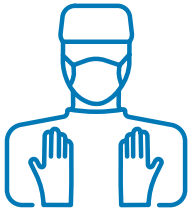
Senhance® Pediatrics Clinical Evidence Compendium

MARCH 2025

Study outcomes including:



Surgeon Benefits (Efficiency & Ergonomics)

Patient Outcomes

Economics

Clinical Utility of Augmented Intelligence and Performance Guided Surgery

Pediatrics Clinical Evidence

Author/Year	Study Title	Study Outcomes
Krebs, et al. Children. 2022 Jun 6.	Robotically Assisted Surgery in Children—A Perspective [30]	
Holzer, et al. Children. 2022 Mar;9(3):302.	First Pediatric Pyeloplasty Using the Senhance® Robotic System—A Case Report[31]	
Puentes, et al. Children. 2023 Jan 18;10(2):178.	Senhance Robotic Platform in Pediatrics: Early US Experience[34]	
Killaars, et al. Children (Basel). 2024 Jan 17;11(1):112.	Robotic-Assisted Nissen Fundoplication in Pediatric Patients: A Matched Cohort Study[46]	
Killaars REM,et al. Children (Basel). 2024 Jul 31;11(8):935.	Robotic-Assisted Surgery in Children Using the Senhance Surgical System: An Observational Study[56]	
Kato D, et al. Asian J Endosc Surg. 2024 Oct;17(4):e13379.	First pediatric pelvic surgery with the Senhance robotic surgical system: A case series[57]	
Eurlings R, et al. Healthcare (Basel). 2024 Aug 26;12(17):1703.	First Results of Pediatric Robotic Inguinal Hernia Repair with the Senhance® Surgical System: A Matched Cohort Study[58]	
Bergholz R, et al. J Robot Surg. 2020 Feb;14(1):191-197.	Evaluation of a new robotic-assisted laparoscopic surgical system for procedures in small cavities[59]	
Krebs TF, et al. J Robot Surg. 2022 Feb;16(1):215-228.	Robotic infant surgery with 3 mm instruments: a study in piglets of less than 10 kg body weight[60]	

Study Overviews

Robotically Assisted Surgery in Children —A Perspective[30]

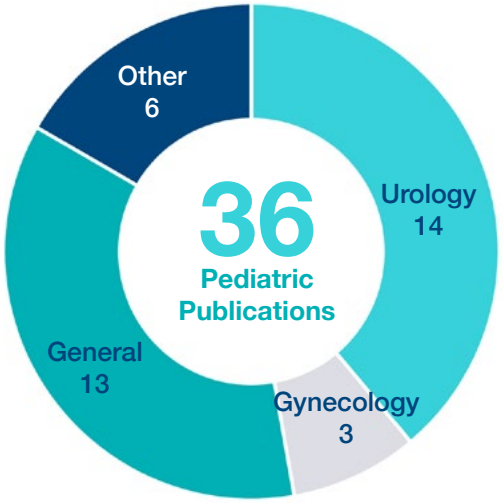
Krebs, et al. Children. 2022 Jun 6.

Overview

The introduction of robotically assisted surgery was a milestone for minimally invasive surgery in the 21st century. Currently, there are two FDA-approved robotically assisted surgery systems for use and development in pediatrics. Specifically, tremor filtration and optimal visualization are approaches which can have enormous benefits for procedures in small bodies. Robotically assisted surgery in children might have advantages compared to laparoscopic or open approaches. This review focuses on the research literature regarding robotically assisted surgery that has been published within the past decade. A literature search was conducted to identify studies comparing robotically assisted surgery with laparoscopic and open approaches. While reported applications in urology were the most cited, three other fields (gynecology, general surgery, and “others”) were also identified.

Conclusion

In total, 36 of the publications reviewed suggested that robotically assisted surgery was a good alternative for pediatric procedures. After several years of experience of this surgery, a strong learning curve was evident in the literature. However, some authors have highlighted limitations, such as high cost and a limited spectrum of small-sized instruments. The recent introduction of reusable 3 mm instruments to the market might help to overcome these limitations. In the future, it can be anticipated that there will be a broader range of applications for robotically assisted surgery in selected pediatric surgeries, especially as surgical skills continue to improve and further system innovations emerge.



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First Pediatric Pyeloplasty Using the Senhance® Robotic System—A Case Report[31]

Holzer, et al. Children. 2022 Mar;9(3):302.

Pyeloplasty

Overview

A pediatric robotic pyeloplasty has been performed with the Senhance® robotic system for the first time in January 2021 on a 1.5-year-old girl with symptomatic ureteropelvic junction stenosis. A Senhance® robotic system (Asensus Surgical® Inc., Durham, NC, USA) with three arms and 5 mm instruments was used, providing infrared eye tracking of the 5 mm camera and haptic feedback for the surgeon, facilitating suturing of the anastomosis and double-J stent insertion.

Conclusion

The use of the robotic system was shown to be safe and feasible; long term follow-up will be conducted subsequently in pediatric surgery.

Key Results

The robotic surgery lasted 4.5 h, was uneventful and successful, without recurrence of the ureteropelvic junction obstruction after six months, and with normal development of the patient's growth and organ function.

Senhance Robotic Platform in Pediatrics: Early US Experience[34]

Puentes, et al. Children. 2023 Jan 18;10(2):178.

Cholecystectomy, Inguinal Herniorrhaphy, Orchidopexy, Cyst Exploration

Overview

Introduction: Different robotic systems have been used widely in human surgery since 2000, but pediatric patients require some features that are lacking in the most frequently used robotic systems. Hypothesis: The Senhance® robotic system is a safe and an effective device for use in infants and children that has some advantages over other robotic systems. Methods: All patients between 0 and 18 years of age whose surgery was amenable to laparoscopy were offered enrollment in this IRB-approved study. We assessed the feasibility, ease and safety of using this robotic platform in pediatric patients including: set-up time, operative time, conversions, complications and outcomes.

Conclusion

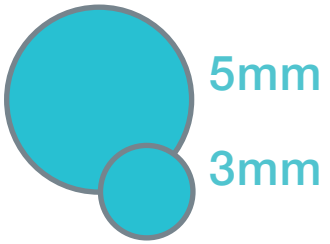
Our initial experience with the Senhance® robotic platform suggests that this is a safe and effective device for pediatric surgery that is easy to use, and which warrants continued evaluation. Most importantly, there appears to be no lower age or weight restrictions to its use.

Key Results

Eight patients, ranging from 4 months to 17 years of age and weighing between 8 and 130 kg underwent a variety of procedures including: cholecystectomy (3), inguinal herniorrhaphy (3), orchidopexy for undescended testes (1) and exploration for a suspected enteric duplication cyst (1). All robotic procedures were successfully performed. The 4-month-old (mo), 8 kg patient underwent an uneventful robotic exploration in an attempt to locate a cyst that was hidden in the mesentery at the junction of the terminal ileum and cecum, but ultimately the patient required an anticipated laparotomy to palpate the cyst definitively and to excise it completely. There was no blood loss and no complications. Robotic manipulation with the reusable 3 mm instruments proved successful in all cases.

0
complications

0
blood loss



Successful robotic manipulation with 3mm instruments

Robotic-Assisted Nissen Fundoplication in Pediatric Patients: A Matched Cohort Study[46]

Killaars, et al. Children (Basel). 2024 Jan 17;11(1):112.

Nissen Fundoplication

Background

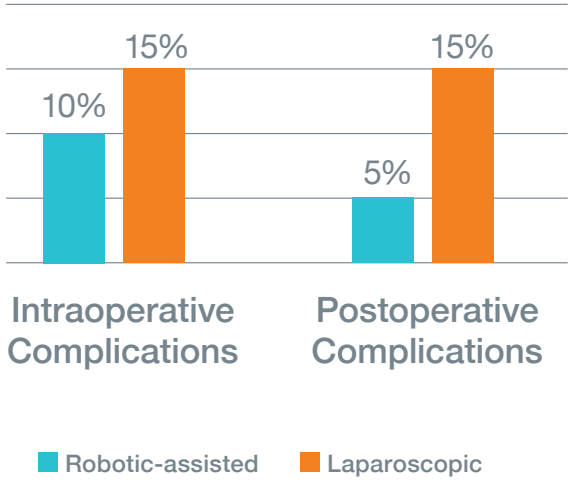
Nissen Fundoplication (NF) is a frequently performed procedure in children. Robotic-assisted Nissen Fundoplication (RNF), with the utilization of the Senhance® Surgical System (SSS®) (Asensus Surgical® Inc., Durham, NC, USA) featuring 3 mm instruments, aims to improve precision and safety in pediatric surgery. This matched cohort study assesses the safety and feasibility of RNF in children using the SSS®, comparing it with Laparoscopic Nissen Fundoplication (LNF).

Methods and results

Twenty children underwent RNF with the SSS® between 2020 to 2023 and were 1:1 matched with twenty LNF cases retrospectively selected from 2014 to 2023. Both groups were similar regarding male/female ratio, age, and weight. Two of the twenty RNF cases (10%) experienced intraoperative complications, whereas three in the LNF group of whom two required reinterventions. The observed percentage of postoperative complications was 5% in the RNF group compared to 15% in the LNF group ($p = 0.625$). The operative times in the RNF group significantly dropped towards the second study period ($p = 0.024$).

Conclusions

Utilizing SSS® for NF procedures in children is safe and feasible. Observational results may tentatively suggest that growing experiences and continued development will lead to better outcomes based on more accurate and safe surgery for children.



Utilizing Senhance Surgical System for Nissen Fundoplication procedures in children is safe and feasible.

NEW

Robotic-Assisted Surgery in Children Using the Senhance Surgical System: An Observational Study[56]

Killaars REM,et al. Children (Basel). 2024 Jul 31;11(8):935.

Background

Robotic-assisted surgery (RAS) holds many theoretical advantages, especially in pediatric surgical procedures. However, most robotic systems are dedicated to adult surgery and are less suitable for smaller children. The Senhance® Surgical System (SSS®), providing 3 mm and 5 mm instruments, focuses on making RAS technically feasible for smaller children. This prospective observational study aims to assess whether RAS in pediatric patients using the SSS® is safe and feasible.

Methods and results

A total of 42 children (aged 0-17 years, weight ≥ 10 kg) underwent a RAS procedure on the abdominal area using the SSS® between 2020 and 2023. The study group consisted of 20 male and 22 female individuals. The mean age was 10.7 years (range 0.8 to 17.8 years), with a mean body weight of 40.7 kg (range 10.1 to 117.3 kg). The 3-mm-sized instruments of the SSS® were used in 12 of the 42 children who underwent RAS. The RAS procedures were successfully completed in 90% of cases. The conversion rate to conventional laparoscopy was low (10%), and there were no conversions to open surgery. One of the 42 cases (2%) experienced intraoperative complications, whereas six children (14%) suffered from a postoperative complication. Overall, 86% of the patients had an uncomplicated postoperative course.

Conclusions

The results of the current observational study demonstrate the safety and feasibility of utilizing the SSS® for abdominal pediatric RAS procedures. The study provides new fundamental information supporting the implementation of the SSS® in clinical practice in pediatric surgery.

	Mean Age (years)	Mean Weight (kg)
Nissen fundoplication (n=11)	10	37.2
Inguinal hernia repair (n=10)	6.3	24.7
Cholecystectomy (n=5)	14.9	69.9
Appendectomy (n=4)	10.7	38.8
Ileocecal resection (n=2)	15.8	54
Ladd's procedure and appendectomy (n=2)	10.9	42.5
Cecostomy (n=2)	14.7	41.6
Heller-Dor procedure (n=2)	11.6	36.1
Other (n=4)		

NEW

First pediatric pelvic surgery with the Senhance robotic surgical system: A case series[57]

Kato D, et al. Asian J Endosc Surg. 2024 Oct;17(4):e13379.

Anorectoplasty, Rectal pull-through

Overview

The Senhance® robotic system (Senhance [Asensus Surgical Inc., Naderhan, NC, USA]) is a new surgical assistive robot following the da Vinci Surgical System that has been demonstrated to be safe and efficacious. Herein, we report the first case series of pediatric pelvic surgery using Senhance.

Key Results

Two anorectoplasties and one rectal pull-through coloanal anastomosis for rectal stenosis were performed in three children (5-9 months, 7-9 kg) using a 10-mm three-dimensional (3D) 4K camera and 3 and 5 mm forceps operated with Senhance. None of the patients had intraoperative complications or a good postoperative course.

Conclusions

Pediatric pelvic surgery with Senhance could be performed precisely and safely with a small body cavity. With its beautiful 3D images, motion of forceps with reduced tremor, and availability of 3-mm forceps, Senhance may be better suited for children compared with other models.

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NEW

First Results of Pediatric Robotic Inguinal Hernia Repair with the Senhance® Surgical System: A Matched Cohort Study[58]

Eurlings R, et al. Healthcare (Basel). 2024 Aug 26;12(17):1703.

Inguinal Hernia

Introduction

Inguinal hernia repair (IHR) is one of the most common procedures in pediatric surgery. In children, the application of robotic surgery is limited, meaning safety and efficacy is still to be assessed. This report is the first one worldwide that describes inguinal hernia repair in children using the Senhance® Surgical System (SSS®). The aim of this matched cohort study is to assess safety and feasibility of robot-assisted IHR (RIHR) in children, compared to conventional laparoscopic IHR (LIHR).

Patients and methods

This pilot study included 26 consecutive patients between 3 months and 8 years old who underwent RIHR (31 IH's) with the SSS® between 2020 and 2024. These cases were matched based on gender, age, and unilateral or bilateral IH, with 26 patients (32 IH's) who underwent conventional LIHR.

Results

There was a significant difference in total anesthesia time, which is most likely due to the extra time needed to dock the robot in the RIHR cases. No significant difference was seen in surgical time. One recurrence (3.2%) was diagnosed in both groups. One patient in the LIHR group was readmitted on the day of discharge due to a hemorrhage. No intervention was necessary, and the patient was discharged 1 day later.

Discussion

In this pilot study, the use of the robotic system was safe and feasible. More experience, further improvement of the system for use in very small children, and investigation in a larger sample size with long-term follow-up is necessary to evaluate efficacy.

	No Significant Differences between Robotic & Laparoscopic
Net-surgical time	✓
Conversion to open	✓
Postoperative hospital stay	✓
Readmission within 30 days	✓
Recurrence	✓
Other complications	✓

NEW

Evaluation of a new robotic-assisted laparoscopic surgical system for procedures in small cavities[59]

Bergholz R, et al. J Robot Surg. 2020 Feb;14(1):191-197.

Abstract

No data exists concerning the application of a new robotic system with 3-mm instruments (Senhance™, Transenterix, Milano, Italy) in small cavities. Therefore, the aim of this study was to test the system for its performance of intracorporal suturing in small boxes simulating small body cavities. Translucent plastic boxes of decreasing volumes (2519-90 ml) were used. The procedures (two single stitches, each with two consecutive surgical square knots) were performed by a system-experienced and three system-inexperienced surgeons in each box, starting within the largest box, consecutively exchanging the boxes into smaller ones. With this approach, the total amount of procedures performed by each surgeon increased with decreasing volume of boxes being operated in. Outcomes included port placement, time, task completion, internal and external instrument/instrument collisions and instrument/box collisions. The procedures could be performed in all boxes. The operating time decreased gradually in the first three boxes (2519-853 ml), demonstrating a learning curve. The increase of operating time from boxes of 599 ml and lower may be attributed to the increased complexity of the procedure in small cavities as in the smallest box with the dimensions of 2.9 × 6.3 × 4.9 cm. This is also reflected by the parallel increase of internal instrument-instrument collisions. With the introduction of 3-mm instruments in a new robotic surgical system, we were able to perform intracorporal suturing and knot tying in cavities as small as 90 ml. Whether this system is comparable to conventional three-port 3-mm laparoscopic surgery in small cavities-such as in pediatric surgery-has to be evaluated in further studies.

NEW

Robotic infant surgery with 3 mm instruments: a study in piglets of less than 10 kg body weight[60]

Krebs TF, et al. J Robot Surg. 2022 Feb;16(1):215-228.

Abstract

No data exist concerning the appication of a new robotic system with 3 mm instruments (Senhance®, Transenterix) in infants and small children. Therefore, the aim of this study was to test the system for its feasibility, performance and safety of robotic pediatric abdominal and thoracic surgery in piglets simulating infants with a body weight lower than 10 kg. 34 procedures (from explorative laparoscopy to thoracoscopic esophageal repair) were performed in 12 piglets with a median age of 23 (interquartile range: 12-28) days and a median body weight of 6.9 (6.1-7.3) kg. The Senhance® robotic system was used with 3 mm instruments, a 10 mm 3D 0° or 30° videoscope and advanced energy devices, the setup consisted of the master console and three separate arms. The amount, size, and position of the applied ports, their distance as well as the distance between the three operator arms of the robot, external and internal collisions, and complications of the procedures were recorded and analyzed. We were able to perform all planned surgical procedures with 3 mm robotic instruments in piglets with a median body weight of less than 7 kg. We encountered two non-robot associated complications (bleeding from the inferior caval and hepatic vein) which led to termination of the live procedures. Technical limitations were the reaction time and speed of robotic camera movement with eye tracking, the excessive bending of the 3 mm instruments and intermittent need of re-calibration of the fulcrum point. Robotic newborn and infant surgery appears technically feasible with the Senhance® system. Software adjustments for camera movement and sensitivity of the fulcrum point calibration algorithm to adjust for the increased compliance of the abdominal wall of infants, therefore reducing the bending of the instruments, need to be implemented by the manufacturer as a result of our study. To further evaluate the Senhance® system, prospective trials comparing it to open, laparoscopic and other robotic systems are needed.

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