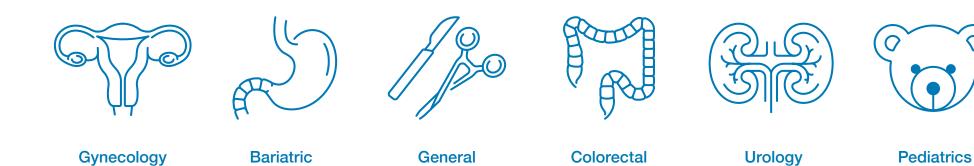




# Senhance® Clinical Evidence Compendium

**MAY 2024** 

#### Publications across multiple specialties including:



#### Study outcomes including:





**Outcomes** 



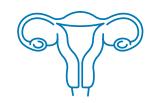


**Economics** 

Clinical Utility of Augmented Intelligence and Performance Guided Surgery



#### **Gynecology Clinical Evidence**



Author/Year	Study Title	Study Outcomes
Fanfani, et al. J Minim Invasive Gynecol. Sep-Oct 2015;22(6):1011-7.	TELELAP ALF-X Robotic-assisted Laparoscopic Hysterectomy: Feasibility and Perioperative Outcomes <sup>8</sup>	
Fanfani, et al. Surg Endosc. 2016 Jan;30(1):215-21.	The New Robotic Telelap Alf-X In Gynecological Surgery: Single-Center Experience9	
Coussons, et al. Int J Med Robot. 2021 Aug;17(4):e2261	Senhance® Surgical System in Benign Hysterectomy: A Real-World Comparative Assessment of Case Times and Instrument Costs vs Da Vinci Robotics and Laparoscopic Assisted Vaginal Hysterectomy Procedures <sup>5</sup>	
Alletti, et al. J Robot Surg. 2018 Jun;12(2):229-234.	The Senhance™ Surgical Robotic System ("Senhance") for Total  Hysterectomy in Obese Patients: A Pilot Study²	
Alletti, et al. J Minim Invasive Gynecology, Mar-Apr 2016;23(3):378:83.	Telelap ALF-X vs Standard Laparoscopy for the Treatment of Early-Stage Endometrial Cancer: A Single-Institution Retrospective Cohort Study <sup>3</sup>	
Fanfani, et al. J Minim Invasive gnecology, Sep-Oct 2016;23(6):933-8.	Total Laparoscopic (S-LPS) Versus TELELAP ALF-X Robotic-Assisted  Hysterectomy: A Case-Control Study <sup>Z</sup>	
McCarus, et al. JSLS. Jan-Mar 2021;25(1)	Senhance® Robotic Platform System for Gynecological Surgery <sup>14</sup>	
Rossitto, et al. Int J Med Robot. 2016 Dec;12(4):613-619.	Use of Robot-Specific Resources and Operating Room Times: The Case of Telelap Alf-X Robotic Hysterectomy <sup>15</sup>	
Stephan, et al. Surg Technol Int. 2021 May 20;38:103-107.	The TransEnterix European Patient Registry for Robotic-Assisted  Laparoscopic Procedures in Urology, Abdominal, Thoracic, and Gynecologic  Surgery ("TRUST") <sup>21</sup>	
Sassani, et al. Int Urogynecol J. 2022 Mar 21.	Sacrocolpopexy Experience with a Novel Robotic Surgical Platform 27	
Glass Clark, et al. Int Urogynecol J. 2023 Jan;34(1):87-91.	Surgical Cost of Robotic-Assisted Sacrocolpopexy: A Comparison of Two Robotic Platforms <sup>32</sup>	



#### **Bariatric Clinical Evidence**



Author/Year	Study Title	Study Outcomes
Khitaryan AG, et al. Khirurgiia (Mosk). 2023;(11):82-88.	The first experience of robot-assisted bariatric surgery using the Senhance system in patients with morbid obesity <sup>37</sup>	
Tran, et al. JSLS. 2024 Jan-Mar;28(1). e2023.00031.	Early Experience with the Senhance Surgical System in Bariatric Surgery <sup>38</sup>	



#### **General Surgery Clinical Evidence**



Author/Year	Study Title	Study Outcomes
Samalavicius, et al. Hernia. 2021 Sep 30.	Inguinal Hernia Tapp Repair Using Senhance® Robotic Platform: First Multicenter Report from the Trust Registry <sup>17</sup>	
Stephan, et al. Visceral Med 2018 Feb;34(1):31-36.	First Experiences with the New Senhance® Telerobotic System in Visceral Surgery23	
Samalavicius, et al. Acta Chir Belg. 2021 Feb 5:1-4.	Robotic Cholecystectomy Using Senhance® Robotic Platform Versus Laparoscopic Conventional Cholecystectomy: A Propensity Score Analysis18	
Schmitz, et al. Surg Technol Int. 2019 Nov 10;35:113-119.	Robotic-Assisted Nissen Fundoplication with the Senhance® Surgical System: Technical Aspects and Early Results19	
Stephan, et al. Surg Technol Int. 2021 May 20;38:103-107.	The TransEnterix European Patient Registry for Robotic-Assisted  Laparoscopic Procedures in Urology, Abdominal, Thoracic, and Gynecologic  Surgery ("TRUST") <sup>21</sup>	
Stephan, et al. Surg Technol Int. 2020 Nov 28;37:63-67.	First Clinical Use of 5 mm Articulating Instruments with the Senhance®_Robotic System <sup>22</sup>	
Montlouis-Calixte, et al. J Robot Surg. 2019 Oct;13(5):643-647.	Senhance® 3-mm Robot-Assisted Surgery: Experience on First 14 Patients in France4	
Aggarwal, et al. Surg Innov. 2020 Apr;27(2):136-142.	Initial Experience with a New Robotic Surgical System for Cholecystectomy <sup>1</sup>	
Schmitz, et al. Surg Technol Int. 2019 May 15;34:243-249.	Robotic Inguinal Hernia Repair (TAPP)— First Experience with the New Senhance™ Robotic System <sup>20</sup>	
Samalavicius, et al. J Robot Surg. 2020 Apr;14(2):371-376.	Robotic Surgery Using Senhance® Robotic Platform: Single Center Experience with First 100 Cases <sup>16</sup>	
Sasaki, et al. Asian J Endosc Surg. 2023 Apr;16(2):225-232.	Initial 30 Cholecystectomy Procedures Performed with the Senhance Digital Laparoscopy System <sup>33</sup>	



#### **General Surgery Clinical Evidence, cont.**



Author/Year	Study Title	Study Outcomes
Staib, et al. Surg Technol Int. 2023 Jul 18:42:sti42/1662.	Safety in Senhance™ Robotic Gastrointestinal Surgery in 530 Patients <sup>39</sup>	
Menke, et al. Surg Endosc. 2023 Nov;37(11):8254-8262.	Learning curves and procedural times in Senhance®-robotic assisted fundoplication: results from 237 consecutive patients undergoing robotic fundoplication in a single center as part of the European TRUST Robotic Surgery Registry Study <sup>40</sup> .	
Menke, et al. J Robot Surg. 2024 Feb 28;18(1):94.	The stress for surgeons: exploring stress entities with the robotic senhance surgical system <sup>41</sup>	



#### **Colorectal Clinical Evidence**



Author/Year	Study Title	Study Outcomes
Darwich, et al. J Robot Surg. 2020 Apr;14(2):297-304.	A Roadmap for Robotic-Assisted Sigmoid Resection in Diverticular Disease Using a Senhance® Surgical Robotic System: Results and Technical Aspects®	
Hirano, et al. Tech Coloproctol. 2021 Apr;25(4):467-471.	Robot-Assisted Surgery with Senhance® Robotic System for Colon Cancer: Our Original Single-incision Plus 2-Port Procedure and a Review of the Literature <sup>10</sup>	
Lin, et al. Int J Med Robot. 2021 Apr;17(2):e2206.	An Early Experience with the Senhance® Surgical Robotic System in Colorectal Surgery: A Single-Institute Study13	
Samalavicius, et al. Tech Coloproctol 2022 Jun;26(6):437-442.	Robotic Colorectal Surgery Using the Senhance® Robotic System: A Single Center Experience26	
Sasaki, et al. Asian J Endosc Surg. 2022 Jul;15(3):613-618.	Short-Term Results of Robot-Assisted Colorectal Cancer Surgery Using Senhance Digital Laparoscopy System <sup>29</sup>	
Khitaryan, et al. Coloproctology. 2023; vol.22, no.4, p.89-98.	The first experience of using robot-assisted ventral rectopexy with a mesh implant using the Senhance system in the treatment of patients with obstructive defecation syndrome <sup>42</sup>	



#### **Urology Clinical Evidence**



Author/Year	Study Title	Study Outcomes
Kaneko, et al. Int Cancer Conf J. 2021 Apr 29;10(3):228-232.	Initial Experience of Laparoscopic Radical Nephrectomy Using the Senhance® Robotic System for Renal Cell Carcinoma <sup>11</sup>	
Kastelan, et al. Int J Med Robot. 2021 Aug;17(4):e2269.	Upper Urinary Tract Surgery and Radical Prostatectomy with Senhance® Robotic System: Single Center Experience- First 100 Cases <sup>12</sup>	
Venckus, et al. World J Urol. 2021 Dec;39(12):4305-4310.	Robotic-Assisted Radical Prostatectomy with the Senhance® Robotic Platform: Single Center Experience <sup>24</sup>	
Stephan, et al. Surg Technol Int. 2021 May 20;38:103-107.	The TransEnterix European Patient Registry for Robotic-Assisted  Laparoscopic Procedures in Urology, Abdominal, Thoracic, and Gynecologic  Surgery ("TRUST") <sup>21</sup>	
Kulis, et al. Int J Med Robot. 2022 Feb; 18(1):e2344.	Comparison of Extraperitoneal Laparoscopic and Extraperitoneal Senhance Radical Prostatectomy <sup>25</sup>	
Lin, et al. Journal of Urology. 2022 May 1.	Transperitoneal Radical Prostatectomy Using the Senhance Robotic System: Initial Case Series, Learning Curve and Cost Analysis 28	
Kulis, et al. Acta Clin Croat. 2022 Oct;61(Suppl 3):45-50.	Senhance Robotic Radical Prostatectomy <sup>35</sup>	
Bačak Kocman, et al. Acta Clin Croat. 2022 Oct;61(Suppl 3):76-80.	Anesthesia for Robot-Assisted Radical Prostatectomy - A Challenge for Anaesthesiologist <sup>36</sup>	
Hudolin, et al. Int J Med Robot. 2023 Dec;19(6):e2549.	Senhance robotic radical prostatectomy: A single-centre, 3-year experience <sup>43</sup>	
Lin, et al. Prostate Cancer Prostatic Dis. 2024 Mar;27(1):116-121.	Comparison of Senhance and Da Vinci Robotic Radical Prostatectomy:  Short-term Outcomes, Learning Curve, and Cost Analysis <sup>44</sup>	
Kulis, et al. Wold J Urol. 2024 Jan 20;42(1):39.	Robotic-assisted radical prostatectomy: a multicenter experience with the Senhance Surgical System <sup>45</sup>	



#### **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 <sup>31</sup>	
Puentes, et al. Children. 2023 Jan 18;10(2):178.	Senhance Robotic Platform in Pediatrics: Early US Experience <sup>34</sup>	
Killaars, et al. Children (Basel). 2024 Jan 17;11(1):112.	Robotic-Assisted Nissen Fundoplication in Pediatric Patients: A Matched Cohort Study <sup>46</sup>	



**Study Overviews** 



## Initial Experience with a New Robotic Surgical System for Cholecystectomy<sup>1</sup>

Aggarwal, et al. Surg Innov. 2020 Apr;27(2):136-142.









Cholecystectomy

#### **Overview**

A prospectively maintained database of the first 20 patients undergoing cholecystectomy with the Senhance was reviewed at a single hospital. Data including operative time, console time, set up time, and adverse events were collected, with clinical outcome and operative time as primary outcome measures. A cohort of 20 patients having laparoscopic cholecystectomy performed by the same surgeon was used as a comparator group.

#### Conclusion

Our results and successful outcome of the patients in this series suggest that this system is safe, effective, and feasible for cholecystectomy.

#### **Key Results**

The 2 groups had comparable demographic data (age, sex, and body mass index). In the Senhance group, 19 of the 20 procedures (95%) were completed robotically. The median (interquartile range) total operating, docking, and console times were 86.5 (60.5-106.5), 11.5 (9-13), and 30.8 (23.5-35) minutes, respectively. In the laparoscopic group, the median (interquartile range) operating time was 31.5 (26-41) minutes. Postoperatively, only one patient had a surgical complication, namely a wound infection treated with antibiotics.



In the Senhance group, 19 of the 20 procedures (95%) were completed robotically.



## **TELELAP ALF-X Robotic-assisted Laparoscopic Hysterectomy: Feasibility and Perioperative Outcomes**<sup>8</sup>

Fanfani, et al. J Minim Invasive Gynecol. Sep-Oct 2015;22(6):1011-7.









Hysterectomy

#### **Overview**

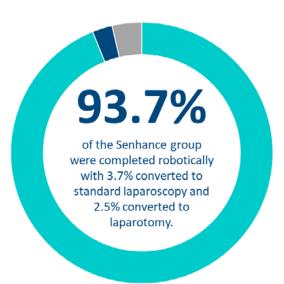
From October 2013 to May 2014, 80 patients underwent TELELAP ALF-X hysterectomy. The study population was divided into 2 groups according to surgical procedures: total hysterectomy 6 bilateral salpingo-oophorectomy (group 1) and endometrial cancer patients staged with pelvic lymphadenectomy (group 2).

#### Conclusion

As new technology evolves, critical appraisal of patient-related outcomes, use, cost, and access to minimally invasive hysterectomy must remain a priority. Despite the relative small number of our series, we showed the feasibility and safety of total TELELAP ALF-X hysterectomy for benign and malignant disease.

#### **Key Results**

The median age was 51 years (range, 48–79), and the median body mass index was 24 kg/m2 (range, 17.3–34.2). Forty-five patients (56.2%) had previous surgery. The median operative time was 140 minutes (range, 58–320) in group 1 and 197 minutes (range, 129–290) in group 2 (p , .001). The median docking time was 8 minutes (range, 3–25). During the study period, a significant trend in operative time reduction was observed. Procedures were successfully performed without conversion in 93.7% of cases. We observed 2 (2.5%) intraoperative complications, 3 (3.7%) conversions to standard laparoscopy, and 2 (2.5%) to laparotomy. The median time to discharge was 2 days (range, 1–5). One patient (1.2%) was readmitted in the early postoperative period.



Procedures were successfully performed without conversion in 93.7% of cases. We observed 2 (2.5%) intraoperative complications, 3 (3.7%) conversions to standard laparoscopy, and 2 (2.5%) to laparotomy.



### The New Robotic Telelap Alf-X in Gynecological Surgery: Single-Center Experience<sup>9</sup>

Fanfani, et al. Surg Endosc. 2016 Jan;30(1):215-21.









Hysterectomy, Mono/Bilateral Salpingo-Oophorectomy, Cyst Removal, Myomectomy, Endometrial Cancer Staging

#### **Overview**

Between September 2013 and May 2014, 146 patients were enrolled in this Phase II study trial. Patients with presumed benign or borderline adnexal disease, and benign and early-stage malignant uterine disease were prospectively included.

Sixty-two patients (32.5%) underwent mono/bilateral salpingo-oophorectomy or cyst removal (Group A), four patients (2.7%) myomectomy (Group B), 46 patients (31.5%) total hysterectomy (Group C), and 34 (23.3%) endometrial cancer staging (Group D).

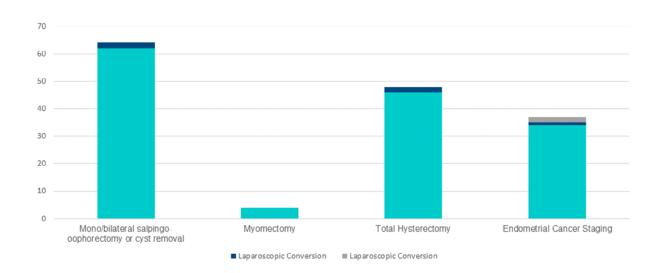
#### Conclusion

When performed by experienced minimally invasive surgeons, TELELAP ALF-X is feasible and safe.

#### **Key Results**

Median age was 52 years (range 19-79 years), and median BMI was 23.7 (range 17.3-34.0 kg/m(2)). Sixty-two patients (32.5%) underwent mono/bilateral salpingo-oophorectomy or cyst removal (Group A), four patients (2.7%) myomectomy (Group B), 46 patients (31.5%) total hysterectomy (Group C), and 34 (23.3%) endometrial cancer staging (Group D). Median docking time was 7 min (range 3-36). Median OT was 35 min (range 17-145) in the Group A, 40 min (range 10-50) in the Group B, 133 min (range 58-320) in the Group C, and 160 min (range 69-290) in the Group D. Reduction in OT over the study period for hysterectomy (p < 0.001) and adnexal surgery (p < 0.002) was observed. We registered two laparoscopic conversion (3.2%) in the Group A and two (4.3 %) in the Group C. In the Group D,

we showed one (2.9%) laparoscopic and two (5.8%) laparotomic conversions. One patient (2.17%) in the Group C was readmitted in the early postoperative period for severe vaginal bleeding.



Median OT was 35 min (range 17-145) in the Group A, 40 min (range 10-50) in the Group B, 133 min (range 58-320) in the Group C, and 160 min (range 69-290) in the Group D.

We registered two laparoscopic conversion (3.2%) in the Group A and two (4.3 %) in the Group C. In the Group D, we showed one (2.9%) laparoscopic and two (5.8%) laparotomic conversions.



### Robotic Inguinal Hernia Repair (TAPP)— First Experience with the New Senhance<sup>™</sup> Robotic System<sup>20</sup>

Schmitz, et al. Surg Technol Int. 2019 May 15;34:243-249.









Inguinal Hernia

#### **Overview**

From March to September 2017, 76 inguinal hernia repairs in 64 patients were performed using the Senhance Robotic System. Patients were between 18 and 90 years of age, eligible for a laparoscopic procedure with general anesthesia, had no life-threatening disease with a life expectancy of less than 12 months, and a body mass index (BMI) < 35. A retrospective chart review was performed for a variety of pre-, peri-, and postoperative data including, but not limited to, patient demographics, hernia characteristics, and intraoperative and postoperative complications.

#### Conclusion

Compared to conventional laparoscopic transabdominal preperitoneal (TAPP) hernia repairs, there was no significant difference in operative time or perioperative complications.

Additionally, there was no significant learning curve detected due to its intuitive applicability. Therefore, the Senhance™ Robotic System promises broad applicability across a range of laparoscopic general surgical operations.

#### **Key Results**

Fifty-four male and 10 female patients were included in the study. Median age was 56.5 years (range 22-86 years), and median BMI was 25.9 kg/m2 (range 19.5-31.8 kg/m2). Median docking time was seven minutes (range 2-21 minutes), and median operative time was 48 minutes (range 18-142 minutes). Two cases were converted to standard laparoscopic surgery due to robot malfunction and abdominal wall bleeding, respectively. Median length of stay was one day.

Compared to conventional laparoscopic transabdominal preperitoneal (TAPP) hernia repairs, there was no significant difference in operative time or perioperative complications.

Additionally, there was no significant learning curve detected due to its intuitive applicability.



## Inguinal Hernia Tapp Repair Using Senhance® Robotic Platform: First Multicenter Report from the TRUST Registry<sup>17</sup>

Samalavicius, et al. Hernia. 2021 Sep 30.









Inguinal Hernia

#### Overview

We included 271 cases of robotic inguinal hernia TAPP repair using the Senhance® robotic platform from four different centers between March 2017 and March 2020. Key data points were intraoperative and postoperative complication rate, operating time, length of hospital stay, postoperative pain score and time required to get back to a daily routine that were inserted in the TransEnterix European Patient Registry for Robotic assisted Laparoscopic Procedures in Urology, Abdominal Surgery, Thoracic and Gynecologic Surgery (TRUST).

#### Conclusion

Robotic inguinal hernia TAPP repair shows inspiring results. It is a safe and doable procedure.

Our data from the TRUST registry showed acceptable rates of postoperative complications and a low conversion rate. The results confirm that robotic inguinal hernia repair is feasible and safe.

Based on results of the present study, we conclude that surgery with the Senhance robotic system is feasible in a short-term outcome, performing TAPP repair in patients with unilateral inguinal hernia. Our results are comparable with those achieved either in laparoscopic or in (robotic) Da Vinci inguinal hernia repair.

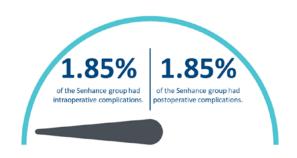
#### **Key Results**

We report 203 cases of unilateral and 68 cases of bilateral inguinal hernia repairs. Mean operative time was 74  $\pm$  35 min (range 32–265 min), robotic IHR has longer operative time compared to laparoscopic procedure, which in literature on average takes 53 vs. 74 min, although there was no significant difference between robotic console time and laparoscopic TAPP repair time.

Postoperative complications occurred in five (1.85%) cases, the intraoperative complication rate was five (1.85%). In the literature, postoperative complication rates vary between 7.5 and 11.5%. This is comparable to our study's overall postoperative complication rates.

The average subjective patient-related pain score after the procedure was  $3 \pm 1.9$  (range 1–9), Pain was another parameter that showed a better short-term result compared to laparoscopy in literature (3 vs 3.85).

Length of hospital stay was  $39 \pm 28$  h (range 4–288 h), and recovery time was  $9.65 \pm 8$  days (range 1–36 days). Total length of hospital stay was significantly shorter in our robotic group (39 h), compared to 46 h for laparoscopy in literature.



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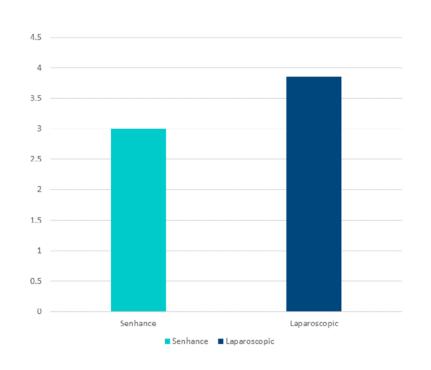


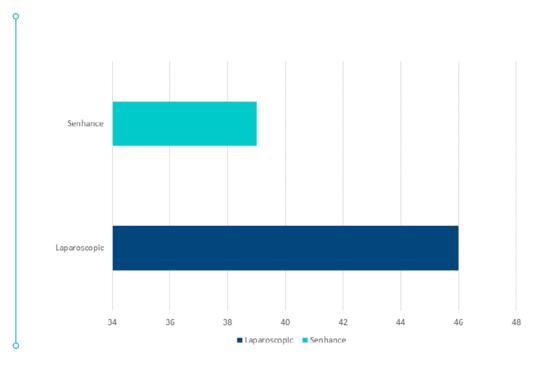
## (cont...) Inguinal Hernia Tapp Repair Using Senhance® Robotic Platform: First Multicenter Report from the TRUST Registry<sup>17</sup>



Samalavicius, et al. Hernia. 2021 Sep 30.

Inguinal Hernia





The average subjective patientrelated pain score after the procedure was  $3 \pm 1.9$  (range 1–9), Pain was another parameter that showed a better short-term result compared to laparoscopy in literature (3 vs 3.85).

Total length of hospital stay was significantly shorter in our robotic group (39 h), compared to 46 h for laparoscopy in literature.



### First Experiences with the New Senhance® Telerobotic System in Visceral Surgery<sup>23</sup>

Stephan, et al. Visceral Med 2018 Feb;34(1):31-36.



From Within the first 6 months, 116 Senhance procedures were performed with the Senhance System. The integration program is described.

#### Conclusion

Our initial experience confirms that the Senhance system is suitable and safe for procedures in general and visceral surgery. The robotic system allows the surgeon to concentrate on the matter at hand. At no time is he/she limited by an uncomfortable or restricting position at the operating table. The application is safe due to the unproblematically quick changeover to normal laparoscopy and easy to integrate due to the very short system integration times (docking times). Since it is a laparoscopic-based system, following an integration program will enable experienced laparoscopic surgeons to very quickly manage more complex procedures. Due to lower costs, introducing robotic surgery starting with simple and standardized procedures is more feasible.

#### **Key Results**

The integration program intended to start with simple and well-standardized clinical cases. We chose inguinal hernia repair using the TAPP (transabdominal preperitoneal) technique as the starting procedure. Subsequently, we added upper gastrointestinal surgery and cholecystectomies, and colorectal procedures have since also been included.

For experienced laparoscopic surgeons, the learning curve is very short since the system is based on laparoscopic surgery and the technique and the handling of the instruments are identical.

After about 30 operations, the console time of an inguinal hernia repair corresponded approximately to the incision-to-suture time of a normal laparoscopy.









Inguinal Hernia Repair, Ventral Hernia Repair, Nissen Fundoplication, Toupet Fundoplication, Cholecystectomy, Sigmoid Resection, Colectomy

For experienced laparoscopic surgeons, the learning curve is very short since the system is based on laparoscopic surgery and the technique and the handling of the instruments are identical.

After about 30 operations, the console time of an inguinal hernia repair corresponded approximately to the incision-to-suture time of a normal laparoscopy.



#### Senhance® Surgical System in Benign Hysterectomy: A Real-World Comparative Assessment of Case Times and Instrument Costs vs Da Vinci Robotics and Laparoscopic Assisted Vaginal Hysterectomy Procedures<sup>5</sup>

Coussons, et al. Int J Med Robot. 2021 Aug;17(4):e2261









**Total Laparoscopic Hysterectomy** 

#### **Overview**

Comparison of retrospective, learning curve benign hysterectomy cost and case time data from Senhance TLH cases with similar Da Vinci robotic cases and LAVH cases.

#### Comparative Results of Senhance vs. Da Vinci (in Benign Hysterectomy)

	Senhance (n=26)		Da Vinci (n=56)		P-V Value
Parameter	Median	IQR	Median	IQR	
Console Time (min)	91.5	68-114	96	69.5-122	0.898
Surgery Elapsed Time (min)	139.5	119-172.5	108.5	88-127.5	<0.001
Instrument Costs (min)	\$559	119-172.5	\$1,393	\$1150-1393	<0.001
Median Cost Savings by Senhance (\$)	-\$834.00		NA		

#### Comparative Results of Senhance vs. LAVH (in Benign Hysterectomy)

	Senhance (n=26)		LAVH (n=34)		P-V Value
Parameter	Median	IQR	Median	IQR	
Console Time (min)	91.5	68-114	NA	NA	NA
Surgery Elapsed Time (min)	138.5	119-172.5	97.5	84-123	<0.001
Instrument Costs (min)	\$559	\$162-624	\$498	\$467-506	<0.336
Median Cost Savings by LAVH (\$)	\$61.00		NA		

#### Conclusion

Senhance system appears to offer a cost-effective minimally invasive surgical option in benign hysterectomy surgery compared to Da Vinci, with comparable case time; and statistically comparable costs to LAVH albeit with longer cases times, at least during the learning curve period.

#### **Key Results**

Senhance Gyn surgeons in their learning curve when compared to Da Vinci learning curve Gyn surgeons achieved lower median instrument costs (\$559 vs \$1,393, respectively, p<0.001). Senhance and LAVH case costs were comparable (\$559 vs \$498, p=0.336).

Senhance® system appears to offer a cost-effective minimally invasive surgical option in benign hysterectomy surgery compared to Da Vinci, with comparable case time; and statistically comparable costs to LAVH



## The Senhance<sup>™</sup> Surgical Robotic System ("Senhance") for Total Hysterectomy in Obese Patients: A Pilot Study<sup>2</sup>

Alletti, et al. J Robot Surg. 2018 Jun;12(2):229-234.







Hysterectomy, Hysterctomy with Bilateral Salpingo-Oophorectomy

#### **Overview**

This pilot study was aimed to value the feasibility and safety of Senhance Robotic Platform for hysterectomy in obese patients. Ten obese patients (30 < BMI < 40) underwent elective Senhance total extrafascial hysterectomy with bilateral salpingo-oophorectomy at the Division of Gynecologic Oncology of "Policlinico A. Gemelli" Foundation, Rome, Italy. Perioperative and postoperative outcomes data were recorded.

100 mL (50-200). No conversions to laparotomy were recorded. No intra- and 30-day postoperative complications were registered. The median ileus was 17 h (12-36) and the median time to discharge was 2 days (1-4). The median VAS scores registered at 2, 4, 12, and 24 h were, respectively, 2 (1-3), 2 (1-3), 4 (1-8), and 3 (1-5).

#### Conclusion

Our study results suggest that Senhance platform could be safe for hysterectomy even in obese patients. More clinical data are needed to determine whether this approach would offer any additional benefits in a new middle line between standard laparoscopy and robotics.

#### **Key Results**

The median age was 60 years (range 51-75) and the median BMI was 33.3 kg/m2 (range 30.4-38.3). The median uterine weight was 112.5 g (range 77-225). Indication to total hysterectomy was early-stage (FIGO Stage IA) endometrial cancer in 100% of patients. The median operative time (OT) was 110 min (70-200). The median docking time was 10.5 min (5-25). The median estimated blood loss was

Intra - and 30-day post op complications for obese patients

Our study results suggest that Senhance platform could be safe for hysterectomy even in obese patients.

No conversions to laparotomy were recorded. No intra- and 30-day postoperative complications were registered.



## Telelap ALF-X vs Standard Laparoscopy for the Treatment of Early-Stage Endometrial Cancer: A Single-Institution Retrospective Cohort Study<sup>3</sup>

Alletti, et al. J Minim Invasiv Gynecology, Mar-Apr 2016;23(3):378:83.









Radical Hysterectomy, Bilateral Salpingo-Oophorectomy, Pelvic Lymphadenectomy

#### Overview

The study involved 89 patients affected by early-stage endometrial cancer who underwent elective surgical staging between October 2013 and September 2014. Among them, 43 (48.3%) underwent Telelap ALF-X staging (ALF-X group), and 46 (51.7%) underwent conventional laparoscopic staging (laparoscopic group).

#### Conclusion

Based on operative outcomes and complication rates, our results suggest that the Telelap ALF-X approach is feasible and safe for endometrial cancer staging; however, further studies are needed to definitively assess the role of Telelap ALF-X early-stage endometrial cancer staging.

#### **Key Results**

In the ALF-X group, the median operative time was 128 minutes (range, 69-260 minutes) for subgroup 1 and 193 minutes (range, 129-290 minutes) for subgroup 2. In the laparoscopic group, the median operative time was 82 minutes (range, 25-180 minutes) in subgroup 1 and 104 minutes (range, 36-160 minutes) in subgroup 2. The difference in operative time between subgroups was statistically significant

in both the ALF-X and laparoscopic groups (p = .000). In subgroup 1 of the ALF-X group, there was 1 conversion to standard laparoscopy (2.3%) and 2 conversions to laparotomy (4.7%) (p = .234). No conversions to laparotomy occurred in the laparoscopic group. Postoperative complications included 1 case of pelvic hematoma (2.3%) in subgroup 1 of the ALF-X group and 1 case of subocclusion and 1 case of pulmonary edema (4.3%) in subgroup 1 of the laparoscopic group.

Based on operative outcomes and complication rates, our results suggest that the Telelap ALF-X approach is feasible and safe for endometrial cancer staging



## A Roadmap for Robotic-Assisted Sigmoid Resection in Diverticular Disease Using a Senhance® Surgical Robotic System: Results and Technical Aspects<sup>6</sup>

Darwich, et al. J Robot Surg. 2020 Apr;14(2):297-304.









Sigmoid Resection

#### **Overview**

We report in this study our first results in robotic-assisted sigmoid resection for diverticular disease using the Senhance™ Surgical Robotic System, while introducing a standardized roadmap for engaging the robotic arms. 12 patients underwent a sigmoid resection using the Senhance™ Surgical Robotic System. All four arms of the robotic system were engaged during all procedures according to a previously devised roadmap. A 4-trocar technique was used in all patients. Perioperative data, including those regarding technical difficulties, were collected and analyzed.

the mean docking time were 219 min (204–305), 149 min (124–205) and 10 min (6–15), respectively. The mean length of stay was 9 days (6–15). There was one major complication (8.3%, Clavien–Dindo IIIb). There were no mortalities. No other complications were observed. No patients were readmitted after discharge.

#### Conclusion

The Senhance™ Surgical Robotic System can be used safely in sigmoid resection for diverticular disease after adequate training and systematic planning of the different steps of the procedure.

#### **Key Results**

Two procedures were converted into standard laparoscopy. There were no conversions to open surgery. The mean age of the patients was 62.5 years (47–79). One third of the patients were males. The mean BMI was 27 kg/m2 (19–38). The mean operative time, the mean console time and

Conversions to open surgery

## O readmissions

There were no conversions to open surgery.

There were no mortalities. One major complication was observed. No patients were readmitted after discharge.



#### Total Laparoscopic (S-Lps) Versus Telelap Alf-X Robotic-Assisted Hysterectomy: A Case-Control Study<sup>7</sup>

Fanfani, et al. J Minim Invasiv Gynecology, Sep-Oct 2016;23(6):933-8.









Hysterectomy

#### **Overview**

This study compares the feasibility and safety of the TELELAP ALF-X system and standard laparoscopy for total hysterectomy to treat patients with benign and early malignant gynecologic disease. Between October 2013 and May 2015, 203 women underwent TELELAP-ALF X (group 1) or standard laparoscopic (group 2) total hysterectomy and were enrolled.

(p = .055). The median estimated blood loss was 57 mL (range, 0-600 mL) in group 1 and 99 mL (range, 0-400 mL) in group 2, with no significant differences between the 2 groups (p = .963). Procedures were successfully performed without conversion in 94.3% of cases in the group 1 and in all cases in group 2. Early postoperative pain was significantly lower in group 2.

#### Conclusion

TELELAP ALF-X hysterectomy in patients with benign and early malignant gynecologic disease is feasible and safe and can be considered a valid option for these patients.

#### **Key Results**

In group 1, the median age was 55 years (range, 40-79 years), median body mass index (BMI) was 25 kg/m(2) (range, 17-38 kg/m(2)), and 51 patients (58%) had undergone previous abdominal surgery. In the control group, the median age was 55 years (range, 34-90 years), median BMI was 25 kg/m(2) (range, 17-41 kg/m(2)), and 31 patients (27%) had previous abdominal surgery. The median operative time was 147 minutes (range, 58-320 minutes) in group 1 and 80 minutes (range, 22-300 minutes) in group 2

TELELAP ALF-X hysterectomy in patients with benign and early malignant gynecologic disease is feasible and safe and can be considered a valid option for these patients.



## Robot-Assisted Surgery With Senhance® Robotic System for Colon Cancer: Our Original Single-Incision Plus 2-Port Procedure and a Review of the Literature<sup>10</sup>

Hirano, et al. Tech Coloproctol. 2021 Apr;25(4):467-471.

Colectomy

#### Overview

The Senhance robotic system provides such advantages as an eye-tracking camera control system, haptic feedback, operator comfort, and reusable endoscopic instruments. The aim of this small study was to assess the feasibility and safety of performing a reduced-port robot-assisted colectomy for colon cancer with the use of a novel robotic system. his was a single-center retrospective study of eight patients with colon cancer who underwent single-incision plus 2-port robot-assisted colectomy with the Senhance robotic system (SILS+2-S) between December 2019 and March 2020 at our hospital.

was 18.3. The surgical margins were negative in all eight patients. There was neither morbidity nor mortality associated with the procedure, and no Clavien-Dindo classification Grade II-IV complications occurred.

#### Conclusion

SILS+2-S is a safe and feasible approach for patients with colon cancer. Further studies are needed to validate the advantages of SILS+2-S and to evaluate the long-term oncological outcomes.

#### **Key Results**

One patient was converted to laparoscopy due to a damaged scope holder. The mean operative and console times were 229.1 and 139.1 min, respectively. The mean intraoperative blood loss was 49.4 ml. The mean length of the umbilical incision was 3.0 cm. The mean number of harvested lymph nodes

SILS+2-S is a safe and feasible approach for patients with colon cancer.



## Initial Experience of Laparoscopic Radical Nephrectomy Using the Senhance® Robotic System for Renal Cell Carcinoma<sup>11</sup>

Kaneko, et al. Int Cancer Conf J. 2021 Apr 29;10(3):228-232.



We herein describe our initial experience of Senhance® assisted laparoscopic radical nephrectomy (LRN) for renal cell carcinoma (RCC) with detailed figures and videos. Case 1: A left renal tumor was incidentally detected in a 52-year-old female on ultrasonography. Case 2: A right renal tumor was detected in a 67-year-old male with epigastric pain on computed tomography.

#### Conclusion

Senhance® assisted LRN for RCC was safely and precisely performed. Furthermore, the operator was comfortable during the surgery.

#### **Key Results**

Senhance® assisted LRN was completed without conversion to conventional LRN or open surgery in both cases. The pneumoperitoneum time, console time and estimated blood loss in case 1 and case 2 were 173 min, 143 min and 3 mL, and 154 min, 122 min and 50 mL, respectively.and three patients had grade II complications.









Nephrectomy

Conversions to LRN

Conversions to open surgery

Senhance® assisted LRN was completed without conversion to conventional LRN or open surgery in both cases.



#### **Upper Urinary Tract Surgery and Radical Prostatectomy** with Senhance® Robotic System: Single Center **Experience-First 100 Cases**<sup>12</sup>

Kastelan, et al. Int J Med Robot. 2021 Aug;17(4):e2269.



The Senhance® robotic surgery system is a novel robotic platform used in several European and World centres. We present our experience in urologic surgery using this platform. From May 2019 to December 2020, we performed 30 operations of upper urinary tract (UUT) and 70 extraperitoneal radical robotic prostatectomies (RRP).

#### Conclusion

The Senhance® robotic system is a safe and feasible approach to urological surgery.









Urology, Prostatectomy

#### **Key Results**

The average estimated blood loss for UUT was 30, and for RRP 200 ml. The average operating time for UUT was 160, and for RRP 200 min. In-hospital stay for UUT was on average 4, and for RRP 5 days. In UUT group, one patient had Clavien-Dindo complication grade II and one had IIIb. In RRP, three patients had grade I complications and three patients had grade II complications.

#### An Early Experience with the Senhance® Surgical Robotic System in Colorectal Surgery: A Single-Institute Study<sup>13</sup>

Lin, et al. Int J Med Robot. 2021 Apr;17(2):e2206.

#### Overview

From June 2019 to December 2019, patients who underwent Senhance surgical robot-assisted colorectal surgery in our hospital were retrospectively analyzed. We focused on the short-term outcomes. In total, 46 patients were enrolled in the study. Colorectal cancer was the most common indication for surgery (39 patients).

#### Conclusion

Our findings demonstrate the feasibility and safety of the Senhance surgical robotic system in colorectal

surgery. Care should be taken regarding the indications and patient selection.

#### **Key Results**

The median total operation time was 283 min, and the median blood loss was 50 cc. Meanwhile, the median number of harvested lymph nodes was 20. Elderly age, advanced American Society of Anaesthesiologists stage, and right-sided colon surgery were associated with the occurrence of complications greater than grade III.









Colorectal

Our findings demonstrate the feasibility and safety of the Senhance® surgical robotic system in colorectal surgery.



## Senhance® Robotic Platform System for Gynecological Surgery<sup>14</sup>

McCarus, et al. JSLS. Jan-Mar 2021;25(1)



The clinic routinely collects surgical and outcome data for all patients and procedures. Data on robotic surgery in hysterectomy, salpingectomy, endometriosis excision, and lysis of adhesions was evaluated.

Conclusion

This initial experience with Senhance Surgical System provided a stable, precise surgical technique with enhanced visualization within the confined space of the abdomen during gynecological surgery. The initial results suggest high patient satisfaction with gynecological surgery and resulting scars. Further study is needed to validate the findings.

#### **Key Results**

Fifteen consecutive patients that underwent gynecological surgery using the Senhance System were assessed. Average age was 47.27 years (31 - 63 years). Ten procedures were robotic total laparoscopic hysterectomy and 14 of 15 procedures had at least one salpingectomy. Average blood loss was 52.7 mL (10 - 100 mL). Pain scores at discharge averaged 1.42 and 2.73 at two weeks post-surgery. Minimal pain medication was used. Patient satisfaction with the surgery was 98% and satisfaction with scarring was 100%. Return to normal activities and

to work averaged 7.93 and 11.1 days respectively. The haptic feedback and the platform visualization of the procedure was useful. The system provided more surgeon control over both camera and tools compared to previously used robotic systems and traditional laparoscopic surgery.

98<sup>%</sup> satisfaction with surgery

100% satisfaction with scarring









Total Laparoscopic Hysterectomy, Total Laparoscopic Hysterectomy with Salpingoectomy

This initial experience with Senhance Surgical System provided a stable, precise surgical technique with enhanced visualization within the confined space of the abdomen during gynecological surgery. The initial results suggest high patient satisfaction with gynecological surgery and resulting scars.

Patient satisfaction with the surgery was 98% and satisfaction with scarring was 100%. Return to normal activities and to work averaged 7.93 and 11.1 days respectively. The haptic feedback and the platform visualization of the procedure was useful. The system provided more surgeon control over both camera and tools compared to previously used robotic systems and traditional laparoscopic surgery.



## Robotic Cholecystectomy Using Senhance® Robotic Platform Versus Laparoscopic Conventional Cholecystectomy: A Propensity Score Analysis<sup>18</sup>

Samalavicius, et al. Acta Chir Belg. 2021 Feb 5:1-4.



A retrospective case - matched analysis was performed for all patients who underwent cholecystectomy from November 2018 to November 2019. Robotic Cholecystectomy cases were matched to Laparoscopic Cholecystectomy. RC was performed using Senhance robotic platform. Propensity score matching analysis with a ratio of 1:1 (RC: LC) was performed. The groups were matched according to age, sex, body mass index (BMI). All procedures were performed by two same experienced robotic surgeons at Klaipeda University Hospital (O.D. and V.E.). A total of 40 patients underwent RC or LC.

surgery. One patient in robotic group was reoperated on postoperative day 5 regarding sub-hepatic haematoma. The only statistical significance was in operative time (p < .05) which was longer in RC group. Median docking time was 12 min (range 5-23).



Robotic cholecystectomy using Senhance robotic platform appears to be safe in comparison with laparoscopic cholecystectomy. Laparoscopic cholecystectomy might be feasible in gaining robotic surgery skills.

#### **Key Results**

There were no statistical differences between groups in concern of length of hospital stay, blood loss or complications. There were no bile duct injuries in either group, no intraoperative complications, no conversions either RC to LC or LC to open









Cholecystectomy

Conversions

intraoperative complications

There were no statistical differences between groups in concern of length of hospital stay, blood loss or complications. There were no bile duct injuries in either group, no intraoperative complications, no conversions either RC to LC or LC to open surgery.



## Robotic-Assisted Nissen Fundoplication with the Senhance® Surgical System: Technical Aspects and Early Results¹9

Schmitz, et al. Surg Technol Int. 2019 Nov 10;35:113-119.







Nissen Fundoplication

#### **Overview**

Between March 2017 and July 2019, we performed 36 surgeries of the upper GI tract with the Senhance® Surgical System. Eighteen patients underwent the classic Nissen fundoplication and are the subject of this study.

#### Conclusion

This first report of robotic-assisted Nissen fundoplication with the Senhance® Surgical System demonstrates technical feasibility. After successful introduction of the Senhance® Ultrasonic, our conversion rate to standard laparoscopic surgery was significantly reduced.

#### **Key Results**

Seven male and 11 female patients were included in the study. The median age of the cohort was 58.5 years (range 30-81 years) and the median body mass index (BMI) was 30.4 kg/m2 (range 22.7-40.1 kg/m2). The median total operative time was 95.5 minutes (range 68-194 minutes) and, despite the small sample size, we observed a significant learning curve throughout the study period (p<0.05). Before the introduction of the Senhance® Ultrasonic energy device, conversion to laparoscopic fundoplication was necessary in two patients. We performed one re-do laparoscopy on the day of surgery due to pain without any significant intraoperative findings and one laparoscopic revision to Toupet fundoplication after seven months due to dysphagia.



## The TransEnterix European Patient Registry for Robotic-Assisted Laparoscopic Procedures in Urology, Abdominal, Thoracic, and Gynecologic Surgery ("TRUST")<sup>21</sup>

Stephan, et al. Surg Technol Int. 2021 May 20;38:103-107.



The study population consists of 871 patients who underwent robotic surgery with the Senhance™ platform. The most common procedures were hernia repairs (unilateral and bilateral), cholecystectomies, and prostatectomies. The procedures were performed in five centers in Europe between February 2017 and July 2020 by experienced laparoscopic surgeons.

#### Conclusion

Our series shows these procedures are safe and reproducible. The findings suggest that the surgical results after robotic surgery with the Senhance™ system are promising. Long-term data regarding complication rates should be the subject of future studies.

#### **Key Results**

220 (25.3 %) out of 871 patients had a unilateral hernia repair, 70 (8.0%) a bilateral hernia repair, 159 (18.3%) underwent a cholecystectomy, and 168 (19.3%) a prostatectomy. The other procedures included visceral, colorectal, and gynecological surgery procedures. The median docking time was 7.46 minutes for the four most common procedures. The duration of surgery varied from 32 to 313 minutes, the average time was 114.31 minutes. Adverse events were rare overall. There were 48 (5.5 %) adverse events out of 871 patients, 24 of

them (2.8 % of all cases) were severe. Out of all 24 severe adverse events, five events (20.8%) were likely related to the robot, 17 events (70.8%) were unlikely related to the robot, and two events (8.3%) could not be categorized. Regarding complications following unilateral hernia repairs, data from 212 patients was available. Thirteen (6.1%) complications occurred, and six of those (2.8%) were serious. Out of 68 patients with a bilateral hernia repair, six patients (8.8%) developed complications, three of which were severe (4.4%). The complication rate was 2.8% in the patients following a cholecystectomy (4/144); two of them serious. After prostatectomy, six out of 141 patients (4.3 %) had complications; one serious (0.7%) No mortality was observed. Data about unplanned conversions to laparoscopic surgery could be collected from 761 patients which is a rate of 3.7%. There were 12 conversions out of 760 procedures to open surgery (1.6%).



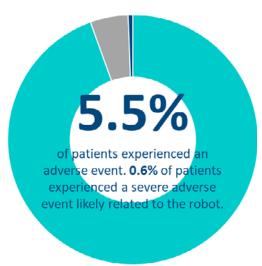






Cholecystectomy, Prostatectomy, Unilateral Hernia Repairs, Bilateral Hernia Repairs

## 7.46 min median docking time for the four most common procedures



**3.7**%

of procedures were converted to laparoscopy. 1.6%

of procedures were converted to open surgery.



## Robotic-Assisted Radical Prostatectomy with the Senhance® Robotic Platform: Single Center Experience<sup>24</sup>

Venckus, et al. World J Urol. 2021 Dec;39(12):4305-4310.



Prostatectomy

#### Overview

A prospective analysis of 127 robot-assisted radical prostatectomies was performed. Patient demographics, preoperative and intraoperative parameters, histopathological examination results, intraoperative and early postoperative complications were obtained and analyzed.

#### Conclusion

Robotic prostatectomy using a Senhance® robotic system is feasible, and warrants further study to determine whether it can improve patient outcomes.

#### **Key Results**

Of 127 patients, 16.5% (n = 21) underwent a pelvic lymph node dissection, 29.1% (n = 37) underwent one sided or bilateral nerve sparing. Post-operative extracapsular invasion ( $\geq$  pT3) was found in 15% (n = 19) of the cases and a Gleason score  $\geq$  7 in 74.8% of all patients. Our median operative time was 180  $\pm$  41.98 min [interquartile range (IQR) 150-215], and median blood loss was 250  $\pm$  236 (IQR 175-430) ml. Of 127 patients, 33.9% (n = 43) had positive margins, of them 28.7% in pT2 and 57.9% in pT3. Fifteen patients (11.8%) experienced complications, of them only three had Clavien-Dindo  $\geq$  3. Operation time decreased by about 60 min and estimated blood loss decreased by about 200 ml from the initial experience of each surgeon.



## Use of Robot-Specific Resources and Operating Room Times: The Case of Telelap Alf-X Robotic Hysterectomy<sup>15</sup>

Rossitto, et al. Int J Med Robot. 2016 Dec;12(4):613-619.









Total Laparoscopic Hysterectomy

#### Overview

Cost analysis was performed on 81 patients who underwent a Telelap ALF-X robotic hysterectomy. Data were collected during a phase II study trial conducted at the University Hospital A. Gemelli, Catholic University, Rome. According to micro-costing technique, surgical team costs, materials and operating theatre usage were recorded during each surgical intervention. Cost data were provided by the hospital's accounting office. Probabilistic sensitivity analysis was carried out in order to test the robustness of the results by assuming an Inv-norm random variable.

#### Conclusion

This study shows that Telelap ALF-X robotic hysterectomy is feasible and safe and could offer specific advantages in terms of cost.

#### **Key Results**

The base case analysis showed a cost/patient of €3391.82. The new robotic device requires a low consumption of robotic materials. Sensitivity analysis showed that the most sensitive cost driver was use of the operating theatre.

This study shows that Telelap ALF-X robotic hysterectomy is feasible and safe and could offer specific advantages in terms of cost.

The base case analysis showed a cost/patient of €3391.82. The new robotic device requires a low consumption of robotic materials.



## Robotic Surgery Using Senhance® Robotic Platform: Single Center Experience with First 100 Cases¹6

Samalavicius, et al. J Robot Surg. 2020 Apr;14(2):371-376.









#### **Overview**

We present a prospective analysis of the first 100 robotic surgeries in abdominal surgery, gynecology, and urology in Klaipeda University Hospital, Klaipeda, Lithuania.

#### Conclusion

Our experience with different types of robotic surgeries allows us to state that the Senhance® robotic system is feasible and safe in general surgery, gynecology, and urology, and wider implementation of this system worldwide is simply a question of time.

#### **Key Results**

Out of 100 operated patients during the mentioned period, 49 were female and 51 men, age range 27-79 years, on an average 55 years. 39 underwent robotic abdominal surgical procedures, 31-urological, and 30 gynecological surgeries. Duration of surgery varied from 30 min to 6 h and 5 min, on an average 2 h 25 min. Almost half 49 (49%) were operated on for malignant diseases: prostate cancer-27, renal cell carcinoma-1, endometrial cancer-7, ovarian cancer-1, colorectal cancer-13 (7 colon and

6 rectum). In-hospital stay was on an average 4 days, range 1-15 days. There were 3 (3%) conversions: two to laparoscopy (both undergoing robotic radical prostatectomy) and one to open (undergoing total hysterectomy). 6 (6%) complications occurred during 30 postoperative days, 2 demanding surgery. According to the Clavien-Dido classification, they were grade II in 3, grade III a in 1 and grade III b in 2 cases. There was no mortality in this patient population.

"The Senhance® system is using reusable resterilizable instruments and adaptors and is compatible with many of the currently available visualizations systems including fluorescence technology. In different health economic settings this may have a positive impact on the economical feasibility applying robotic surgery."

There were 3 (3%) conversions: two to laparoscopy (both undergoing robotic radical prostatectomy) and one to open (undergoing total hysterectomy). 6 (6%) complications occurred during 30 postoperative days, 2 demanding surgery.

There was no mortality in this patient population.



### Senhance® 3-mm Robot-Assisted Surgery: Experience on First 14 Patients in France<sup>4</sup>

Montlouis-Calixte, et al. J Robot Surg. 2019 Oct;13(5):643-647.



The objective of this article is to present our experience with the 3-mm instruments using the Senhance surgical robotic system in gynecological and abdominal surgery from July to December 2017 by a retrospective observational study. All patients who underwent a robot-assisted 3-mm laparoscopic procedure with the Senhance surgical robotic system were enrolled.

#### Conclusion

There are few 3-mm instruments available with the Senhance surgical robotic system, which limits the number of interventions. However, it is possible to perform gynecological interventions with 3-mm instruments on an outpatient basis in complete safety. It is possible to perform cholecystectomies by pairing the use of 3-mm and 5-mm instruments.

#### **Key Results**

Two separate populations were involved: nine female gynecological patients and five digestive surgery patients. Five cholecystectomies, three annexectomies, four ovarian cystectomies, one myomectomy and one endometriotic nodule resection were performed. For the gynecological cases, the median time spent at the console was 37 min (12–77), while

the total duration of the intervention was 81.33 min. All the interventions were performed on an outpatient basis. There were no postoperative complications. The average visual analog scale for pain (VAS) was  $2.11 \pm 1.91$ ) on D0. For the abdominal surgery cases, the median time was  $39 \pm 1.02 \pm 1.0$ 









Cholecystectomy, Annexectomy, Ovarian Cystectomy, Myomectomy, Nodule Resection

postoperative complications

laparoscopy conversion

There were no postoperative complications and no postoperative complications in the 2 weeks following the operation. There was one laparoscopy conversion.



### First Clinical Use of 5 mm Articulating Instruments with the Senhance® Robotic System<sup>22</sup>

Stephan, et al. Surg Technol Int. 2020 Nov 28;37:63-67.



While the well-known Da Vinci® robotic system (Intuitive Surgical, Inc., Sunnyvale, CA) uses 8 mm articulated instruments, the Senhance® robotic system (TransEnterix, Morrisville, NC), available since 2016, uses 5 mm instruments, which is the standard size in laparoscopy. We report here the first 43 procedures using 5 mm articulating instruments with the Senhance® System (TransEnterix). From September 9, 2019, to January 15, 2020, we performed 43 various robotic-assisted abdominal procedures.)

#### Conclusion

The first impression of the participating surgeons and surgical nurses was that the smaller instruments were easy to handle after special training and offered a wider range of movement within the surgical field. All of the surgeons involved saw advantages with the use of 5 mm articulating instruments.

Senhance® (TransEnterix) 5 mm articulating instruments are technically stable and can be safely used in various abdominal procedures. The initial results suggest that these 5 mm articulating instruments can be a supportive tool in further robotic surgery, providing advantages in suturing and dissection with less risk of injury to surrounding tissue.

#### **Key Results**

Articulating instruments were connected to the robotic arm and used for tissue dissection (inguinal hernia repair, cholecystectomy, and sigmoid resection) on the left hand of the robot arm and for suturing (inguinal hernia repair) on the right hand of the robot arm.

We observed technical issues in three patients: two resulted from user error and one occurred due to a software update. No technical issues were observed in the remaining 40 cases. There were two unscheduled conversions to laparoscopic surgery and no conversions to open surgery. No case of damage to surrounding tissue was observed. In one case, the branches of the grasper were jammed due to severe clot buildup after extensive coagulation following a strong bleed. After unproblematic laparoscopic bleeding control, robotic surgery was continued. There were no further intraoperative or early postoperative complications.









Inguinal Hernia Repair, Cholecystectomy, Sigmoid Resection

All of the surgeons involved saw advantages with the use of 5 mm articulating instruments.

Senhance® (TransEnterix) 5 mm articulating instruments are technically stable and can be safely used in various abdominal procedures. The initial results suggest that these 5 mm articulating instruments can be a supportive tool in further robotic surgery, providing advantages in suturing and dissection with less risk of injury to surrounding tissue.



### Comparison of Extraperitoneal Laparoscopic and Extraperitoneal Senhance Radical Prostatectomy<sup>25</sup>

Kulis, et al. Int J Med Robot. 2022 Feb; 18(1):e2344.



Radical Prostatectomy

#### **Overview**

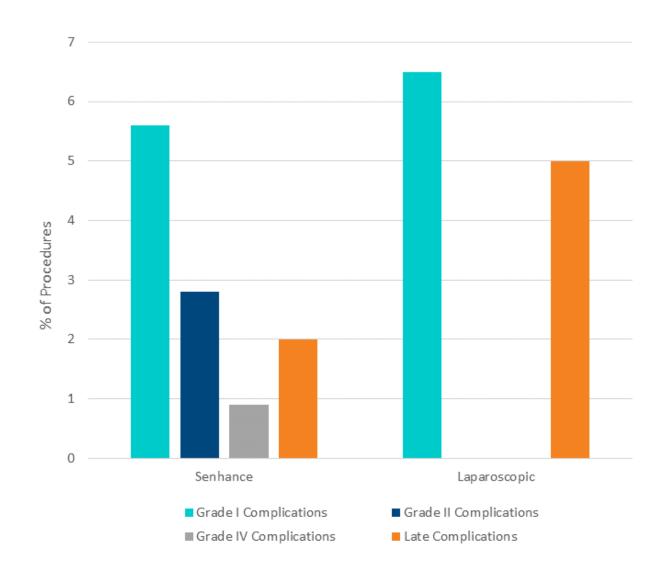
Senhance is novel robotic platform which can be used to perform radical prostatectomy (RP). We compare our results of robotic RP to similar patients operated with laparoscopic technique. A prospective study of 61 patients operated laparoscopically and 107 patients operated using the Senhance robotic system. We have analyzed operative and postoperative results in both groups.

#### Conclusion

Senhance robot-assisted RP is safe, feasible and offers good and comparable functional and oncological outcomes to laparoscopy. The transition to robotic surgery with a relatively fast learning curve can be done effectively for surgeons with previous laparoscopic experience.

#### **Key Results**

There was no difference in the operative time, estimated blood loss, positive surgical margins, length of hospitalization and catheterization. There were 4 (6.5%) Clavien-Dindo grade I complications, and 5 (8.1%) late complications in laparoscopy. There were 6 (5.6%) Clavien-Dindo grade I, 3 (2.8%) grade II, 1 (0.9%) grade IV complications and 2 (1.9%) late complications in robotic group.





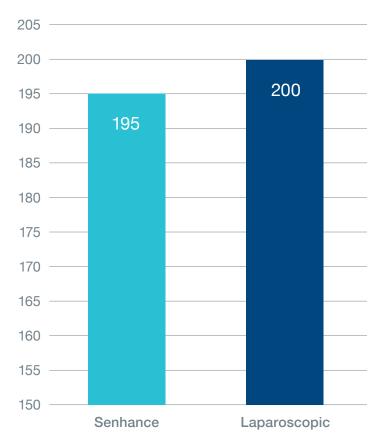
### (cont...) Comparison of Extraperitoneal Laparoscopic and Extraperitoneal Senhance Radical Prostatectomy<sup>25</sup>

Kulis, et al. Int J Med Robot. 2022 Feb; 18(1):e2344.



**Radical Prostatectomy** 

#### **Median Operating Time in Minutes**



There was no difference in operative time, estimated blood loss, positive surgical margins, length of hospitalization, and catheterization between the Senhance and laparoscopic groups.

The transition to robotic surgery with a relatively fast learning curve can be done effectively for surgeons with previous laparoscopic experience.



### Robotic Colorectal Surgery Using the Senhance® Robotic System: A Single Center Experience<sup>26</sup>

Samalavicius, et al. Tech Coloproctol 2022 Jun;26(6):437-442.









Colectomy

#### Overview

The aim of this study was to evaluate the initial experience of a single robotic center with the Senhance® robotic systems (TransEnterix Surgical Inc, Morrisville, NC, USA) in colorectal surgery. We performed a retrospective analysis of prospectively collected data of patients who underwent colorectal surgery using the Senhance® robotic systems, from November 2018 to November 2020. Perioperative, intraoperative, and short-term postoperative data were assessed.

### Conclusion

In our experience, surgery using the new Senhance® robotic system was safe and feasible in surgery of the colon and rectum. Randomized controlled trials comparing this type of colorectal surgery with laparoscopic and/or other types of robotic surgery are needed

### **Key Results**

There were 57 patients (28 women and 29 men, mean age 61.7  $\pm$  6.2 years [range 23-84 years]). Forty-eight (84.2%) patients underwent surgery for colorectal cancer (22 colon cancer and 26 rectal cancer) and 9 (15.8%) for benign conditions. Mean operating time was 194 min  $\pm$  57.8 min (range 90-380 min). In total, 27(47.4%) operations were

performed on the colon and 30 (52.6%) on the rectum; mean length of postoperative hospital stay was 8  $\pm$  6.2 days (range 3-48 days). There were 2 (3.4%) conversions to open surgery. No intraoperative complications occurred. Seven patients (12.3%) had postoperative complications 3 (5.3%) of whom had to be treated under general anesthesia. There was no mortality. In 48 patients operated on for colorectal cancer, the mean lymph-node harvest was 18  $\pm$  7.9 (range 7-38 lymph nodes). In the rectal cancer group of 26 patients, the distal resection margin was 3.3  $\pm$  1.8 cm.

In our experience, surgery using the new Senhance® robotic system was safe and feasible in surgery of the colon and rectum



### Sacrocolpopexy Experience with a Novel Robotic Surgical Platform<sup>27</sup>

Sassani, et al. Int Urogynecol J. 2022 Mar 21.



Sacrocolpopexy

### **Overview**

The objective was to describe early experience performing sacrocolpopexy using a novel robotic surgical platform. This is a case series of all women who underwent robotic-assisted sacrocolpopexy using a new robotics platform (TransEnterix Senhance) between January 2019 and July 2021. All sacrocolpopexies were performed by a single Female Pelvic Medicine and Reconstructive surgeon at a large academic institution. Perioperative information including complications was abstracted from the medical record. Anatomical recurrence was defined as any anatomical point at or past the hymen (≥0). Data are descriptive, with Mann-Whitney U test used for comparison of operative time between the first and second half of the patients.

### Conclusion

Our case series demonstrates feasibility and successful early adoption of a new robotics platform for robotic sacrocolpopexy.

### **Key Results**

A total of 25 sacrocolpopexies were performed using the new robotics platform. Mean age was 62.3 years (±9.2) and mean BMI was 26.5 (±3.8). Ten (40.0%) patients had a prior hysterectomy. Most (n = 21, 84.0%) had stage III or IV prolapse preoperatively. Mean operative time was 210.2 min (±48.6) and median estimated blood loss was 35 ml (IQR 25-50). Mean operative time decreased between the first and second half of the patients (231.7 min vs 190.3 min, p = 0.047). There were no major intraoperative complications. Median follow-up time was 16 weeks (IQR 4-34) and there were no subjective recurrences or retreatments during this period. Two patients (8.0%) had anatomical recurrence without subjective bother. There were two postoperative readmissions (8.0%) within 30 days for small bowel obstruction, one treated surgically and the other with nonsurgical management



Mean operative time decreased between the first and second half of the patients (231.7 min vs 190.3 min, p = 0.047).

Our case series demonstrates feasibility and successful early adoption of a new robotics platform for robotic sacrocolpopexy.



# Transperitoneal Radical Prostatectomy Using the Senhance® Robotic System: Initial Case Series, Learning Curve and Cost Analysis<sup>28</sup>

Lin, et al. Journal of Urology. 2022 May 1.



The Senhance robotic surgical system (TransEnterix Inc, Morrisville, NC, USA) is a novel laparoscopy-based robotic system, equipped with eye tracking system, haptic feedback system, and reusasble instruments. Currently, only two studies reported their experiences on extra-peritoneal radical prostatectomy. To assess the feasibility, learning curve and cost analysis of the transperitoneal Senhance robotic radical prostatectomy. From Aug 2019 to July 2021, the Senhance robotic radical prostatectomies were performed in 44 biopsy confirmed prostate cancer patients. Perioperative data were collected. Complications were graded with Clavien-Dindo classification. Learning curve was analyzed with CUSUM (cumulative summation) method classified by surgeon's laparoscopic experiences. Total cost for the each operation was also recorded.

removed at a median of 7 (3-17) days after surgery. There were 10 cases (22.7%) with Clavien-Dindo grade I/II complications and no case with grade III or IV complications. Among 44 patients, 17( (38.6%) had positive margins, of those 6 cases (13.6%) in pT2 and 11 (25.0%) cases in pT3. Total cost for each Senhance robotic radical prostatectomy was NT\$61000-110000 (about US \$2200-3970), compared with NT\$180000-250000 (about US 6400-8900) in Da Vinci robotic radical prostatectomy in Taiwan.



The Senhance robotic system is technically feasible and economically affordable. The learning curve depends on surgeons laparoscopic experiences. It may serve as an alternative tool for robotic radical prostatectomy.

### **Key Results**

The median patient age was 67 [64-71.5] years with a mean body mass index of 25.35 [23.3-27.9] kg/m2. The median ASA score was 2±0.35. Median operative time was 246 (107-340) minutes. The median blood loss was 162.5 [50-287.5]ml. Foleys were









### Radical Prostatectomy

### Cost Range of Robotic Radical Prostatectomy



The Senhance robotic system is technically feasible and economically affordable.



### Short-Term Results of Robot-Assisted Colorectal Cancer Surgery Using Senhance Digital Laparoscopy System<sup>29</sup>

Sasaki, et al. Asian J Endosc Surg. 2022 Jul;15(3):613-618.









Colectomy

#### Overview

The Senhance robotic surgical system (TransEnterix Inc, Morrisville, NC, USA) is a novel laparoscopy-based robotic system, equipped with eye tracking system, haptic feedback system, and reusasble instruments. Currently, only two studies reported their experiences on extra-peritoneal radical prostatectomy. To assess the feasibility, learning curve and cost analysis of the transperitoneal Senhance robotic radical prostatectomy. From Aug 2019 to July 2021, the Senhance robotic radical prostatectomies were performed in 44 biopsy confirmed prostate cancer patients. Perioperative data were collected. Complications were graded with Clavien-Dindo classification. Learning curve was analyzed with CUSUM (cumulative summation) method classified by surgeon's laparoscopic experiences. Total cost for the each operation was also recorded.

20.0%). D2 or D3 dissection was performed in each operation, and D3 dissection was performed in 41 cases (74.5%). The median operative time was 240 minutes, the median blood loss was 5 mL, there were no intraoperative complications, and there were no cases of intraoperative blood transfusion. The median postoperative hospital stay was 7 days, which was comparable to conventional laparoscopic surgery. Postoperative complications of grade 2 or higher in the Clavien-Dindo classification were observed in two cases.

### Conclusion

The short-term results of 55 colorectal cancer surgery cases using the Senhance Digital Laparoscopy System were excellent and the system was introduced and surgery was safely performed.

### **Key Results**

The median age was 71 years. There were 31 males and 24 females, and the median body mass index was 23.1 kg/m2. Fifteen patients had a history of abdominal surgery. The most common surgical technique was ileocecal resection (18 cases, 32.7%), followed by high anterior resection (11 cases,

There were no intraoperative complications, and there were no cases of intraoperative blood transfusion.

The short-term results of 55 colorectal cancer surgery cases using the Senhance Digital Laparoscopy System were excellent.



### Robotically Assisted Surgery in Children —A Perspective<sup>30</sup>

Krebs, et al. Children. 2022 Jun 6.







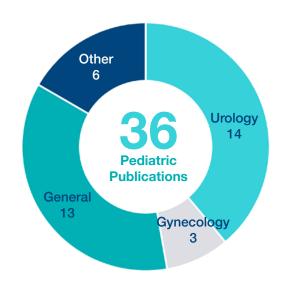


### Overview

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.



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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Specifically, tremor filtration and optimal visualization are approaches which can have enormous benefits for procedures in small bodies.

In total, 36 of the publications reviewed suggested that robotically assisted surgery was a good alternative for pediatric procedures.



### First Pediatric Pyeloplasty Using the Senhance® Robotic System—A Case Report<sup>31</sup>

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.



### Surgical Cost of Robotic-Assisted Sacrocolpopexy: A Comparison of Two Robotic Platforms<sup>32</sup>

Glass Clark, et al. Int Urogynecol J. 2023 Jan;34(1):87-91.









### Sacrocolpopexy

#### Overview

Robotic assistance in pelvic organ prolapse surgery can improve surgeon ergonomics and instrument dexterity compared with traditional laparoscopy but at increased costs. The objective of this study is to compare total costs for robotic-assisted sacrocolpopexy (RSC) between two robotic platforms at an academic medical center. A retrospective cohort of Senhance (Asensus) RSC between 1/1/2019 and 6/30/21 was matched 2:1 with Da Vinci (Intuitive) RSC. Primary outcome was total costs to hospital system; secondarily we evaluated cost sub-categories. Purchase costs of the robotic systems were not included. T-test, chi-square, and Fisher's exact tests were used. A multivariable linear regression was performed to model total costs adjusting for potential confounders.

tive complications, or short-term postoperative complications between platforms (all p > 0.05). On univariable analysis, costs were similar (Senhance \$5368.31  $\pm$  1486.89, Da Vinci \$5741.76  $\pm$  1197.20, p = 0.29). Cost subcategories (medications, supplies, etc.) were also similar (all p > 0.05). On multivariable linear regression, total cost was \$908.33 lower for Senhance (p = 0.01) when adjusting for operative time, estimated blood loss, concomitant mid-urethral sling, and use of the GelPoint mini port system.

### Conclusion

Despite longer operating times, total cost of robotic-assisted sacrocolpopexy was significantly lower when using the Senhance compared to the Da Vinci system.

### **Key Results**

The matched cohort included 75 subjects. The 25 Senhance and 50 Da Vinci cases were similar overall, with mean age 60.5  $\pm$  9.7, BMI 27.9  $\pm$  4.7, and parity 2.5  $\pm$  1.0. Majority were white (97.3%) and postmenopausal (86.5%) with predominantly stage III prolapse (64.9%). Senhance cases had longer OR times ( $\Delta=32.1$  min, p = 0.01). There were no differences in concomitant procedures, intraopera-



On multivariable linear regression, total cost was \$908.33 lower for Senhance (p = 0.01) when adjusting for operative time, estimated blood loss, concomitant mid-urethral sling, and use of the GelPoint mini port system.



### Initial 30 Cholecystectomy Procedures Performed with the Senhance Digital Laparoscopy System<sup>33</sup>

Sasaki, et al. Asian J Endosc Surg. 2023 Apr;16(2):225-232









Cholecystectomy

### Overview

The Senhance digital laparoscopy system (SDLS) is a novel platform developed for digitization in endoscopic surgery. This retrospective study aimed to evaluate the short-term outcome in the initial 30 consecutive patients.

SDLS cholecystectomies were performed in 30 consecutive patients (13 male, 17 female) by a single surgeon from September 2020 to March 2022. The patients' median age (range) was 77.5 (27-82) years, and median body mass index was 23.3 (19-38) kg/m2. Four trocars were used, three of which were docked to manipulator arms of the SDLS. Surgical procedures performed with the SDLS were almost the same as those by conventional surgery.

### Conclusion

This retrospective study showed that cholecystectomy using the SDLS appeared to be safe and feasible in limited cases without severe inflammation.

### **Key Results**

Median docking time, cockpit time, and operation time in minutes were 4 (3-13), 34 (13-81), and 69 (47-201), respectively. Operation time after the sixth case tended to shorten compared with that for the initial five cases. Three cases (10%) were converted to conventional laparoscopic surgery due to severe cholecystitis, but none required conversion to open surgery. Postoperative complications of Clavien-Dindo grade ≥II were not observed.

#### **Senhance Procedure Time**

Docking time	4 min (3-13)
Cockpit time	34 min (13-81)
Operation time	69 min (47-201)

Operation time after the sixth case tended to shorten compared with that for the initial five cases.



### Senhance Robotic Platform in Pediatrics: Early US Experience<sup>34</sup>

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



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.





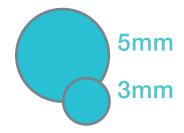




Cholecystectomy, Inguinal Herniorrhaphy, Orchidopexy, Cyst Exploration

Complications

O blood loss



Successful robotic manipulation with 3mm instruments



### Senhance Robotic Radical Prostatectomy<sup>35</sup>

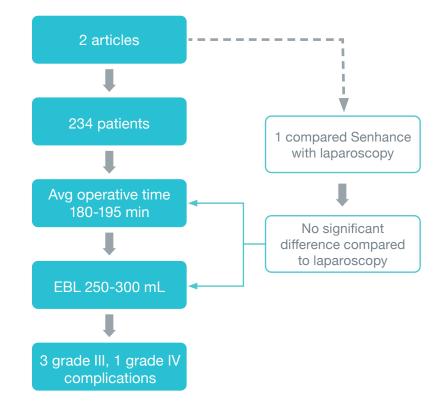
Kulis, et al. Acta Clin Croat. 2022 Oct;61(Suppl 3):45-50.



Radical Prostatectomy

### **Overview**

Since its introduction 20 years ago, robotic radical prostatectomy has become a standard of care in the treatment of localized prostate cancer in many Centers. Until recently, they have all been performed by the only available robotic platform. Senhance is a novel robotic platform that was approved for clinical use. The term Senhance was used to systematically search PubMed and Scopus databases for relevant articles that were afterward filtered for appropriate designs and data reports. There were two reports that met all of the criteria and were included in the review. Both studies were designed as prospective case series with a total of 234 patients where the data including operative data and oncological outcomes were reported. The average operative time ranged between 180 and 195 min, with estimated blood loss between 250 and 300 mL. There was 3 Clavien - Dindo grade III, and 1 Clavien - Dindo grade IV complication reported. One of the studies compared it with laparoscopy, but no significant difference in operative time and blood loss was found. Both studies concluded that the Senhance is a feasible and safe robotic platform for radical prostatectomy.



Senhance is a feasible and safe robotic platform for radical prostatectomy



### Anesthesia for Robot-Assisted Radical Prostatectomy - A Challenge for Anaesthesiologist<sup>36</sup>

Bačak Kocman, et al. Acta Clin Croat. 2022 Oct;61 (Suppl 3):76-80.



Radical Prostatectomy

### Overview

Mininimally invasive surgery has become one of the most popular ones over the last few decades due to many benefits. The advantages are minimal surgical incision, reduced blood loss, reduced postoperative pain, faster postoperative recovery, shorter hospital stay, lower morbidity and better outcomes compared to open surgery. The most common robotic procedures in urology are radical prostatectomies. In UHC Zagreb, since November 2019 until now, there have been more than 180 robotic assisted radical prostatectomies (RALP) using Senhance robotic system performed. As a procedure with many possible complications, it represents a challenge for anaesthesiologist. Some of the problems the anaesthesiologists have to face are related to limited patient access, possible difficulties connected with positioning, pneumoperitoneum, subcutaneous emphysema, possible airway oedema. Pneumoperitoneum has impact on almost every system: cardiovascular, renal, respiratory, gastrointestinal and other. Detailed understanding of physiological changes of RALP, with intraoperative impact on nearly every body system is ultimate. Careful preoperative evaluation and intraoperative conduction minimize the risk of complications, and help patients to reach full recovery in a very short time. Excellent outcomes are the result of individualized approach to the patient and good communication between team members.

### Some problems anaesthesiologists face are related to:

- limited patient access
- possible difficulties connected with positioning
- Pneumoperitoneum
- subcutaneous emphysema
- possible airway oedema

Excellent outcomes are the result of individualized approach to the patient and good communication between team members.





# The First Experience of Robot-Assisted Bariatric Surgery Using the Senhance System in Patients with Morbid Obesity<sup>37</sup>

Khitaryan AG, et al. Khirurgiia (Mosk). 2023;(11):82-88.



To study the results of robot-assisted bariatric surgery using the Senhance system in patients with morbid obesity.

#### Material and methods

A prospective cohort study included 74 patients who underwent bariatric surgery (Senhance digital laparoscopy system) between January 2022 and May 2023. Of these, 12 patients underwent robot-assisted longitudinal gastrectomy, 20 patients - robot-assisted Roux-en-Y gastric bypass, 36 patients - robot-assisted gastric bypass with one anastomosis/mini-gastric bypass, 6 patients - surgical exploration. We assessed duration of surgery, docking, placement of trocars and robotic manipulators, the need for their intraoperative displacement, incidence of intraoperative complications and conversions to laparoscopic surgery, intraoperative blood loss and early postoperative complications, severity of pain syndrome on the 1st day after surgery.

### Results

Mean surgery time was 87 [67, 120], 116 [78, 139], 96 [79, 125] and 141 [112, 184] min, respectively. Intraoperative blood loss was less than 50 ml. There were no complications requiring surgical treatment, cardiovascular, respiratory and other complications within 1 month.

#### Conclusion

Robot-assisted bariatric surgery using the Senhance system is feasible and safe for patients. Immediate results of robotic surgery are comparable to those after laparoscopy. However, large experience and cost-effectiveness analysis are required to assess the feasibility of robotic systems in bariatric surgery.









Longitudinal Gastrectomy, Roux-en-Y Bypass, Mini-gastric Bypass

Robot-assisted bariatric surgery using the Senhance system is feasible and safe for patients. Immediate results of robotic surgery are comparable to those after laparoscopy.





### Early Experience with the Senhance Surgical System in Bariatric Surgery<sup>38</sup>

Tran, et al. JSLS. 2024 Jan-Mar;28(1):e2023.00031.



Sleeve Gastrectomy







### Background and Objectives C

Robotic-assisted surgery advancements have paralleled growing bariatric surgery demands. The Senhance robotic platform offers an alternative to the Da Vinci surgical system but there are limited studies evaluating the Senhance system in bariatric surgery. This study aims to review a single surgeon's experience comparing outcomes between traditional laparoscopic and Senhance-assisted sleeve gastrectomy.

### **Materials and Methods**

All sleeve gastrectomies performed laparoscopically, Senhance-assisted, or Da Vinci-assisted by a single surgeon at an academic center from January 2019 to July 2021 were retrospectively reviewed. Primary outcomes and quality measures were 30-day complications, operative times and length of stay.

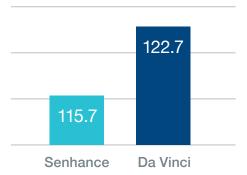
### Results

A total of 268 patients, including 162 laparoscopic, 92 Senhance, and 14 Da Vinci cases, were included. Operative times were significantly longer with Senhance (115.7 min) and Da Vinci (122.7 min), compared to laparoscopic (94.8 min, P<.0001). Length of stay (measured in days) was significantly longer in the Senhance (1.8) and Da Vinci (2.2) groups compared to laparoscopic cases (1.5, P<.0001). These differences remained significant after controlling for age, sex and body mass index. 30-day complication rates were 8.7% (n=8) in the Senhance group, 7.1% (n=1) in the Da Vinci group and 2.5% (n=4) in the laparoscopic group (P=.0567).

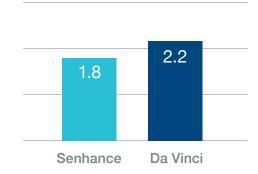
### Conclusion

Senhance-assisted sleeve gastrectomy is safe in bariatric surgery and comparable to laparoscopic sleeve gastrectomy with respect to 30-day complications.

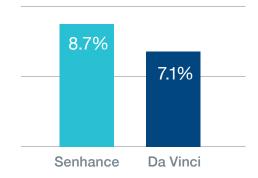
### **Operative Time (min)**



### Length of Stay (days)



### 30-day Complication Rate







### Safety in Senhance<sup>™</sup> Robotic Gastrointestinal Surgery in 530 patients<sup>39</sup>

Staib, et al. Surg Technol Int. 2023 Jul 18:42:sti42/1662.







### **Overview**

The Senhance Robotic System™ (Asensus Surgical, Durham, NC, USA) has been used in abdominal surgery since 2016, and provides an eye-tracker for camera movement and haptic tactile feedback. Safety aspects are very important in robotic surgery, such as regarding the presence of system malfunctions and surgical outcomes. The data for robotic function in gastrointestinal surgical procedures in 530 patients (colorectal surgery, fundoplication, others) were prospectively listed in the TRUST registry after informed patient consent in three German gastrointestinal surgery centers (center A, N = 46 patients; center B, N = 457: center C, N =27). Adverse events were noted in 14.3% (76/530 patients) of the overall surgeries, with an equal distribution among the procedures. Robotic malfunctions, such as console/camera/ arm malfunctions, collisions, or limited motion, were experienced in 5.5 % (29/530 patients), with some differences among the centers (A, 0.0%; B, 4.2%; C, 37%). These differences were explained in terms of team experience and case load. In conclusion, the Senhance™ Robotic System can be safely applied to routine abdominal surgery procedures.

530
gastrointestinal
procedures with
Senhance Robotic
System

across 3 German gastrointestinal surgery centers.

The Senhance<sup>™</sup> Robotic System can be safely applied to routine abdominal surgery procedures.





# Learning Curves and Procedural Times in Senhance®-Robotic Assisted Fundoplication: Results from 237 Consecutive Patients Undergoing Robotic Fundoplication in a Single Center as Part of the European Trust Robotic Surgery Registry Study<sup>40</sup>

Menke, et al. Surg Endosc. 2023 Nov;37(11):8254-8262.







Nissen Fundoplication

### **Background and Objectives**

Gastroesophageal reflux disease requiring an operative solution is common. Minimally invasive surgery to generate an anti-reflux barrier at the distal esophagus following the principle of the "floppy Nissen" technique has become the gold standard. Advanced robotic-assisted systems may deliver more consisted outcomes.

#### **Methods**

This registry study analyzed safety and efficacy of the Senhance® surgical system in the surgical treatment of reflux disease and procedural proficiency. Data from 237 consecutive patients operated in a single center were evaluated. Historic standard laparoscopies from the same center were analyzed to compare robotic surgery learning curve effects.

### Results

Using the Senhance® Surgical System, during the first 50 patients there was a significant decrease in surgery time which was maintained over the duration of study, pointing to the surgical staff's system-specific learning. After this phase, procedural times were comparable between the robotic-assisted and traditional laparoscopic surgery. The effect of learning was greater than for standard laparoscopy. For 237 patients, there were four conversions to laparoscopic surgery. Two serious adverse events were recorded, both cardiac in nature and not related to the use of the robot.

### **Conclusions**

Robotic fundoplication was swiftly implemented in a non-university hospital with 65 surgical beds. The operating time was no longer than in standard laparoscopy, the procedure was more standardized than open or laparoscopic surgery and hospitalization times may have been sustainably shortened. The autonomy at the system's digital platform (cockpit) to conduct robotic fundoplications is a big step forward in surgery.

Significant decrease in surgery time after 50 patients, which was maintained over the duration of study.

After this phase, procedural times were comparable between the robotic-assisted and traditional laparoscopic surgery.



### The Stress for Surgeons: Exploring Stress Entities with the Robotic Senhance Surgical System<sup>41</sup>

Menke, et al. J Robot Surg. 2024 Feb 28;18(1):94.









### Overview

Robotic surgery is on its way to revolutionizing traditional surgical procedures, offering precise and minimally invasive techniques hypothesized to shorten recovery times and improve patient outcomes. While there have been multiple publications on robotic systems' medical and procedural achievements, more emphasis should be put on the surgeon's experience, especially in comparison with laparoscopic surgery. The present report aims to systematically examine the stress impact on surgeons by comparing the robotic Senhance Surgical System (Asensus Surgical, Durham, North Carolina, U.S.A) to laparoscopic surgery. The well-established "SURG-TLX" survey is used to measure distinct stress entities. The "SURG-TLX" survey is a modified version of the NASA-TLX, validated for surgery by M. Willson. Based on a comprehensive database from six centers encompassing various disciplines and surgical procedures, our analysis indicates significantly reduced "overall stress" levels for robotic (cockpit) compared to laparoscopic surgeons. Exploring the "SURG-TLX" stress dimensions further between methods (robotic vs. laparoscopic) and surgeon position (laparoscopic, (robotic) bedside, or (robotic) cockpit) resulted in significantly more Mental (p.value < 0.015), less Physical Demands (p.value < 0.001) and less Distraction (p.value < 0.009) for robotic surgery, especially regarding the robotic cockpit surgeons. This finding suggests that robotic surgery with the Senhance Surgical System contributes to a favorable stress profile for surgeons, potentially enhancing their overall well-being and performance.



Lower PHYSICAL **DEMANDS** with Senhance compared to laparoscopy



Lower **OVERALL STRESS** for cockpit surgeons compared to laparoscopy





### The First Experience of Using Robot-Assisted Ventral Rectopexy with a Mesh Implant Using the Senhance System in the Treatment of Patients with Obstructive Defecation Syndrome<sup>42</sup>

Khitaryan, et al. Coloproctology. 2023; vol.22, no.4, p.89-98.









Rectopexy

### Purpose of the study

To study the initial results of robot-assisted ventral rectopexy with a mesh implant using the new Senhance system in the treatment of patients with obstructive defecation syndrome.

### **Patients and Methods**

This prospective cohort study included patients undergoing surgical treatment of obstructive defecation syndrome due to rectocele and/or rectal prolapse and/or internal intussusception using robot-assisted ventral mesh rectopexy using the Senhance® digital laparoscopy system. An analysis was carried out of the optimal placement of trocars and the location of robotic arms, an assessment of the duration of the intervention, and the volume of intraoperative blood loss. In the postoperative period, we studied the number of relapses, the number of complications and their severity according to the Clavien-Dindo scale, and the severity of pain according to VAS.

### Results

22 patients were included in the study. The average duration of surgical intervention was 87.1 ± 24.3 minutes. The volume of intraoperative blood loss was  $19.8 \pm 9.6$  ml. There was no conversion to open or laparoscopic approaches. No complications of surgical treatment were observed. Pain syndrome on day 1 was, on average, 22.5 mm according to VAS. During the follow-up examination, no anatomical recurrence was detected among the patients; the median follow-up period was 20.4 months (7-22 months).

#### **Conclusions**

Robot-assisted ventral rectopexy using the Senhance® system is effective and safe for the patient. The immediate results of using robotic access are comparable to laparoscopic ones. However, the use of the Senhance® digital laparoscopy system is cost-effective compared to other robotic systems.

> Conversions to open or laparoscopy

**Complications of** surgical treatment observed



### NEW

### Senhance Robotic Radical Prostatectomy: A Single-Centre, 3-Year Experience<sup>43</sup>

Hudolin, et al. Int J Med Robot. 2023 Dec;19(6):e2549.



Extraperitoneal radical prostatectomy

### **Background**

Senhance Surgical System is a novel robotic platform used in University Hospital Centre Zagreb since February 2019. In this study, we present our 3-year experience with this platform.

### Patients and methods

Data were prospectively collected for 200 patients who underwent extraperitoneal robotic radical prostatectomy (RRP) from May 2019 to March 2022.

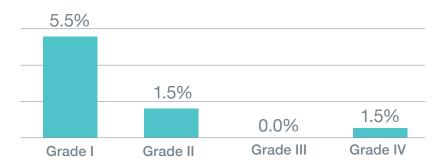
### Results

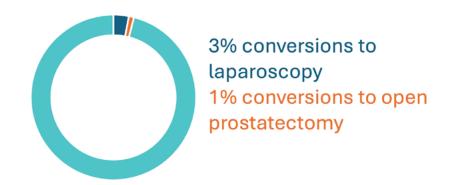
The median age of the patients was 65 years, and the prostate-specific antigen was 6.9 ng/mL. Clinically, most of the patients had T1c stage. The estimated blood loss was 250 mL, and there were 6 conversions to laparoscopic and 2 to open prostatectomy. There were 15 early postoperative complications, 11 Clavien-Dindo classification grade I, 3 grade II and 1 grade IV. Functional outcomes in the first 150 patients: 140 patients (93.3%) had good urinary control. Thirteen patients underwent additional oncological treatment.

### Conclusion

RRP performed with the Senhance robotic platform is a feasible and safe procedure with good initial results.

### **Early Postoperative Complication Rates**







### NEW

# Comparison of Senhance and Da Vinci Robotic Radical Prostatectomy: Short-Term Outcomes, Learning Curve, and Cost Analysis<sup>44</sup>

Lin, et al. Prostate Cancer Prostatic Dis. 2024 Mar;27(1):116-121.









Radical prostatectomy

### **Background**

The Senhance® Robotic System is a new laparoscopy-based platform that has been increasingly used in radical prostatectomy (RP) procedures. The purpose of this study is to compare the outcome of Senhance RP (SRP) with Da Vinci RP (DRP) cases.

### Methods

From August 2019 to April 2022, we prospectively recruited 63 cases of SRP. We compared the perioperative data, postoperative complication rates, short-term surgical outcomes (3-month postoperative undetectable prostate-specific antigen (PSA) and incontinence rates), learning curves, and cost analysis with data from 63 matched Da Vinci Xi RP cases.

### Results

There was no difference in blood loss (BL) (180 versus 180 ml, p = 0.86) and postoperative surgical complication rate (Clavient -Dindo grade I-IV, 25.3 versus 22.2%, p = 0.21) between the SRP cases and the DRP. Regarding the oncologic and continence function, there was no difference between positive margin rate (36.5% versus 41.3%, p = 0.58), rate of undetectable PSA level at postoperative 3 months (68.3 versus 66.7%, p = 0.85), and incontinence rate (14.3 versus 15.9%, p = 1.0) at postoperative 3 months between the two cohorts. The learning curve showed a quick downward slope for laparoscopic experienced surgeons. The median pocket cost for SRP patients in our hospital was \$4170, which was lower than \$7675 for the DRP patients.

#### **Conclusions**

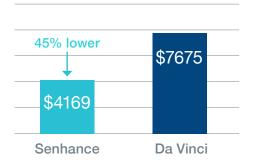
Safety and short-term outcomes are comparable between SRP and DRP. For experienced LRP surgeons, using the Senhance system to perform RP is straightforward. With a more affordable price as its biggest advantage, the Senhance system may serve as a safe and effective alternative for robotic RP.

#### No difference in

- Blood loss
- Postoperative surgical complication rate
- Positive margin rate
- Rate of undetectable PSA level at 3mo postop
- Incontinence rate at 3mo postop

between Senhance and Da Vinci procedures

#### **Median Procedure Cost**





### Robotic-Assisted Radical Prostatectomy: A Multicenter Experience with the Senhance Surgical System<sup>45</sup>

Kulis, et al. Wold J Urol. 2024 Jan 20;42(1):39.









Radical prostatectomy

### **Purpose**

Robotic-assisted surgery for radical prostatectomy is becoming a standard treatment, and respective implementations are expanding. The Senhance Surgical System is a robotic system with existing but limited data on radical prostatectomy, including a lack of multicenter study experiences. The TRUST study aims to fill this gap and explores observations for radical prostatectomy with the Senhance Surgical System.

#### Methods

Between August 2019 and November 2022, 375 patients met inclusion criteria from two European sites. Patients' surgical procedure times, data on conversion, malfunction, adverse events, and pain scores were registered and evaluated. Outcomes were calculated for both sides, combined as a total and compared between the initial (1st-150th case) and later (> 150th case) period.

### Results

The median operating time was 190 min (IQR: 167.5-215.0) and the median docking time was 3 min (IQR: 2.0-5.0). Eighteen cases (4.8%) were converted to standard laparoscopy and two (0.5%) to open. Two perioperative (0.5%) and eleven postoperative adverse events (2.9%) occurred, mostly (83.3%) categorized as mild. Pain scores were reduced from an average of 3.4 (± 1.4) on the postoperative day to 0.9 (± 0.7) at discharge. Compared to our previous data and based on a comparison between our initial and later period, operating time seems to plateau. However, docking time, complication, and conversion rates were successfully reduced.

### Conclusion

We demonstrate progressing safety and efficiency for robotic-assisted radical prostatectomy with the Senhance Surgical System.

> 3 min **Mean Docking Time**

190 min **Mean Operative Time** 

4.8% **Conversion Rate to** Laparoscopy

0.5% **Conversion Rate** to Open

0.5% **Perioperative Adverse Event Rate** 

2.9% **Postoperative Adverse Event Rate** 





### Robotic-Assisted Nissen Fundoplication in Pediatric Patients: A Matched Cohort Study<sup>46</sup>

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









**Nissen Fundoplication** 

### **Background**

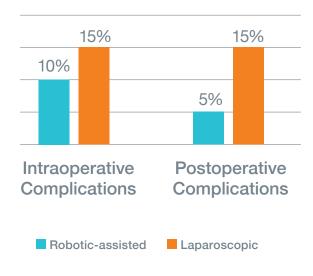
Nissen Fundoplication (NF) is a frequently performed procedure in children. Robotic-assisted Nissen Fundoplication (RNF), with the utilization of the Senhance® Surgical System (SSS®) (Asensus Surgical® Inc., Durham, NC, USA) featuring 3 mm instruments, aims to improve precision and safety in pediatric 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.

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