invasive pediatric surgery, with careful patient selection, structured multidisciplinary training, and protocolized workflows ensuring safety and efficiency. Functional equivalence to conventional laparoscopy, combined with technical advantages of the robotic platform, suggests particular benefit for selected patients and institutional settings.

Future research should focus on larger multicenter, ideally randomized studies, long-term functional and quality-of-life outcomes, cost-effectiveness analyses, and formal modeling of learning curves across institutions and varying surgeon experience. To address the current paucity of multicenter pediatric robotic data, the Asensus® Paediatric Robotic Registry (also referred to as the Asensus®-Mini-Trust Register) was established to collect prospective clinical data on robotically assisted pediatric endoscopic procedures and facilitate international collaboration [28]. Such studies will be essential to define the optimal role of robotic platforms, guide evidence-based practice, and inform future pediatric surgical guidelines.

Conclusion

In conclusion, Senhance®-assisted pediatric Nissen fundoplication is safe, effective, and functionally comparable to conventional laparoscopy. Multidimensional evaluation demonstrates feasibility, reproducibility, and manageable learning curves, even during early implementation. Despite the single-center design and small cohort, structured workflows and team training enable safe adoption. Ongoing multicenter efforts, including the Asensus® Paediatric Robotic Registry, will be crucial to define long-term outcomes and guide evidence-based pediatric robotic surgery.

Declarations

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Compliance with Ethical Standards

Conflicts of Interest: The authors declare no competing interests..

Ethics approval: The study was conducted in line with the principles of the Declaration of Helsinki. The study protocol was approved by the institutional ethics committee (Ethics Committee of the local faculty of medicine, project number 24-0349).

Consent to participate: Written informed consent was obtained from patients and their legal guardians in accordance with age-specific and institutional regulations.

Data availability: Data supporting the results of this study can be obtained from the corresponding author upon reasonable request and after execution of an appropriate data-sharing agreement.

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Figures

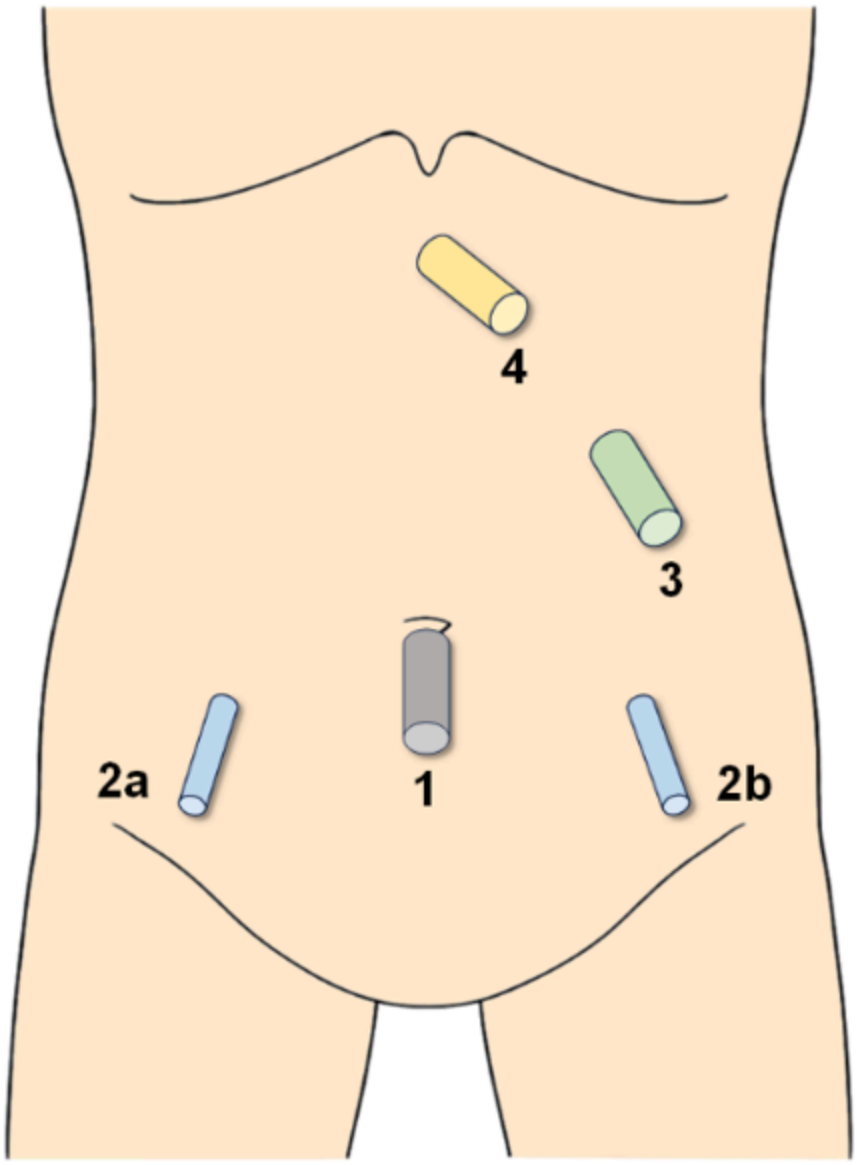


Figure 1

Schematic depiction of the standardized five-port trocar placement for robotic fundoplication. The setup included a 5-mm robotic camera port (1), two robotic instrument ports (2a, 2b), a 5-mm assistant port (3), and a subxiphoid port (4). The illustration is not drawn to scale

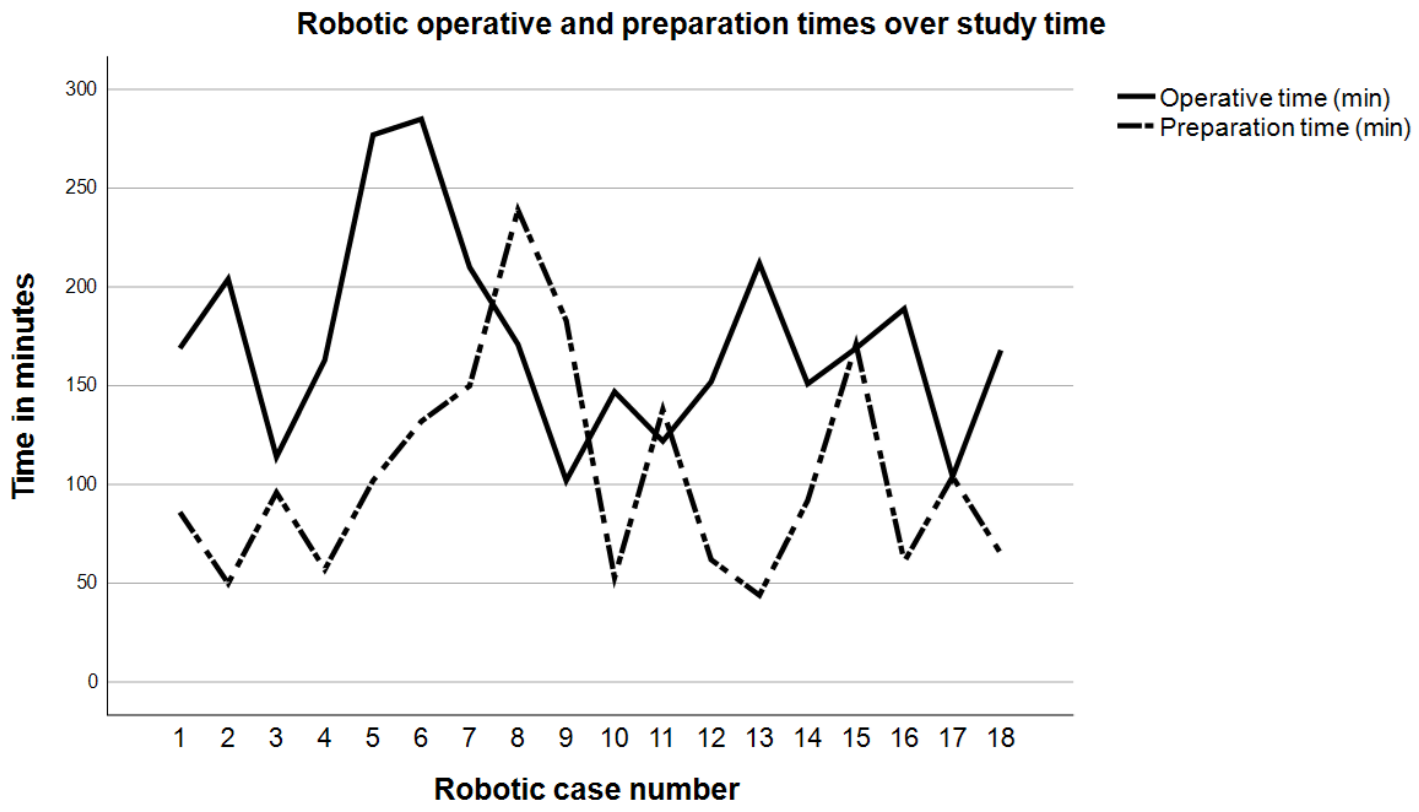


Figure 2

Time course of operative and preparation durations across all 18 robotic fundoplication cases. Each point represents an individual procedure plotted in chronological order. The graph highlights substantial variability during the early cases, followed by a trend toward more stable values with increasing procedural experience

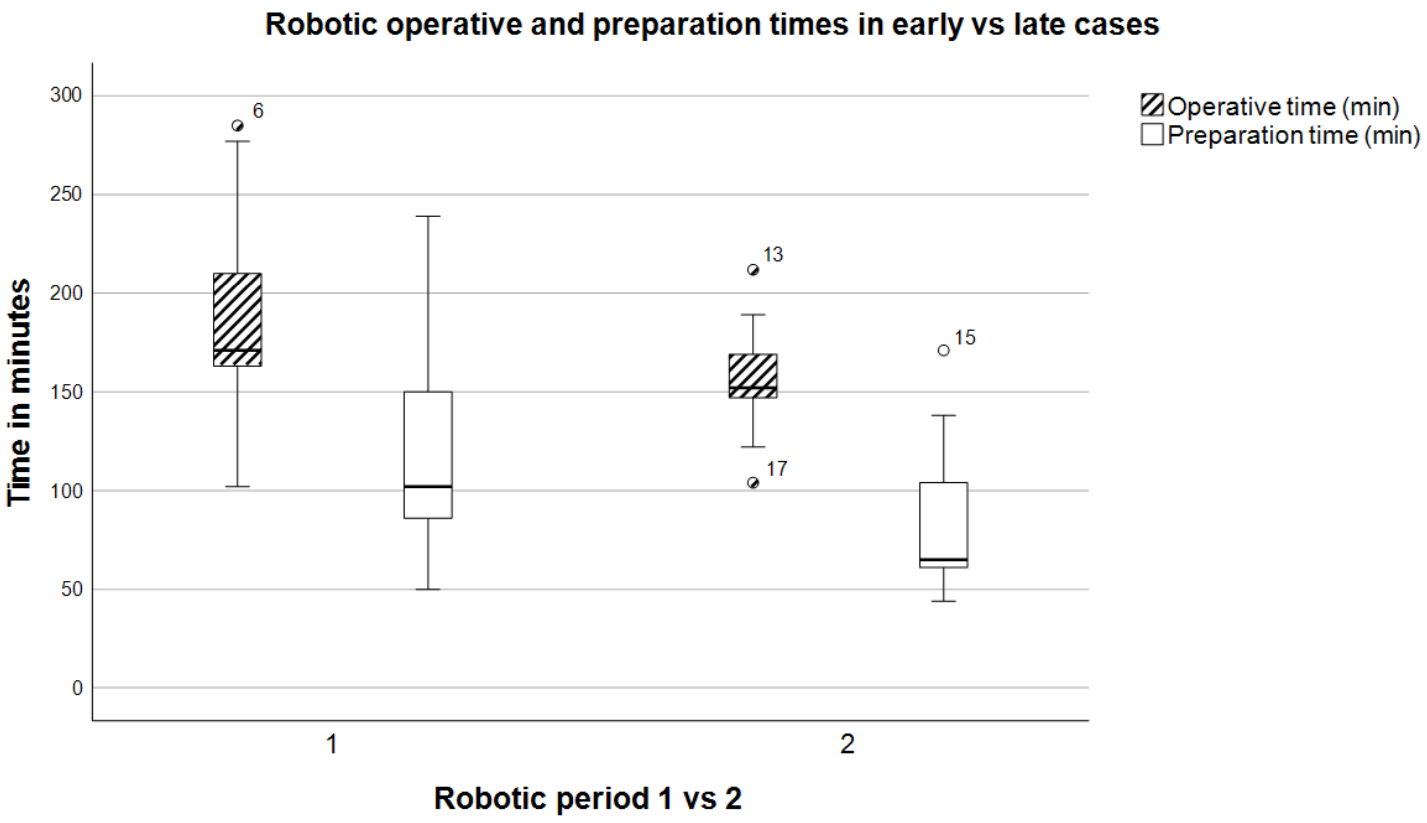


Figure 3

Comparison of intraoperative time metrics between the first nine and last nine robotic cases. Boxplots summarize the distribution of operative and preparation times in the early (Period 1) and later (Period 2) phases of the robotic program. Although both parameters showed lower median values in Period 2, the differences did not reach statistical significance ($p = 0.214$ and $p = 0.195$). Numeric labels next to outliers indicate the chronological case number of the respective robotic fundoplication. None of the upward outliers represent cases that required conversion